

# **Research in global health emergencies: ethical issues**



# Nuffield Council on Bioethics

David Archard (Chair)

Simon Burall

Simon Caney

Melanie Challenger

Tara Clancy

John Dupré\*

Frances Flinter

Elaine Gadd

Andy Greenfield

Anne Kerr

Michael Parker\*\*

Shaun Pattinson (Deputy Chair)

Michael J. Reiss

Mehrunisha Suleman

Christine Watson

Robin A. Weiss

Heather Widdows

\* co-opted member of the Council while chairing the working group on *Genome editing and farmed animals*

\*\* co-opted member of the Council while chairing the working group on *Research in global health emergencies: ethical issues*

## Executive

Hugh Whittall (Director)

Kate Harvey

Katharine Wright

Anna Wilkinson

Peter Mills

Ranveig Svenning Berg

Catherine Joynson

Arzoo Ahmed

Sarah Walker-Robson

Carol Perkins

Sophia Griffiths

Jade Rawling

Richella Logan

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- To identify and define ethical questions raised by recent developments in biological and medical research that concern, or are likely to concern, the public interest;
- To make arrangements for the independent examination of such questions with appropriate involvement of relevant stakeholders;
- To inform and engage in policy and media debates about those ethical questions and provide informed comment on emerging issues related to or derived from the Council's published or ongoing work; and
- To make policy recommendations to Government or other relevant bodies and to disseminate its work through published reports, briefings and other appropriate outputs.

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# Foreword

My time as Chair of the Nuffield Council on Bioethics working group on the ethical aspects of research in global health emergencies has been one of the most pleasurable and intellectually challenging experiences of my working life. It has been a huge privilege to have had the opportunity to work with my fellow working group members on these timely, important, and difficult issues. It has also been an important responsibility. We have been aware at all times of the potential impact of our deliberations on the lives of the people, families, and communities who participate in research, primarily in the interest of others, at a time of great distress, fear, and vulnerability. We have also been cognisant of the fact that the successful conduct of such research to high ethical standards depends crucially upon the work undertaken every day by front-line research workers, health professionals, and volunteers – and of the very real dangers and practical challenges they face in so doing. It is against this background, and with these considerations at the front of our minds, that we have grappled with the difficult ethical aspects of research conducted in such settings and the ethical complexity of the relationships between preparedness, response, and research.

In our deliberations, we have benefitted greatly from the participation of a large number of people who have given generously of their time and experience. This includes those who responded to our initial call for evidence and the many external reviewers of draft versions of the report. We are also grateful to the experts who attended and spoke at our working group meetings. These included: health professionals, scientists, representatives of NGOs and humanitarian organisations, bioethics researchers, and research funders (see Appendices 1 and 2 for a full list). Thank you all for being so generous in sharing your experience and expertise with us and for encouraging us to be bold in our recommendations.

In addition to those named in the Appendices, I would like to express my gratitude to Elysee Nouvet, Anna Chiumento, Bridget Pratt, Fiona McEwen, Stefan Jansen, and Tim McHugh for their informal advice on specific aspects of our work. A very special thank you to Shelley Lees, Vicki Marsh, and Mark Marchant and their colleagues at the African coalition for Epidemic Research, Response and Training (ALERRT) who invited us to join and co-host a workshop in Dakar on the role of community engagement in research during emergencies. In addition to the benefit we gained from the richness of the workshop itself, our participation also made it possible for us to meet and learn from informative and inspirational conversations with community members and Ebola survivors. Thank you too, to Emily Chan – one of our working group members – who made it possible for some of us to attend the International Conference on Silk-road Disaster Risk Reduction and Sustainable Development in Beijing in 2019. The conference and the discussions we had there were an important reminder of the vast range of emergency settings with global health implications and the many different ways in which emergencies present important ethical issues beyond those directly related to health. I would also like to thank Dan O'Connor of the Wellcome Trust for agreeing so enthusiastically and generously when I asked him what he thought about the possibility of spending the first two years of my directorship of the Wellcome Centre for Ethics and Humanities working on this project.

I would like to close with some personal thanks. Firstly, to my colleagues on the working group for the time, enthusiasm, and constructive intellectual energy they have dedicated to this project. What a delightful and fascinating group of people to have had the opportunity to spend time with! It has been a wonderful experience working with you all. Secondly, I would like to express my very, very special thanks to the team at Nuffield. In particular, I want to thank Katharine Wright and Kate Harvey who have put phenomenal energy, commitment, and

expertise into this initiative. Katharine, I have no idea where you find the energy! I also want to acknowledge and thank the wider team at Nuffield, particularly Sarah Walker-Robson, Sophia Griffiths, Jade Rawling, and Richella Logan. This report would simply not have been possible without you.

A handwritten signature in black ink that reads "Michael Parker". The signature is written in a cursive style with a large, sweeping initial 'M'.

**Professor Michael Parker, Chair of the working group**

# Members of the working group

## **Michael Parker (Chair)**

Professor of Bioethics; Director, Wellcome Centre for Ethics and Humanities and the Ethox Centre, University of Oxford

## **Sanjoy Bhattacharya**

Professor, History of Medicine; Director, Centre for Global Health Histories; Director, WHO Collaborating Centre for Global Health Histories, University of York

## **Karl Blanchet**

Professor at the Faculty of Medicine, University of Geneva, and Director of the Centre for Education and Research in Humanitarian Action (CERAH) in Geneva.

## **Simon Caney**

Professor, Political Theory, University of Warwick; Council member

## **Emily Ying Yang Chan**

Professor and Assistant Dean (Development), Faculty of Medicine, Chinese University of Hong Kong (CUHK); Director, Collaborating Centre for the University of Oxford and CUHK Disaster and Medical Humanitarian Response (CCOUC); Visiting Professor, Oxford University Nuffield Department of Medicine; and Visiting Scholar, FXB Center, Harvard University

## **Beatriz da Costa Thomé**

Physician, Preventive Medicine Department, Federal University of São Paulo, Brazil

## **Philippe Guérin**

Professor, Epidemiology and Global Health, Centre for Tropical Medicine and Global Health, University of Oxford; Director, Infectious Diseases Data Observatory (IDDO)

## **Julian Hughes**

Honorary Professor, University of Bristol; Visiting Professor, PEALS, Newcastle University; Deputy Chair of Council to March 2019.

## **Patricia Kingori**

Associate Professor in Sociology and Global Health Ethics; Wellcome Senior Investigator, Wellcome Centre for Ethics and Humanities and the Ethox Centre, University of Oxford

## **Heidi Larson**

Professor of Anthropology, Risk, and Decision Science, Department of Infectious Disease Epidemiology, LSHTM; Director, The Vaccine Confidence Project

## **Soka Moses**

Physician, Ministry of Health, Monrovia, Liberia; site physician for the Ebola survivor Natural History Cohort Study (PREVAIL III) and Partnership for Ebola Virus Research in Liberia (PREVAIL)

## **Sharifah Sekalala**

Associate Professor, School of Law, University of Warwick

## **Julian Sheather**

Special Adviser, Ethics and Human Rights, British Medical Association; Ethics Adviser, Médecins Sans Frontières

## **Paulina Tindana**

Senior Lecturer / Bioethicist, Department of Health Policy, Planning, and Management, University of Ghana





# Terms of reference

1. To consider, in the light of recent developments, how research may ethically be conducted in global health emergencies, and how it may most appropriately be integrated into the wider response to such emergencies.
2. To consider, in particular:
  - the implications of the recognition that undertaking research can be an integral and necessary part of response to a global health emergency;
  - the role of affected populations in shaping the role of research in emergency response, including recognising the potential for diverse views within those populations;
  - the circumstances in which research activities during an emergency may offer the prospect of direct health benefit to participants, and the implications of this for ethical conduct of the research;
  - whether there are circumstances in which the standard ethical requirements for the scrutiny and conduct of research should differ in emergencies; and if so, in what way, and with what justification;
  - the ethical implications of the criteria for declaring a situation to constitute a ‘global health emergency’, and the implications for action before and after the period of the declared emergency if different ethical requirements are held to apply during emergencies; and
  - the responsibilities of multiple stakeholders including research funders, the pharmaceutical industry and their insurers, non-profit organisations, intergovernmental bodies, and governments.
3. In considering the issues above, to take into account:
  - the diverse nature of what might constitute a global health emergency, including disease outbreaks, natural or industrial disasters, conflict, and widespread drug resistance;
  - the speed of innovation in research and research methods; and
  - the nature of national obligations to assist those beyond their borders.
4. To write a report and make recommendations to improve the contribution that ethically conducted research may make to emergency response in the future.



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# Executive summary

## Introduction and Chapter 1: scope and context

1. This report from an international working group established by the Nuffield Council on Bioethics explores the complex and contested question of how research can be conducted ethically during major health emergencies and humanitarian crises. Research can play an essential role in improving the effectiveness of the health response to those affected by such emergencies, but is often ethically contested because of the highly challenging environment in which it takes place.
2. 'Research ethics' is often thought to refer only to the process of independent ethical review that all research involving human participants should receive. We make the case for a much broader approach to research ethics. Ethical challenges in global health emergencies include:
  - Being alert to questions of power and influence: how are the voices of those who are most affected by emergencies meaningfully included in deciding what research takes place, where and how?
  - Achieving appropriate study designs and flexible review systems that are sensitive to the difficult contexts in which research is taking place.
  - Achieving meaningful consent processes within a wider ethical system of governance, to ensure people's interests are respected.
  - Responding to the need for greater fairness in collaborations between researchers and research institutions in different countries.
  - Considering when and how data and biological samples provided during an emergency may ethically be used by other researchers.
  - Finding ways to ensure front-line research workers are better supported in addressing the ethical dilemmas they face.
3. In considering these ethical aspects of research in global health emergencies, we take a broad and inclusive approach, both to circumstances that might be characterised as 'global health emergencies', and to what activities constitute health-related research.
4. Our concern with 'research' encompasses a wide range of evidence-generating activities whose primary aim is to improve the health-related aspects of emergency preparedness, mitigation and response. These include clinical trials of novel treatments and vaccines, social science research, epidemiological studies, implementation research, and health systems research, as well as less formalised ways in which data are used to improve response within the humanitarian sector.
5. 'Global health emergencies' are not rigidly defined but include situations with many or all of the following features that render much-needed research very difficult:
  - Disruption from some kind of relatively stable norm (including where such disruption is long-term, for example where populations are left without civil or political rights). Potential causes of such disruption include infectious disease outbreaks, natural disasters, and human-made disasters such as conflict, bioterrorism, and industrial accidents;
  - Significantly raised risks to physical or mental well-being at both individual and population level;

- Pressures of time, creating tensions between research and response timescales, and exacerbating the challenges of multidisciplinary working;
  - Uncertainty, making decision-making in these time-limited contexts particularly difficult for all concerned;
  - Fear, distress, and sometimes panic, potentially undermining populations' ability or desire to engage with research; and
  - Need for a multi-country and multi-agency response associated with inevitable tensions and differences in approach between different actors, and with scope for disagreement over control, responsibility, and legitimacy.
6. It is these challenges of multi-country and multi-agency coordination, rather than the health implications of the emergency for other countries, that provide the primary justification for our focus on 'global' health emergencies. While it was not our aim to explore the ethical conduct of research in emergencies contained by individual nation states, we note, however, that many of the issues that arise for researchers in 'domestic' emergencies may be very similar to those in global health emergencies.
7. Ethics is not just about the behaviour of people directly involved in the research. The decisions taken at policy level, by funders, regulators, research institutions, journals, and others, are very influential in shaping and limiting the possibilities for ethical research conducted on the ground. Our recommendations are aimed at those organisations whose policies and actions could bring about real change.

## **Chapter 2 – Research in context: experience of participants and researchers**

### **Community leadership and agency**

8. Narratives from those with personal experience of being affected by emergencies, whether infectious disease outbreaks, or human-made or natural disasters, are an essential part of the evidence base when exploring the ethical challenges of effective emergency response and research. Although the features of emergencies described in Chapter 1 undermine and disrupt everyday life and institutions, affected communities nevertheless take a leading role themselves in emergency response. This has important consequences for the ethical conduct of research associated with that response, including questions of legitimacy and accountability of external actors to those communities.
9. Studies and evaluations of the 2004 Indian Ocean tsunami, Hurricane Katrina, the Syrian conflict, and the compound disaster at Fukushima, provide a rich source of examples of emergency response initiated and owned by affected communities. Many of these involve active roles by those who in ordinary circumstances would not have had influence in their communities, including young people and women. Such active engagement and ownership of emergency response by local communities and civil society organisations has been associated with longer-term benefits and sustainability. In contrast, failure on the part of some international organisations to engage meaningfully with local populations has led to needs being overlooked or not well understood. While the response to infectious disease outbreaks tends to be more institution-led and dominated by external actors, there is an increasing awareness of the importance of international actors supporting and enabling community health services and community responders in taking the lead.

## Participant experiences

10. Insight into the experiences of people directly affected by emergencies is an essential first step in understanding potential sensitivities in standard research practices and minimising scope for misunderstanding about the role of research. It illustrates how closely interwoven research and response in humanitarian crises are, and how it may be unrealistic to expect people to trust in the good intentions of researchers if their basic needs are not being met. The primary motivation for taking part in intervention-based studies is often the hope of regaining health, and the invitation to take part may be perceived as an 'empty choice' with few, if any, apparent alternatives. Past experience with external organisations, whether related to research or other initiatives, affects participant expectations and can lead to significant misunderstandings, for example about possible future benefits, and consequent distrust.

## Researcher experiences

11. Researchers in global health emergencies work in highly complex, rapidly changing, and often uncoordinated environments. Challenges include the multiplicity of organisations and structures involved in response and research; the diversity of people working in the field, including different motivations and lines of accountability, and rapid turnover; and tension between knowledge generation and the immediate emergency response, particularly for those with clinical skills.

## Chapter 3 – Emergency preparedness: key actors

12. This chapter provides an overview of the major actors and institutions whose capacities and priorities with respect to emergency preparedness, response, and research have a powerful influence on the way in which research can be conducted during emergencies. Those who are most vulnerable, for example through poverty, lack of access to healthcare, and lack of political voice, are disproportionately affected by health emergencies; and underlying neglect often exacerbates the effects of adverse events that subsequently become an emergency. Consideration of the structural factors that affect how health threats become (or are prevented from becoming) global health emergencies is an important precursor for analysing the ethical concerns arising in associated research.

## Influential actors and institutions

13. The way in which research can be conducted during emergencies is influenced by the capacities and priorities of many actors and institutions. These include:
  - **national governments** in developing the resilience both of their healthcare systems (in general, and in their ability to respond in emergencies) and of their health research systems;
  - **intergovernmental organisations** – both in supporting national governments, and in coordinating emergency planning and emergency response and research at local, regional, and head office level;
  - the **humanitarian sector** which, alongside national health systems, can play a central part in direct response to emergencies, in influencing what health research can take place, and increasingly in conducting research themselves;

- the **military (foreign and domestic)**, which can play a sometimes-controversial role both in direct clinical care and research, and in logistical and technical support;
- **private sector actors**, both in their role in funding emergency preparedness through partnerships with intergovernmental agencies and others, and through direct funding of research through the pharmaceutical and biotech sectors;
- **major non-commercial research funders** whose priorities, policies, and processes directly control much of the research that takes place in an emergency, and may either facilitate or limit the ethical options open to researchers seeking funding; and
- **regional and international research networks** focusing on emergency preparedness.

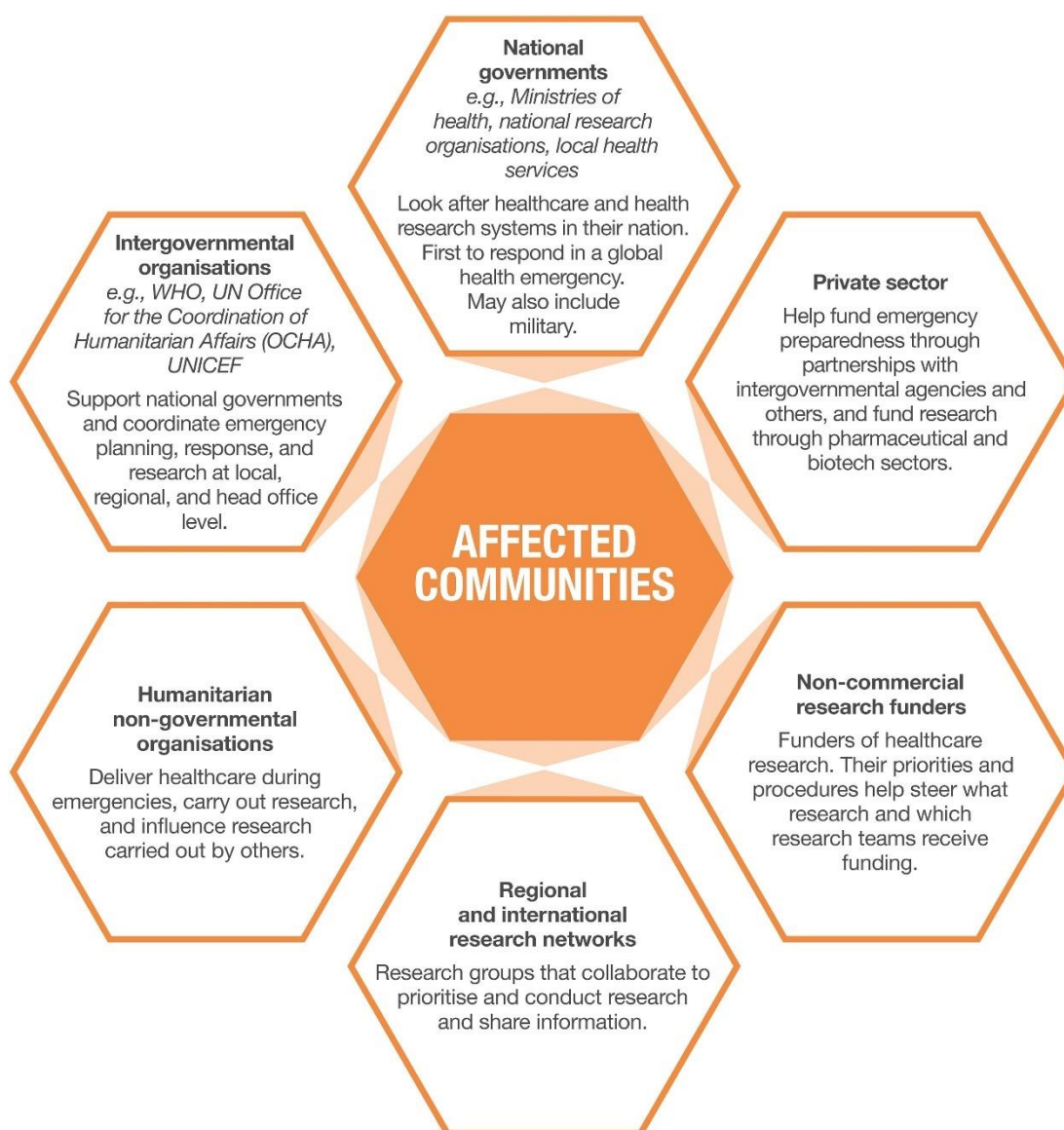


Diagram by Jade Rawling

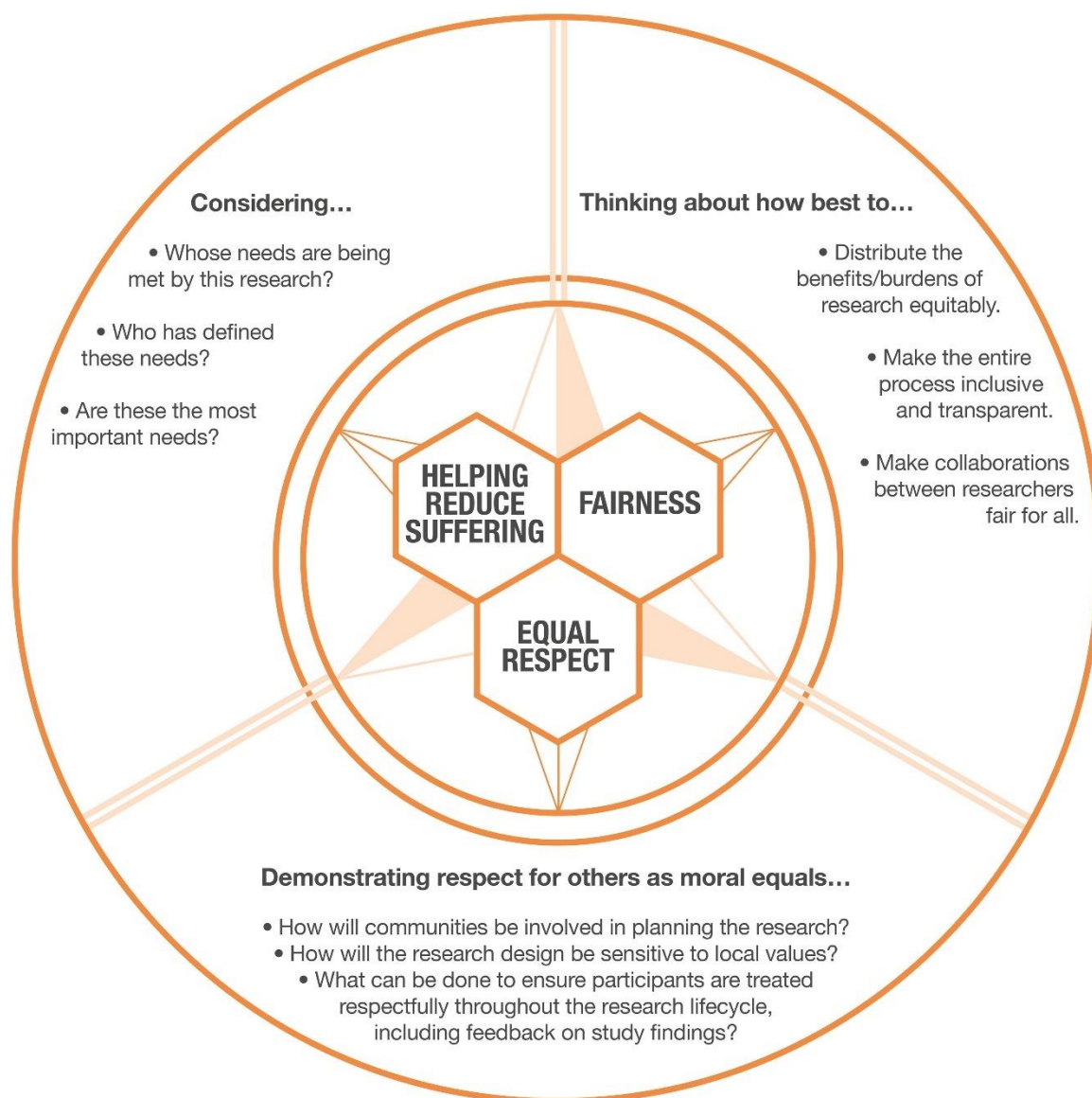


## Role of technology and surveillance in supporting preparedness

14. Technological developments also play an essential part in providing the information necessary to inform the actions and decisions of the institutions listed above. These include monitoring and modelling techniques to inform emergency preparedness for both natural disasters and infectious disease outbreaks, and to help support effective response, for example through cheaper and faster diagnostic techniques. These technologies complement the important role of local communities and health services in being alert to the early signs of emergencies, and initiating local action plans.

## Chapter 4 – Developing an ethical compass

15. Research in global health emergencies unavoidably takes place in non-ideal circumstances, characterised by disruption, uncertainty, and great health need. This can be compounded by competing claims for legitimacy, time pressures, confusion, and distress. These factors present significant practical challenges to ethical decision-making as practitioners struggle to align their ethical obligations to challenging and often chaotic circumstances.
16. Effective research in emergencies also involves cooperation between numerous organisations, which may have conflicting priorities, and which are guided by their own, sometimes distinct, professional and ethical codes of practice. The question of what is (or is not) morally distinct about research in emergencies is thus complicated by the existence of multiple ‘standard’ approaches, including for different kinds of research, in different legal, social, and cultural contexts, and by different organisations and professions with diverse traditions. Crucially, the decisions taken at policy level, by funders, regulators, research institutions, journals, and others also shape and constrain the possibilities for ethical research conducted on the ground.
17. Drawing on the evidence and experience presented to the working group, this report proposes an ‘ethical compass’ to inform higher level policy approaches, and to help provide a common language and a common way of thinking through ethical dilemmas arising in emergencies. The ethical compass is made up of three very widely shared values:
  - **Equal respect:** treating others as moral equals, including respecting their dignity, humanity and human rights;
  - **Helping reduce suffering:** acting in accordance with fundamental duties, founded on solidarity and humanity, to help those in need or suffering from disease; and
  - **Fairness:** including both duties of non-discrimination in the treatment of others, and of the equitable distribution of benefits and burdens.



*Diagram by Jade Rawling*

18. In many cases these values will pull in the same direction, suggesting a clear course of action. In cases where this is not possible, determining whether or not to conduct research will require careful, appropriately inclusive and transparent deliberation, independent review, and explanation. While the value of helping reduce suffering will always be important, considerations of what is fair, and what shows equal respect, must also influence the way research is conducted.
19. The three values provide a tool for thinking through whether ethical principles routinely applied to certain kinds of research, such as standards for informed consent, requirements for ethical review, and the importance of meaningful community engagement, might legitimately be adapted. Possible approaches include:
  - interpreting standard principles in the light of the features of the emergency;
  - recognising additional principles from partners' ethical traditions or in response to local needs; and

- taking action to strengthen other parts of the ‘ethics ecosystem’ where it is recognised that standard principles (such as informed consent), while still important, cannot provide the degree of protection required.

Such decisions may need to be taken on a case-by-case basis with respect to the features of the emergency, guided by consideration of the values.

20. At a policy level, the three values underpin the approach that ‘duty-bearers’ such as governments, funders, employers, and others need to take, to enable and support ethical research during emergencies. This also includes duties to plan to minimise or even prevent the impact of future emergencies through strengthening health and health research systems.

## Chapter 5 – Influence throughout the research endeavour: an inclusive approach

21. Equal respect for persons requires that those planning research should engage seriously and respectfully with relevant stakeholders. The ‘all affected principle’ (the idea those whose interests are fundamentally affected by a process have a right to inclusion) provides a guide to thinking about who has a stake in any particular emergency. This includes governments and research institutions; local health services, voluntary organisations, and research institutions in the affected area; and members of affected communities. Communities are complex and diverse, and it is essential to identify those with informal influence within the different subgroups that make up a community, as well as those with more formal leadership roles.

### Influencing decisions about prioritisation and funding

22. The way funding decisions are taken needs to change: to create a more collaborative approach between funders; and to ensure that a wider range of voices is heard in determining the kind of research that should get funded. A longer-term goal is to shift the power balance in funding decisions towards lower-income countries, and find ways of ensuring publics within those countries have input into research priorities.

### *Supporting collaborative approaches between funders*

23. Funding organisations currently share information about the research they fund in a number of ways, including through WorldReport, an open-access, interactive mapping database highlighting biomedical research investments and partnerships from major funding organisations. The scope of the data shared varies by funder, but typically is retrospective.

#### **Recommendation 1 (directed to the funders of WorldReport)**

**We recommend that the valuable WorldReport initiative, mapping research investments and partnerships, be expanded to include a much wider range of prospective research plans of relevance to global health emergencies. This would facilitate increasingly coordinated planning of research relating to emergency preparedness and response.**

### ***Involving key stakeholders in research priority-setting***

24. Work is currently underway, coordinated by WHO and partners and stakeholders, to strengthen mechanisms for supporting the integration of research into outbreak response, with a primary emphasis on ownership by relevant national authorities, and coordination and technical assistance from relevant stakeholders and partners. This would include agreeing relevant research priorities during infectious disease outbreaks. **We warmly welcome this initiative.**

#### **Recommendation 2 (directed to WHO and other stakeholders)**

**We recommend that WHO work with all stakeholders to expedite the development of mechanisms for supporting the integration of research into outbreak response, including standing operating procedures for agreeing research priorities in infectious disease outbreaks; and that this valuable model is also extended to research in other forms of emergency.**

25. There are well-recognised practical challenges of coordinating funding in tight timeframes between organisations with very different governance structures. A further step towards achieving a responsive and collaborative approach to funding in emergencies would therefore be through the creation of a dedicated source of funding, held under its own governance arrangements, and with its own prioritisation and allocation processes. This would involve funders, once satisfied with the robustness of the governance arrangements, genuinely relinquishing a degree of their power as to how the funding they have contributed will be spent.

#### **Recommendation 3 (directed to Heads of International Research Organizations)**

**We recommend that the Heads of International Research Organizations take the lead in exploring the scope and appetite for the creation of a dedicated pool of resources, established with its own governance arrangements, for funding research for emergency preparedness and response. A necessary requirement of any such funding mechanism would be the diversity of representation from research institutions around the world, particularly among affected countries, among its leadership and decision-making processes, and a strong emphasis on coordination.**

26. While a coordinated approach is essential at the strategic level to avoid duplication and waste, there is also much that can be done by individual funders to facilitate more inclusive approaches to the prioritisation and planning of research at the level of individual grant applications.

#### **Recommendation 4 (directed to funders)**

**We recommend that individual funding bodies should put in place innovative ways in which they can facilitate researchers in involving affected communities directly at the grant application stage – for example through the availability of small seed grants to enable initial scoping work, and sufficient flexibility to enable shifts in focus after grants have been awarded in response to community input.**

## Influencing how research is conducted on the ground

27. Meaningful engagement with affected communities involves the creation of trusting / trustworthy relationships between researchers and diverse parts of those communities. At its best, such engagement should involve affected populations from the beginning and throughout the research endeavour in ongoing dialogue contributing to the design, conduct, and outcomes of research. Developing community engagement networks in advance to facilitate relationships is a key part of emergency preparedness, for example in association with regional research initiatives or community health structures. In the absence of preparedness, a pragmatic approach may be required during an emergency, including scope for learning / adapting in response to feedback as the research progresses. The values of equal respect and fairness, alongside the importance of helping reduce suffering through research, should help guide consideration of how much 'adaptation' of ideal processes is acceptable.
28. A large number of different organisations involved in emergency response and research have significant roles to play in facilitating community engagement activities. The defining line between community engagement in response and in research is unlikely to be clear. National governments have a key responsibility to prioritise investment in sustainable community engagement processes, embedded in local health services and in local emergency planning systems. We highlight the specific role that research funders are well placed to play in supporting and promoting meaningful community engagements in the research they fund.

### Recommendation 5 (directed to funders)

**Research funders should require coherent, achievable and inclusive plans for community engagement in funding proposals, while avoiding being over-prescriptive on how this might be achieved, thus allowing for activities to be guided by reality on the ground. They should include explicit reference to community engagement in budget templates, accompanied by the recognition that budgets need to allow for community activities and reimbursements, as well as staff costs.**

## Chapter 6 – An inclusive approach to study design and review

29. Global health emergencies pose significant challenges to the design and ethical review of research. An ethical approach to these challenges does not involve taking shortcuts or accepting a lack of rigour – but rather is concerned with what is appropriate for the context. We argue for a 'heightened alertness' to ethics, emphasising the importance of being alert to the challenges and vulnerabilities inherent in the situation, but without assuming that the answer is necessarily a more burdensome process. The focus should be on who is involved in that process, and how that process can best fit both the context and the constraints. Our ethical compass provides a guide to consider how standard procedures might need to be adapted and when this can be justified.

### Study design: an inclusive way forward

30. It is unethical to ask people to take part in research unlikely to produce meaningful results, which hence will not help reduce suffering. This highlights the importance of

scientific rigour and validity. It also emphasises the importance of study designs that are locally acceptable: designs that cannot recruit enough participants, for example because of unaddressed local concerns, will not be feasible. Key questions to ask are:

- **Is this the right study for this location and this population / subpopulation?** Who has been involved in identifying and characterising the problem that the research seeks to answer? Will local populations benefit from any positive findings? And then:
- **Is this the right design for this location and this population?** How have local needs, concerns or preferences been taken into account?

**Recommendation 6 (directed to researchers, research institutions, research ethics committees, and funders)**

**Study protocols should be developed with the input of local communities and local researchers before being finalised, in order to ensure that proposed procedures are acceptable to communities, as well as meeting ethical requirements. Even in multi-site trials, there will be elements that can and should be operationalised differently in different sites, in response to engagement and feedback. Ethics committees should actively encourage such involvement, and as a minimum should expect local engagement in the development of appropriate tools for communication and consent procedures.**

***Inclusion criteria***

31. Certain groups, such as children and pregnant women, have traditionally been categorised as ‘vulnerable’ and are less likely to be included in research. This raises questions of fair access to novel interventions: both for those affected at the time (while recognising the uncertainties of any associated benefit); and for equivalent groups in the future (who will be less able to benefit if data relevant to them are not collected). The issue of fair access arises particularly powerfully where a respected body such as the WHO authorises the ‘expanded use’ of interventions that are not yet licensed on the basis of possible benefit. This issue arises equally outside emergencies and is a subject of ongoing debate.

**Recommendation 7 (directed to researchers, sponsors, and ethics committees)**

**Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of ‘vulnerable groups’.**

**Ethical review processes**

32. Independent ethical review (both in the country affected and, where relevant, in other countries) provides an important safeguard for research participants, and the *standard* of review should not be compromised in any way by the emergency context. All concerned (funders, governments, research institutions, and affected populations) need to have assurance that proper scrutiny has taken place. The processes used to achieve that scrutiny, on the other hand, can and should be adapted as necessary to the context, including scope for expediting urgent applications, with flexible means of communication and deliberation.



33. There are many examples of flexible and innovative practice, but these are dependent on sufficient capacity in ethical review. In addition to the widely-acknowledged need to continue to support the general development and confidence of research ethics committees, an important element of emergency preparedness is the development, at both national and regional level, of the collaborative systems and protocols necessary to facilitate prompt and responsive review when an emergency arises. Such systems might include:
- agreeing standardised procedures and templates, potentially at regional as well as national level; and
  - developing ways of drawing in additional ethical expertise within the region to support committees who are struggling or overburdened at the time of an emergency.
34. **Lead responsibility for developing such systems will depend on local circumstances, but could include regional research ethics committee networks. National and regional offices of WHO could also play a valuable facilitative role, as part of supporting emergency planning.**
35. A further important aspect of ethical review is that of access to relevant local expertise to understand both the possible risks of the research and the wider risks to which people are exposed through the emergency. It is also essential to recognise that independent ethical review is only one part of the ‘ethics ecosystem’ and does not absolve researchers from their own duties of ethical reflection.
36. Evidence-gathering activities such as assessing needs and evaluating humanitarian response can also have ethical implications, even though they are not formally classed as ‘research’ and are usually not covered by ethical review systems. Data collectors in these circumstances may need support in thinking through what may be ethically at stake, and what action might need to be taken as a result. Our ethical compass provides a guide for thinking through how evidence-gathering activities may be conducted in ways that show equal respect to those from whom information is being sought, are fair, and are most likely to help reduce suffering. A prompt for explicit discussion of ethical considerations, for example with a manager or colleague, before plans are finalised would help embed such an approach in standard working practices.

#### **Recommendation 8 (directed to humanitarian organisations and their funders)**

**We recommend that humanitarian organisations explicitly build in a step of ‘ethical consideration’ when planning needs assessment, evaluations and other forms of data collection not formally classed as research.**

## **Chapter 7 – Consent and beyond: the wider ethics ecosystem**

37. Even in non-emergency situations, the challenges of seeking genuinely informed consent to research are well-documented. In global health emergencies, factors such as disruption, family separation, lack of access to basic resources and services, and the fear, distress, and powerlessness associated with these experiences, may all exacerbate existing challenges to voluntary and informed decision-making. Research in emergencies may be further complicated by high levels of uncertainty, and by heightened risks for participants, both related and unrelated to the research. In some cases, the

situation of potential participants may mean that agreeing to take part in research appears to be their only option.

38. **Culturally appropriate and respectful consent processes that demonstrate equal respect for participants are as important in emergencies as in any other context.** There are many examples of innovative practices that can be drawn upon to support these processes.
39. **Consent alone, however, is never a sufficient requirement for research to be ethically acceptable. Rather, it is one part of the wider ‘ethics ecosystem’ constituting and supporting ethical research conduct.** This ecosystem includes responsibilities on the part of researchers and ethics committees to be confident that benefits and risks have been carefully scrutinised, risks justified, and wider questions of social justice and social value considered. This can be captured in the question: can what is being asked of potential research participants be justified as fair, given the emergency circumstances they are facing?
40. In circumstances where truly informed consent is challenging because of all the countervailing pressures, research may still be justifiable. However, other parts of the ethics ecosystem will need to be strengthened to make up for the reduced moral role that individual consent can play in that justification. In particular, this involves demonstrating equal respect for communities and community members by developing collaborative and inclusive processes across the lifetime of the research. Various forms of early engagement can play an important role in creating community confidence in research during emergencies:
  - **diverse community and stakeholder engagement in considering the acceptability of study aims** (including exploration of who is likely to benefit from the research) **and study design;**
  - **collaboration with local and national health authorities** to ensure the research is compatible with national research agendas and priorities of local health services, along with verification that there are services available for participants’ ancillary care and other support needs; and
  - **community and stakeholder engagement**, in tandem with engagement with ethics committees, **in developing appropriate recruitment procedures.**

#### **Recommendation 9 (directed to ethics committees)**

**When reviewing proposed consent processes for research in emergency settings, research ethics committees should consider:**

- **whether the proposed consent processes are the best and most sensitive possible that can be achieved in the circumstances;**
- **what other requirements might be needed to ensure respect for participants as people of equal moral worth and agency; and**
- **whether, in all the circumstances, what is being asked of participants can be justified as fair.**

41. There are also recognised exceptions outside the emergency context where individual consent is impossible, for example if a person is unconscious. In some such cases, ethics committees may approve research with high social value on the basis of other protections that promote respect for participants – for example with prior community



consultation about the research, and then permission from relatives. Any proposed waivers of consent in a global health emergency must be particularly closely scrutinised regarding the question of how equal respect for participants is to be secured.

42. A final essential element of respectful relationships with communities hosting the research is to ensure research findings are appropriately disseminated at the end of the project. Dissemination should not only extend to participants, but also through wider community channels in recognition of the part that host communities have played in facilitating that research. Importantly, such dissemination should also include follow-up engagement with key local and national policy-makers to ensure that relevant research findings can be taken up.

#### **Recommendation 10 (directed to ethics committees and funders)**

**Funders should provide a ringfenced budget to support researchers in providing meaningful feedback to their participants, and wider communities, about what their study has learned, and should audit whether this takes place. Ethics committees should similarly look for communication plans across the lifetime of the research when asked to authorise studies.**

## **Chapter 8 – Collaborations and partnerships**

43. Good research relies on bringing together partners with different kinds of expertise who work together collaboratively to ensure that methods and approaches are coherent across the partnership.
- **Effective cooperation** with the many organisations operating on the ground is essential to ensure that research is well-aligned with emergency response needs, and hence to ensure that it best helps reduce suffering. Without cooperation between research agencies, it is likely that populations may be either under- or over-researched, entailing avoidable harm.
  - **Meaningful research collaborations** are much more than cooperation: they involve shared aims and opportunities for all parties involved in the collaboration to shape the research and influence objectives and outcomes. The importance of fair collaborations is underpinned by the ethical imperative to treat others, colleagues as well as research participants, with equal respect.

### **Cooperation between research and response**

44. Research funders should promote profound engagement from the very beginning between researchers and those directly responsible for emergency response, both at strategic level and on the ground. People should not be asked to take part in research, however good its aims, in circumstances where their basic needs are not being met by the response efforts. Good practice examples in recent emergencies include partnerships between research teams and humanitarian partners, such as the World Food Programme, to ensure that such needs are being met before people are asked to contribute to research.

#### **Recommendation 11 (directed to funders)**

**In order to ensure that people’s basic needs are being met when they are being asked to take part in research, funders should routinely expect research teams / research collaborations to include clear partnership plans with relevant service-providers, such as humanitarian organisations and national health departments, when seeking funding for research during emergencies. These arrangements should also include clear plans of action if partners prove unable, at any point, to provide the expected services.**

## **Collaborations within the research sector**

### ***Supporting fair collaborations during emergencies***

45. **The emphasis in our ethical compass on equal and mutual respect between research colleagues, and on the demands of fairness, particularly in responding to historic and current inequities, provide a strong moral basis for policies that create and sustain respectful and meaningful collaborations.** In the immediate need to establish research in response to an emergency, it is important to recognise how the other element of our compass, helping reduce suffering, may act as a partial constraint. Researchers from non-affected high-income countries may be better placed and better resourced to complete research and produce the evidence required to support response than countries that may already be overstretched by the emergency. At the same time, they are unlikely to have the local understanding of needs and perspectives that researchers from the country or region can bring. Honesty between collaboration partners as to the strengths and skills each bring is essential, as is creativity on the part of funders in finding ways to support and incentivise fairer ways of working.

#### **Recommendation 12 (directed to funders)**

**We recommend that funders develop and implement effective and creative ways of promoting and supporting more equitable collaborations, following the principles of the Research Fairness Initiative. In addition to taking account of equity in the review of proposals, these could include taking an active role in linking potential collaborators; providing seed funding for scoping meetings between potential partners from high-income countries and low- and middle-income countries to enable more inclusive input into subsequent funding applications; including budget lines for immediately relevant capacity support of less well-resourced partners; and specific prompts within funding calls to describe how all partners have contributed to the proposed research.**

#### **Recommendation 13 (directed to research institutions)**

**We recommend that research institutions review their performance management systems to ensure that mentoring and supporting overseas colleagues, as part of international collaborations, is recognised and credited.**

### ***Supporting capacity strengthening over the long-term***

46. While time constraints inherent in establishing research collaborations during an emergency inevitably place limits on the priority that can be given at that point to capacity strengthening, such constraints do not apply when considering the longer-term role of funders, research institutions, and others with a role in conducting or supporting research

related to emergency preparedness. **Drawing on the continuing significance of historical injustices that affect research capacity in many low- and middle-income countries, we argue that there is a moral imperative to foster capacity in sustainable ways that, over time, enable the generation and ownership of knowledge to be located directly in affected communities.** This would include supporting institutions in low- and middle-income countries to be in a position to apply directly to funding bodies for research grants, rather than depending on partner institutions in high-income countries.

#### **Recommendation 14 (directed to funders)**

**Research funders should explicitly take a long-term approach to funding capacity strengthening, and in addition to supporting capacity development through international collaborations should aim to shift to direct relationships with research institutions in low- and middle-income countries. They should also consider how to support maximum flexibility at the micro level – for example enabling project leads to approach local partners and explore mutually beneficial arrangements that strengthen local capacity.**

47. While major research funders clearly have an important role to play in supporting sustainable research institutions in low- and middle-income countries, national governments have a responsibility to prioritise the development of research capacity in their countries. This is part of each country's commitments under the International Health Regulations to improve their levels of emergency preparedness. Countries should seek to ensure that capacity gains made during past emergencies are not lost.

#### **Recommendation 15 (directed to national governments)**

**As a key part of national emergency preparedness, national governments should prioritise strengthening academic capacity, including in social science and bioethics, to support the development of national / regional expertise in future. They should also ensure that national ethics committees are adequately resourced and supported.**

48. Finally, we highlight the role of national governments in supporting the international exchange essential for effective research partnerships and the development of individual and organisational capacity. Considerable concerns have been expressed, both in the UK and elsewhere, regarding the implementation of visa policies that appear to be acting as a significant barrier for low- and middle-income country researchers (particularly but not exclusively early career researchers) to travel to high-income countries for workshops, training, or other forms of academic exchange. This is particularly concerning when they have been invited, vouched for, and funded by respected organisations, and where such face-to-face interchange is a crucial part of delivering more equitable collaborative research.

#### **Recommendation 16 (directed to national governments)**

**National governments are urged to be alert to the importance of international collaboration and exchange as part of research capacity development, and to ensure that visa requirements, for example for attending meetings and training, do not in practice prevent academics, vouched for by funders and partner**

research institutions in the receiving country, from being able to attend such events.

## Chapter 9 – Data and samples

49. The collection, storage, and sharing of biological samples and data are essential parts of effective research in global health emergencies. Whilst many ethical issues raised by these activities are the same irrespective of whether samples or data are being used (for example, the importance of equity), there are also important differences. Some of these relate to the fact that samples often constitute a depletable resource, raising issues about which research should be prioritised. Others relate to the social, cultural, or religious status of samples. Still others arise out of the fact that samples can in many cases relatively easily be transformed into data. When we refer to ‘samples and data’, this should not be taken to imply that there are not ethically important differences between them. We note such differences at several points.
50. Sharing data and samples between humanitarian actors, or for future research use, can play an important role in helping reduce suffering in many ways, both during emergencies and in the routine surveillance that forms part of emergency preparedness. However, sharing may also bring with it risks of harm and exploitation (often for those already unfairly burdened or disadvantaged) and can undermine trust. ‘Sharing’ at present also comes in many forms, including with or without strict access and governance arrangements. **Sharing is vital for effective research collaboration, but it must not be exploitative. The questions to ask are: ‘What can be done to ensure the kind of environment in which data and samples can ethically be shared? What are the conditions for equitable and responsible sharing?’**

### The role of individuals and communities regarding future use of data and samples

51. Action is needed both in planning for the long-term, and in response to challenges faced when emergencies arise in the absence of such planning. More evidence is needed to explore culturally appropriate approaches to consent, and to understand what governance arrangements for holding and sharing both data and samples would most effectively minimise unintended harms and underpin community trust. Guidance at national or regional level is urgently needed in many parts of the world.

#### **Recommendation 17 (directed to funders, national and regional research leaders, national governments and all levels of the WHO)**

**We recommend that funders and leading research institutions should prioritise further research, in different parts of the world, on stakeholders’ views as to what consent and governance mechanisms would create sustainable trust and confidence in the sharing of data and samples for future research use. This evidence should then inform the development of guidance, such as that being developed by the African Academy of Sciences. National governments and intergovernmental agencies should actively support such initiatives as an essential part of emergency planning.**

52. However, there will still be many circumstances where scope for data and/or sample sharing arise (with potential for contemporary as well as future benefit), but where no groundwork exists to support researchers. In such circumstances, **there will be a need**

for the development of adaptive approaches recognised as having local legitimacy, and that are committed to developing, over time, fair processes and mutually respectful relationships between stakeholders. One possible approach would be for nationally respected bodies such as national research ethics committees (NRECs) to have the discretion to approve a staged approach to consent for the future use of data and/or samples. This might involve the retention of data and samples collected for a person's treatment (whether within the context of interventional research or in non-research contexts) until it is feasible to establish a legitimate process.

53. Finally, we turn to the sensitive question of 'legacy' or archive samples taken and stored in past emergencies where the scope of any consent given is not clear. Such samples may represent a highly valuable (in some cases very rare or even unique) resource with scope to contribute to important developments in understanding and treatment, particularly of rare or novel pathogens. Making responsible use of such samples is strongly supported by the emphasis in our ethical compass of helping reduce suffering. However, such potential benefits can never entirely 'trump' the other two elements of our compass: equal respect and fairness.

#### **Recommendation 18 (directed to research institutions holding 'legacy' or archive samples, and to the WHO)**

**We recommend that all research institutions currently holding substantial sample collections share this information on an inventory (to be held by a body such as the WHO or a regional Centre for Disease Control). Where the scope of the consent provided is unclear, they should commit to discussions with relevant national governments, national and regional research leaders, and community representatives such as survivor organisations, about what form fair and respectful future use of these samples might take.**

#### **Recommendation 19 (directed to funders, governments and other regulators, and WHO)**

**We recommend that, in the future, any international research collaborations that intend to collect and store samples prospectively for future research use, should be required to register that collection (including information, for example, about the relevant disease, the number of samples, and the location of the biorepository) in a publicly available database.**

### **Exploring professional and institutional barriers to sharing**

54. Barriers to effective sharing of either data or samples during (and in the aftermath of) global health emergencies include:
- concerns about the quality of one's own data;
  - holding on to data or samples because this is perceived to be the only form of control a researcher may have;
  - data being shared but not in any useable form; and
  - limited commitment to research by some governments.
55. **Equitable sharing** requires systems that give researchers in low-income countries the same opportunities as those in high-income countries to benefit from the data and

samples that they have acquired themselves, and from open ‘sharing’ arrangements. **Responsible sharing** includes ensuring that data and samples, once shared, are used to optimum effect. In addition to existing good practice initiatives to promote such sharing, we make a number of recommendations to journals, research institutions, and funders in order to ensure that:

- primary data and sample collectors are appropriately credited for their work;
- funding policies support not only sharing data but also effective reuse; and
- the findings of research are made accessible to a wide range of stakeholders, in addition to through academic publishing routes.

#### **Recommendation 20 (directed to journals and research institutions)**

**We recommend that journals and research institutions explore innovative ways to recognise significant intellectual input into research findings short of direct involvement in writing: for example through more inclusive authorship criteria or other forms of recognising primary research contributors on a named basis. We further recommend consideration of publication policies that actively promote the inclusion of primary researchers in any later re-analysis of shared data and/or samples, and ensure that those working in low- and middle-income countries can access research findings freely.**

#### **Recommendation 21 (directed to funders)**

**We recommend that funders consider how they can take a more active role with respect to the future responsible use of data and samples, once these have been made more widely available. In addition to monitoring how their grantees meet any existing obligations to make data not only available but useable (for example through requiring compliance with the FAIR principles), this could include specific funding policies to support secondary analysis, building, for example on the model of the WorldWide Antimalarial Resistance Network study groups.**

#### **Recommendation 22 (directed to funders)**

**We recommend that funders explore ways in which they can require, and support, their grantees to share their research findings in accessible and timely ways with key policy stakeholders. We further recommend that they consider ways in which they could help ensure findings, including negative findings, are publicly accessible in non-academic formats, for example through the development of shared platforms.**

## **Chapter 10 – Practical ethical issues faced by front-line workers**

56. Those working on the front-line of research in global health emergencies – which may include those with professional health or other academic qualifications, research assistants, drivers, security personnel, and volunteer healthcare workers – can face particularly challenging, often dangerous, working conditions. There is an increasing awareness of the need to support front-line workers better in dealing with ethical challenges that emerge during their involvement with a study, accompanying the recognition that ethical review cannot resolve all issues.



## Welfare and fair treatment of front-line workers

57. The role of front-line workers may be inherently risky, and there can be a tension between respect for the welfare of research workers, and effective conduct of the planned research. Funders, employers, and research ethics committees have a duty to consider the welfare of workers, alongside the welfare of participants and the value of the research, and to ensure action is taken to mitigate foreseeable risks. Local knowledge will be crucial in recognising such risks, and in identifying how to prevent or mitigate them.
58. Differential terms of employment between local and international workers, or between different staff groups such as those with or without professional qualifications, can be exploitative, are a source of concern to many in the field, and may undermine scope for respectful collaboration. While equal respect underpins equality of treatment, how this is realised in practice is not straightforward, as in lower-income settings this creates other sources of inequality: paying all workers international rates, for example, could seriously undermine local health systems and economies.

### Recommendation 23 (directed to research institutions)

**We recommend that research institutions, when setting policies, both in general and for a particular emergency, should explicitly consider whether those conditions represent a ‘fair offer’ in the circumstances. We suggest that elements of a fair offer will include:**

- being transparent about how rates of pay are set, and the basis for any differential treatment of local / international workers;
- working with other partner organisations, in particular those responsible for providing routine health services in the location where the research is planned, to understand the context and potential consequences of employers’ decisions;
- aiming to provide the highest attainable standard of care and support for any person working on behalf of the institution, whose care needs arise as a result of that work;
- providing explicit justification for any differences in treatment with respect to safeguarding and safety; and
- including temporary and indirectly employed (e.g., sub-contracted) workers within these considerations.

59. **While the primary responsibility for the fair treatment of front-line workers rests with employers, research funders also have responsibilities in this area, both to allow for any costs involved, and to ensure that research employers’ responsibilities in this area are scrutinised within the grant system.**

## Ethical support for front-line workers

60. While careful review processes and collaborative work with local communities to understand local needs and sensitivities can play a part in reducing ethical dilemmas facing front-line workers, such dilemmas are still an inevitable part of working in an emergency. Those on the front-line (who are often the least well-supported) need to have access to timely, high quality ethics support in a variety of forms. There is a particular need for a flexible platform to provide timely ethics advice and support for those involved in all aspects of research in emergencies, including those funding, planning, and carrying

out research. In response to this need, a pilot network has been launched that aims to facilitate timely responsive advice in this way; conduct empirical ethics research to inform such advice; and develop ethics capacity low- and middle-income countries to ensure that the network grows to reflect global perspectives.

#### Recommendation 24

**There is a need for a flexible, well-funded platform to provide timely ethics advice and support for those involved in all aspects of research in emergencies, including those funding, planning, and carrying out research. We welcome the launch of the Public Health Emergency Ethics Preparedness and Response (PHEEPR) Network. We welcome, in particular, the planned focus on the support for ethics capacity in low-income settings, and the recognition of the central importance of such sources of ethics advice being widely dispersed around the world.**

### Chapter 11 – Afterword from the Chair of the working group

61. Global health emergencies are not amenable to easy definition. The agencies, communities, and people who are brought together in the conduct of research within such emergencies bring with them different moral concerns, commitments, and values. Engaging seriously with these differences is an important requirement for any attempt to understand the ethical dimensions of research in emergencies.
62. Resisting moral relativism or bioethical paralysis in the face of these problems, our response has been to attempt to offer sensible advice to those who face them in practice. Our contribution has two elements. One of these is crystallised in our concept of an ethical compass, comprising substantive normative commitments to equal moral respect, helping reduce suffering, and fairness. Our second contribution, illustrated by our choice of focus for Chapters 5–10, has been to identify a number of particularly salient, morally significant, aspects of research in global health emergencies, and to offer an informed, in-depth analysis of the nature of the problems and difficult decisions to be made, in the light of the evidence we received.
63. Important cross-cutting themes of this report include:
  - **How the successful conduct of research to high ethical standards depends crucially upon the moral and ethical work undertaken every day by front-line research workers, health professionals, and volunteers.** The importance of this work – the moral craft of day-to-day ethical research – is very often not fully appreciated or rewarded. It is, however, essential.
  - **The vital importance of properly resourced preparedness between emergencies.** Preparedness and emergency planning are essential for many reasons: they mean emergencies are less likely to happen and more manageable when they do occur. They also mean that the requirements for valuable, ethical research to be conducted are more likely to be in place.
64. Above all, we have tried to bear in mind throughout our deliberations that research undertaken in the context of global health emergencies involves real people, families, and communities. It asks a great deal of them, primarily in the interests of others, at a time of great distress, fear, and vulnerability. We take this opportunity to acknowledge and celebrate the contribution of those who take part in such research.



## Introduction

This report from an international working group established by the Nuffield Council on Bioethics explores the complex and contested question of how research can be conducted ethically during major health emergencies and humanitarian crises. The importance of this issue for the many millions of people threatened by, or living with the consequences of, health emergencies around the world is increasingly recognised. In June 2017, for example, *The Lancet* published a special series highlighting the essential role research can play in improving the effectiveness of the health response to those affected by humanitarian crises – and mapping the limited quantity and quality of such research data in many aspects of health-related humanitarian activity.<sup>1</sup> In setting out its agenda for improving the evidence for health in humanitarian crises, the series brought to the fore the tension between the claim that there is an ethical imperative to gather good data in order to provide better services, and the belief reportedly still held by many practitioners that research in disaster settings is unethical.<sup>2</sup> Recent outbreaks of Ebola have similarly drawn international attention both to the valuable role of health research in such contexts (for example in improving the evidence base for the effectiveness of experimental vaccines); and to the concerning lack of consensus about how such research might be conducted ethically.

In this report, we explore these ethical questions with reference to many kinds of health-related emergency around the world. These range from outbreaks of infectious diseases for which there are currently no effective licensed treatments – such as the Ebola, Zika, and Nipah viruses – to the health impacts of both natural and human-made disasters, including the consequences of conflict and mass movements of people, and complex emergencies where two or more of these forms of disaster come together.<sup>3</sup> The World Health Organization (WHO) has highlighted a number of causes underlying the increasing number of infectious disease outbreaks, commenting that: “climate change, emerging diseases, exploitation of the rainforest, large and highly mobile populations, weak governments and conflict [are] making outbreaks more likely to occur and more likely to swell in size once they did”.<sup>4</sup> Conflict and extreme climate events underpin the increasing number of people in need of humanitarian assistance;<sup>5</sup> and both the numbers of displaced people, and the length of time they are displaced, are increasing.<sup>6</sup>

The aims of the Nuffield Council’s project are twofold: on the one hand, to support and promote the contribution that ethically-conducted research can make to current and future emergency preparedness and response; and on the other to help reduce the risk that unethical health-related research is conducted during emergencies. In support of these aims, the working group

<sup>1</sup> *The Lancet* (2017) *Health in humanitarian crises (series)*, available at: <https://www.thelancet.com/series/health-in-humanitarian-crises>. See also: Kohrt BA, Mistry AS, Anand N *et al.* (2019) Health research in humanitarian crises: an urgent global imperative *BMJ Global Health* **4(6)**: e001870.

<sup>2</sup> O’Mathúna D, and Siriwardhana C (2017) Research ethics and evidence for humanitarian health *The Lancet* **390(10109)**: 2228-9.

<sup>3</sup> For example, the Fukushima earthquake / tsunami / nuclear disaster.

<sup>4</sup> BBC News (7 June 2019) *Large Ebola outbreaks new normal, says WHO*, available at: <https://www.bbc.co.uk/news/health-48547983>. See also: Fouque F, and Reeder JC (2019) Impact of past and on-going changes on climate and weather on vector-borne diseases transmission: a look at the evidence *Infectious Diseases of Poverty* **8(1)**: 51; Global Preparedness Monitoring Board (2019) *A world at risk: annual report on global preparedness for health emergencies*, available at: [https://apps.who.int/gpmb/assets/annual\\_report/GPMB\\_annualreport\\_2019.pdf](https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf); and SciDev.net (24 June 2019) *Humanitarians turn sights on climate risk*, available at: <https://www.scidev.net/global/climate-change/feature/humanitarians-turn-sights-on-climate-risk.html>.

<sup>5</sup> OCHA (2019) *Global humanitarian overview 2020*, available at: [https://www.unocha.org/sites/unocha/files/GHO-2020\\_v8.7%2006122019%202pm.pdf](https://www.unocha.org/sites/unocha/files/GHO-2020_v8.7%2006122019%202pm.pdf), at page 4.

<sup>6</sup> *ibid.*, at page 13; and International Displacement Monitoring Centre (2019) *Global report on internal displacement*, available at: <http://www.internal-displacement.org/global-report/grid2019/>.

has sought to provide an in-depth characterisation of where the ethical problems lie; help develop a common understanding of what constitutes ethical research and research ethics in such circumstances; and, where appropriate, make practical recommendations for change.

In approaching this challenging topic, we recognise the substantial body of academic and policy work already undertaken in this field. These include (to name only a few) the ethical consensus statement generated in response to research experiences in the aftermath of the 2004 tsunami;<sup>7</sup> guidance developed by the World Health Organization (WHO) in response to the challenges of the 2014–16 Ebola outbreak;<sup>8</sup> literature on areas such as the ethical challenges of the humanitarian health sector<sup>9</sup> and the ethics of study design in infectious disease outbreaks;<sup>10</sup> and the ongoing work of the Post-Research Ethics Analysis (PREA) project to develop a tool to assist researchers in reflecting on ethical issues in humanitarian research.<sup>11</sup> Our aim has been to build on, and complement, existing and contemporaneous work. Here, we bring together in one place the relevant ethical issues, and considerations for how to approach them, while recognising that this is an area in which consensus on the right approach may be hard-won.

A note on methodology. Throughout this project, we have sought input from as diverse a range of contributors as possible: in terms of geography, and in type of emergency, research topic, discipline, and professional role; from the highly personal experiences of participants and researchers to the policies and concerns of major institutions. We have also heard from those whose primary concern is to respond directly to the health needs of those affected by emergencies, and for whom research is rightly a secondary concern. We have hosted or attended workshops in the Philippines, Singapore, Lebanon, and Senegal; and attended international conferences in China, South Africa, the US, Ireland, and the UK (see Appendix 1). Our working group includes members from Hong Kong, Ghana, Liberia, and Brazil, and UK-based colleagues from India and Uganda; and we received responses to our call for evidence from over 30 countries (see Appendices 1 and 2, and map overleaf). We have endeavoured throughout to base our thinking and our findings on what we have heard from these very rich sources, alongside what is reported through the published literature. We are nevertheless aware that our gaze has been restricted, not least by our focus on literature and communication in English. Recognising these limitations, we hope that this report will provide a fruitful starting point for further debate, both in an inclusive manner at international level, and at country level as national institutions grapple with their own emergency planning.

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<sup>7</sup> Sumathipala A, Jafarey A, Castro L *et al.* (2010) Ethical issues in post-disaster clinical interventions and research: a developing world perspective. Key findings from a drafting and consensus generation meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007 *Asian Bioethics Review* **2(2)**: 124-42.

<sup>8</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>.

<sup>9</sup> See, for example, Hunt M, Schwartz L, Pringle J *et al.* (2014) A research agenda for humanitarian health ethics *PLoS Currents* **6**: ecurrents.dis.8b3c24217d80f3975618fc9d9228a144; Eckenwiler L, Pringle J, Boulanger R *et al.* (2015) Real-time responsiveness for ethics oversight during disaster research *Bioethics* **29(9)**: 653-61; and Gailits N, Nouvet E, Pringle J *et al.* (2019) *Blurring lines: complexities of ethical challenges in the conduct of West African Ebola research*, available at: <https://www.elrha.org/wp-content/uploads/2019/10/Gailits-et-al.-Blurring-Lines-Ethical-Challenges-in-West-African-Ebola-Research.pdf>.

<sup>10</sup> See, for example, Rid A, and Emanuel EJ (2014) Ethical considerations of experimental interventions in the Ebola outbreak *The Lancet* **384(9957)**: 1896-9; and Lanini S, Zumla A, Ioannidis JPA *et al.* (2015) Are adaptive randomised trials or non-randomised studies the best way to address the Ebola outbreak in West Africa? *The Lancet Infectious Diseases* **15(6)**: 738-45.

<sup>11</sup> PREA (2019) *Getting started with the PREA Tool*, available at: <https://www.preatool.com/guide/domain/>.



### ***Taking a broad approach to the ethics of research***

This report makes the case for considerably broadening the traditional understanding of what is thought of as ‘research ethics’. A rigorous approach to the standard research ethics questions of appropriate study design, independent scrutiny, and the fair treatment of research participants is essential for the ethical conduct of research, but is not sufficient. Research ethics questions cannot be considered in a vacuum without reference to context: both the specifics of an emergency as it unfolds at a particular time and location; and with respect to broader structural, political, and power concerns. Health-related research in many health emergencies takes place in the context of deep historical inequities and ongoing imbalances in power and influence, raising important questions of justice.<sup>12</sup>

We recognise that there are many factors that this report cannot influence, not least the causes of conflict that underlie or exacerbate many humanitarian crises. Nevertheless we have kept these larger concerns in view and acknowledge their importance when we consider the duties and responsibilities of the many stakeholders concerned in regulating, funding, facilitating, reviewing, conducting, and reporting research concerned with the health response to an emergency. Existing levels of inequity, both between and within countries, whether in terms of the capacity of their health and research infrastructures, in their economic circumstances, or in their global influence, have important consequences for those duties and responsibilities. For example: how are decisions made as to what research to fund and, by necessary implication, what *not* to fund? In what direction does the value of the research flow? Whose voices are being heard at different points in the research endeavour and whose benefit is being considered and prioritised? What is required to promote well-founded trust between participants, researchers, and other key players such as local health professionals in contexts

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<sup>12</sup> See, for example, Keller RC (2006) Geographies of power, legacies of mistrust: colonial mistrust in the global present *Historical Geography* 34: 26-48; and Nunes J (2016) Ebola and the production of neglect in global health *Third World Quarterly* 37(3): 542-56.

where the grounds for such trust may be absent in the early stages of emergency response? **In brief, ethics is not just about the behaviour of people on the ground, but also the functioning of processes that, however remote they may seem at times to front-line research workers and participants, exert powerful influence on the options actually open to those directly involved in research activities.**

During the writing of this report, it became clear that for a significant number of actors in the research community, and among emergency responders, the word ‘ethics’ has acquired a bad name, being primarily associated with bureaucratic and burdensome processes, rather than being concerned with questions relating to good conduct throughout the whole research endeavour.<sup>13</sup> Such a (mis)perception needs to be taken seriously. The need for more flexible and responsive approaches to ethical scrutiny must be recognised: processes should never become ends in themselves, and must add value if they are to be justified. At the same time, it was equally clear to us that many researchers working in this area consider, and are deeply sensitive to, questions of right conduct in research and the fair treatment of participants and collaborators, whether or not they badge these considerations as ‘ethical’. For example, imbalances of influence and power in research, and the way these contribute to inequitable collaborations, and to the prioritising of the research needs of some populations over others, emerged as matters of serious concern to many researchers. By focusing on the significance of these higher-level ethical questions, and their relevance for policies that shape researchers’ work, we hope to show how ‘ethics’ can and do support people in real-world settings struggling with complex realities on the ground. Similarly, throughout this report we aim to translate ethical considerations and approaches into practical policy recommendations that could change future practice.

### ***Structure of this report***

**Chapters 1–3** set out the background that provides the empirical basis for the rest of the report:

- **Chapter 1** sets out the scope of our inquiry, explaining the broad approach taken to what constitutes a ‘global health emergency’ and the nature of the research and other evidence-gathering activities with which we are concerned. It also sketches out the complicated regulatory background against which research takes place.
- **Chapter 2** draws on the contributions we received directly, and on the published literature, to present the experiences of those affected by various kinds of emergency both in leading / participating in emergency response, and in participating in associated research. It then presents the experiences of researchers on the ground.
- **Chapter 3** provides an overview of some of the many organisational and structural factors that control and influence how research may be conducted in an emergency, with a particular focus on the role of nation states, intergovernmental organisations, and multi-country / multi-agency collaborations in emergency preparedness.

**Chapter 4** explores the ethical questions emerging from the evidence presented in these first three chapters and sets out an ‘ethical compass’ to guide both policy and practice.

**Chapters 5–10** consider the implications of this ethical compass across different areas:

- **Chapter 5** explores questions of power and influence throughout the research endeavour, with a focus on how the voice of affected populations and other

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<sup>13</sup> See, for example, Parker M, and Allen T (2013) Questioning ethics in global health, in *Ethics in the field: contemporary challenges*, MacClancy J, and Fuentes A (Editors) (Oxford: Berghahn), who further express concerns as to how at times ethics processes may be used to protect vested interests.

stakeholders can be meaningfully included in determining what research takes place, where, and how.

- **Chapter 6** looks at questions of study design and review, with links to the earlier discussion of stakeholder engagement.
- **Chapter 7** explores issues of 'consent and beyond', considering the role of the wider ethics ecosystem alongside participant consent in ensuring the fair treatment of research participants.
- **Chapter 8** is concerned with ethical and effective collaborations both within the research sector, and between response and research actors.
- **Chapter 9** considers the issues that arise in sharing data and samples.
- **Chapter 10** explores the role of front-line research workers, and what might be required to ensure that they are better supported.

**Chapter 11** is the final chapter, and draws together common themes across the report, with emphasis on the moral and ethical work undertaken every day by front-line research workers, health professionals, and volunteers; and on the vital importance of properly resourced emergency preparedness.



# Chapter 1

Scope and context



# Chapter 1 – Scope and context

## Chapter 1: overview

This report takes a broad and inclusive approach, both to circumstances that might be characterised as ‘global health emergencies’, and to what activities constitute health-related research.

Our concern with ‘research’ encompasses a broad range of evidence-generating activities whose primary aim is to improve the health-related aspects of emergency preparedness, mitigation, and response. These include clinical trials of novel treatments and vaccines, social science research, epidemiological studies, implementation research, and health systems research, as well as less formalised ways in which data are used to improve response within the humanitarian sector. ‘Global health emergencies’ should not be rigidly defined but include situations with many or all of the following features that render much-needed research very difficult:

- **Disruption from some kind of relatively stable norm** (including where such disruption is long-term, for example where populations are left without civil or political rights). Potential causes of such disruption include infectious disease outbreaks, natural disasters, and human-made disasters such as conflict, bioterrorism, and industrial accidents.
- **Significantly raised risks to physical or mental well-being** at both individual and population level;
- **Pressures of time**, creating tensions between research and response timescales, and exacerbating the challenges of multidisciplinary working;
- **Uncertainty**, making decision-making in these time-limited contexts particularly difficult for all concerned;
- **Fear, distress, and sometimes panic**, potentially undermining populations’ ability or desire to engage with research; and
- **Need for a multi-country and multi-agency response** associated with inevitable tensions and differences in approach between different actors, and with scope for disagreement over control, responsibility, and legitimacy.

It is these challenges, rather than the health implications of the emergency for other countries, that provide the primary justification for our focus on ‘global’ health emergencies.

Those undertaking research in the challenging circumstances of a global health emergency are accountable to a patchwork of sometimes inconsistent and conflicting regulatory and governance mechanisms. In addition to the requirements of national legal systems, these include international human rights and humanitarian law; ethical guidelines for different kinds of research operating at international, regional, and local level; and specific technical requirements for investigational medicinal products.

## Introduction

- 1.1 We begin by briefly outlining the scope of this report: both in terms of the kind of health emergencies with which we are concerned; and of the kind of evidence-generating activities that are included within the concept of ‘research’. We recognise that neither of these terms lends itself to simple definition. Indeed, responses to our call for evidence demonstrated how contentious, and at times political, such definitions may be (see Box 1.1). While it is important to be able to speak meaningfully of what is at stake, or within



scope, we take the view that formal definitions are not always required – and can be contentious and exclusionary, rather than constructive and consensual.<sup>14</sup> Moreover, the differences between the definitions adopted by diverse bodies, and the different implications of a situation being categorised as an ‘emergency’, can themselves be a source of ethical debate.

- 1.2 As we set out below, **we take a broad and inclusive approach to the circumstances that might be characterised as global health emergencies. We also draw attention to the very wide range of activities, the aim of which is to generate evidence in this field, and note the extent to which these may often raise similar issues (in particular from the perspective of those to whom the data relate), even if some of them are not formally classified as research by regulators** (see paragraphs 1.28). The implications of this broad approach, and the necessity in some circumstances for drawing clear lines where required for the purposes of guidance and law, are made explicit throughout this report. We emphasise that what is ethical may be distinct from what is legally required, and that ethics may sometimes demand more than simply practising in accordance with relevant law. Our aim is to develop a rich and practically-oriented understanding of the ethical issues at stake, rather than being prescriptive or narrowly regulatory.

#### Box 1.1: What constitutes a ‘global health emergency’? Responses to our call for evidence

Our invitation to comment on a working definition of a global health emergency set out in our call for evidence elicited strong, and often conflicting, responses.

“Best to have as minimal a definition as possible – soft and contextual.” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

“Global Health Emergency is an important definition – particularly given its focus in capturing the scale of an emergency – that is in case there is a threat to the rest of the world and if the magnitude warrants a foreign intervention.” *Anonymous respondent*

“It is helpful to have a broad definition of global health emergency that is inclusive of man-made and natural disasters, armed conflict, forced displacement, and disease outbreaks as there are many similarities in the ethical questions related to research across these different types of crises.” *Anonymous respondent*

“I have difficulty in grouping all types of emergencies under the heading of global health emergency. There are different types of emergencies which I do not think should be lumped together.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“One issue that is difficult to capture in any definition is if / when an event, through becoming a chronic situation, no longer constitutes a global health emergency – or

<sup>14</sup> See, for example, the extended discussions of when it is right for the WHO to designate a situation a ‘public health emergency of international concern’ and whether or not it is significant since, in itself, this is not a necessary step to release resources to help step up response: The Telegraph (16 April 2019) *World must ‘step up’ in the fight against an escalating Ebola outbreak*, available at: <https://www.telegraph.co.uk/news/2019/04/16/world-must-step-fight-against-escalating-ebola-outbreak/>; The Lancet (2019) The politics of PHEIC *The Lancet* **393(10190)**: 2470; and The Guardian (18 July 2019) *The Guardian view on Ebola in the DRC: help needed - and dialogue too*, available at: <https://www.theguardian.com/commentisfree/2019/jul/18/the-guardian-view-on-ebola-in-the-drc-help-needed-and-dialogue-too>.

whether the long-term nature of some events does not exclude them from the definition”.  
*Anonymous respondent*

“We acknowledge that definitions are necessary for identifying when certain mechanisms need to be triggered so that necessary interventions and research meet people’s needs, are timely and are fit for the context.” *Wellcome*

“... the word “global” is too often (mis)used these days, so the term “health emergency of international concern” could be preferable. For instance, we can hardly say that the earthquake in Haiti was a “global” problem, unless if we link this to the “global” media coverage.” *Raffaella Ravinetto, Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Marianne van der Sande, Head of the Public Health Department, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Anne Buvé, Vice-Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium*

“Research in linguistics of “international” vs. “global” health found difficulty in differentiating between them. My suggestion is to make it as simple as possible and standardize it so that research and action will end up meaning the same thing when they talk about this thing called “global health”.” *Dr Najeeb Al-Shorbaji, Consultant*

“There is [a] lack of clarity around the nature of the health impacts: a famine has health impacts which may destabilise a region causing different health impacts. Is that a health emergency?” *Anonymous respondent*

## What we mean by ‘global health emergency’

- 1.3 **This report is concerned with emergency contexts where health-related research could play a valuable part in improving the quality and/or effectiveness of the response (both at the time and in similar circumstances in the future), but where the nature of the emergency itself puts pressure on the ethical conduct of that research.** Such contexts might, variously, be described as ‘public health emergencies’, ‘humanitarian crises’, natural or human-made ‘disasters’, or ‘complex emergencies’ involving multiple causes.<sup>15</sup> They are associated with significant risks to physical or mental well-being, at both the individual and population level. Such risks to health may be accompanied by threats to many other aspects of welfare, for example through threats to livelihoods and to social and family structures.
- 1.4 By referring specifically to ‘global’ health emergencies, we focus our analysis particularly on those emergencies that are unlikely to be successfully prevented, contained, or managed by a single affected country, and hence where other countries and/or external agencies are involved in the response. Such external involvement brings associated challenges of effective cooperation, collaboration, political sensitivity, and the management of power differentials and potentially conflicting goals.<sup>16</sup> Existing response capacity within an affected country may be overwhelmed in a number of ways: for example because of an existing lack of health infrastructure, workers, or resources; because the nature of the emergency has destroyed or undermined capacity to respond; or because of uncertainty or lack of knowledge, for example where no effective treatment or control mechanisms yet exist. Each of these scenarios may present both policy-

<sup>15</sup> See, for example, Keen D (2008) *Complex emergencies* (Cambridge: Polity Press).

<sup>16</sup> See, for example, Barakat S, Connolly D, Hardman F *et al.* (2014) *Beyond fragility: a conflict and education analysis of the Somali context*, available at: <https://www.york.ac.uk/media/iee/documents/UNICEF%20Beyond%20fragility.pdf> for an exploration of how the provision of basic services (in this case of education) in disrupted societies needs to be underpinned by careful political analysis.

makers and those working on the ground with a range of ethical challenges. The last example (i.e., where there are no effective treatments), in particular, highlights how global health emergencies may arise in high-income countries (HICs) and are not limited to settings where health resources are already seriously constrained.<sup>17</sup>

- 1.5 We recognise that this account of what makes an emergency ‘global’ rests on an implicit ethical claim: that there is a moral obligation on the part of the international community, founded on solidarity, to offer support in such cases, even where there is no immediate and direct threat to other countries.<sup>18</sup> It is our endorsement of that ethical claim, and an awareness of the additional practical and ethical challenges associated with the actions of external actors consequent on such an obligation, that underpins the focus of this report. Concerns about ‘global health security’ and the implications emergencies may hold for other countries (whether low-income countries (LICs) or HICs) are relevant but are not a primary justification for this focus.<sup>19</sup> We are also aware that the concept of ‘global health’ is itself contested, particularly with respect to the roles, responsibilities, and relationships of different parties (see Box 1.2).
- 1.6 It should be emphasised that **we are not using the term ‘global’ to distinguish from what is ‘regional’ (in the sense of the WHO Regions) or what is ‘international’, but simply in the sense of necessitating participation in the emergency response from outside the country.** Such involvement in research in these circumstances might draw on a wide range of bodies in addition to the many organisations and individuals already engaged in-country, including: intergovernmental agencies (whether at regional or head office level), international or regional non-governmental organisations (NGOs), multi-country research collaborations, philanthropic research funders, the commercial pharmaceutical and biotechnology sector, or foreign country institutions such as overseas aid departments and national research funders.

### Box 1.2: Meanings of ‘global health’

The terminology of ‘global health’, and its implied contrast with ‘international health’ is contested, and far from self-explanatory. One definition of global health is “an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasises transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of population-based prevention with individual-level clinical care”.<sup>20</sup>

It has been argued that the widespread shift to the use of this term from the earlier usage of ‘international health’ is representative of wider changes in working contexts in which United Nations (UN) agencies like the WHO found themselves from the 1980s onwards.<sup>21</sup> This new era, it is suggested, has been marked by funding trends brought in

<sup>17</sup> For example, the modelling of Disease X: Business Insider (29 July 2018) *A leading medical institution created a simulation that shows how a new disease could kill 900 million people - and it reveals how unprepared we are*, available at: <https://www.businessinsider.com/pandemic-virus-simulation-johns-hopkins-shows-vulnerability-2018-7?r=US&IR=T>; and the modelling of smallpox bioterrorism: Science Alert (21 February 2019) *Chilling new research shows how dire a smallpox bioterror attack could actually get*, available at: <https://www.sciencealert.com/this-is-how-bad-a-worst-case-smallpox-bioterror-attack-could-actually-get>.

<sup>18</sup> For a discussion of solidarity as an ethical concept, see: Nuffield Council on Bioethics (2011) *Solidarity: reflections on an emerging concept in bioethics*, available at: <https://nuffieldbioethics.org/publications/solidarity>.

<sup>19</sup> See, for example, Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* **15(3)**: 362-76.

<sup>20</sup> Koplan JP, Bond TC, Merson MH *et al.* (2009) Towards a common definition of global health *The Lancet* **373(9679)**: 1993-5.

<sup>21</sup> Brown TM, Cueto M, and Fee E (2006) The World Health Organization and the transition from “international” to “global” public health *American Journal of Public Health* **96(1)**: 62-72.

by new 'global' funders, in the shape of ambitious and active philanthropies and multilateral agencies seeking to be independent of governmental control and keen to promote new, transborder initiatives without geographical or political impediment.

Such a shift in funding power and the creation of a new global approach to health action has certainly taken place.<sup>22</sup> However, some continue to advocate for the ongoing use of the term 'international health', arguing that international cooperation is integral to supporting the health and well-being of vulnerable populations; that national governments play a key role in protecting and improving a country's health, and that not all solutions are 'global'.<sup>23</sup> Moreover, despite shifts in funding power, many countries have retained their independence in health diplomacy and international affairs, seeking to exercise national autonomy and control through regional and international negotiations and activity. Given these tensions, it is unsurprising that 'global health' continues to be deployed and understood in a plethora of ways in policy circles, as well as by academic researchers who work with or evaluate their activities.

For the purposes of this report, the term 'global health' is used in a democratic and inclusive mode. We use it to refer to activities being carried out in partnership by actors in the World Health Organization (WHO) and other similar UN agencies; national governments (both those providing and receiving financial aid, material assistance, and workers); overseas workers seconded by governments and other agencies to work in crisis sites alongside national workers; NGOs within and from outside affected countries (including faith-based bodies); and international and domestic philanthropic foundations and their representatives. This is work carried out in a multiplicity of locations, with a range of languages, methodologies, and legal structures. Global health research activities within these settings are similarly diverse. This report therefore accepts the importance of studying and engaging with many actors involved in mobilising, analysing, and publishing data to allow better understandings of – and responses to – crisis situations.

- 1.7 There are several, sometimes competing, definitions of what constitutes an 'emergency', developed for different purposes and by different organisations (see Box 1.3 and Appendix 3). For example, a declaration that an event constitutes an emergency may release funds from dedicated sources; step up the level of a particular organisation's response in predetermined ways; or permit the use of special legal powers or restrictions. It would neither be possible, nor helpful, to adopt any one of these definitions for the purposes of this report: the multiplicity of definitions, underpinned by different values and priorities, form part of the complex reality with which we are concerned. Indeed, if we adopted one particular definition, this might have the potential to obscure the fact that a key feature of the ethical landscape is the need for researchers and research funding agencies to act in a space where there is a lack of consensus about the meaning of terms and their application.<sup>24</sup>

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<sup>22</sup> See, for example, Clinton C, and Sridhar D (2017) Who pays for cooperation in global health? A comparative analysis of WHO, the World Bank, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance *The Lancet* **390(10091)**: 324-32.

<sup>23</sup> See, for example, Johns Hopkins Bloomberg School of Public Health (2019) *Why we are named the Department of International Health*, available at: <https://www.jhsph.edu/departments/international-health/about-us/why-the-department-is-named-international-health.html>.

<sup>24</sup> For an account of the implications of categorising a particular situation as a health emergency of a health-related humanitarian crisis, see: Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* **15(3)**: 362-76.

**Box 1.3: Definitions of emergencies / disasters by different organisations**

- A **'public health emergency of international concern'** (PHEIC) is defined in the 2005 International Health Regulations (IHR) as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response." The declaration of a PHEIC by the WHO's Director-General gives the WHO temporary powers, for example with respect to sharing public health information with or without a country's consent.
- Both the WHO and the UN Refugee Agency (UNHCR) distinguish between **different levels of emergency** in order to define necessary levels of response. The WHO defines four categories of emergencies, from ungraded (monitored but not requiring WHO response) to Grade 3 (a single or multi-country event with substantial public health consequences involving substantial WHO support). The UNHCR distinguishes between level 1 (proactive preparedness) to level 3 (whole of UNHCR response).
- **UNHCR** holds that a **humanitarian emergency** is "any situation in which lives, rights or well-being of refugees, internally displaced people, asylum-seekers or stateless people are threatened unless immediate action is taken; and which demands extraordinary measures because current UNHCR capacities at country and regional level are insufficient." The aim of such a designation is to ensure that "appropriate attention and support are provided".
- **The UN Office for Disaster Risk Reduction (UNDRR)** defines a 'disaster' as "a serious disruption of the functioning of a community or a society at any scale due to hazardous events interacting with conditions of exposure, vulnerability and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts." It notes that 'emergency' is sometimes used interchangeably with the term 'disaster'.
- **The UN Inter-Agency Standing Committee (IASC)** defines a '**complex emergency**' as "a humanitarian crisis in a country, region or society where there is a total or considerable breakdown of authority resulting from internal or external conflict, and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the ongoing UN country programme".
- **Definitions used by the humanitarian sector** often focus on disruptive events affecting a society's ability to cope: for example the **International Federation of Red Cross and Red Crescent Societies (IFRC)** describes a disaster as "a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community's or society's ability to cope using its own resources."
- **Many governments** have powers to declare states of emergency in response to critical situations affecting public health and safety within their jurisdiction, for purposes such as authorising access to particular financial resources (for example federal assistance in the US) or providing for specific time-limited powers to be exercised.

*For further details and references, see Appendix 3*

- 1.8 Instead of adopting or proposing a specific definition, we have therefore identified of features of such emergencies that, both individually and in combination, make it particularly challenging to conduct research ethically, and hence where further ethical analysis is required. We focus on circumstances with the following features:



- **Disruption from some kind of relatively stable ‘norm’.** There are multiple possible causes of such disruption including: natural and human-made disasters; outbreaks of infectious diseases; conflict; mass migration of peoples; and political disruption that leaves populations in limbo without civil or political rights.<sup>25</sup> Such disruption, by its nature, interrupts the normal flow of life and may threaten the very fabric of that life: it makes affected populations more vulnerable, both physically and emotionally; and it potentially undermines the infrastructure that supports both the provision of broader health services, and the conduct of research designed to improve health and health services. Disruptive events may simultaneously increase the need for research (to learn how better to respond in these different, more uncertain, and more difficult circumstances) and undermine the systems and processes that help underpin the ethical conduct of that research. They may also increase the perceived and actual value of health services and responses, and therefore raise questions among affected populations of the value of research.
- **Significant risks to physical or mental well-being,** arising from that disruption, at both individual and population level.
- **Pressures of time:** additional challenges for conducting research arise when the effectiveness of response is directly linked to the timeliness with which that response is undertaken. The timescales for planning and conducting research and producing results may be in tension with the short timeframes for response efforts. Even where it proves possible to start research studies within the necessary timescale, the sense of urgency, and existence of many competing priorities for participants, may make meaningful consent procedures very difficult to achieve.
- **Uncertainty,** and the challenges this creates for decision-making by all concerned: both for those involved in developing and scrutinising research proposals, and for those invited to consider taking part. The nature and impact of the uncertainty, and the associated ethical challenges, may differ considerably depending on the nature of the emergency. Scientific uncertainty with respect to experimental products for conditions that have no effective vaccines or treatments, for example, brings with it both the risks of acting prematurely with insufficient knowledge, and the competing risks of delaying or failing to act within the time-limited window when action is possible. The physical disruption inherent in many natural or human-made emergencies, on the other hand, may be a cause of very different kinds of uncertainty, affecting the way people may engage with both services and research, and potentially generating important research questions in terms of how services can best be delivered in these fluid circumstances.
- **Fear, distress, and sometimes panic** engendered by a crisis are likely to affect populations’ ability or desire to engage with research. This could potentially undermine the development of trust-based relationships between researchers and local populations and put further pressure on fair recruitment procedures.
- **Challenges arising from the multi-country, multi-agency, and multisectoral nature of the response:** tensions are likely to arise with respect to cooperation between responders and researchers, and between different agencies and sectors involved in emergency response and research (including local and national governments, intergovernmental agencies, the humanitarian sector, research funding

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<sup>25</sup> We recognise that here are also other situations, such as mass gatherings, where similar public health and research challenges may arise, even though they would not usually be thought of as ‘emergencies’: see, for example, Tam JS, Barbeschi M, Shapovalova N *et al.* (2012) Research agenda for mass gatherings: a call to action *The Lancet Infectious Diseases* **12**(3): 231-9.

bodies, and research institutions). There may also be scope for competing interests, values, and priorities among actors.

#### Box 1.4: Examples of global health emergencies within the scope of this report

##### Nipah virus outbreaks: Malaysia and Kerala

Nipah virus is rare and has a high case fatality rate. There is no vaccine or treatment – other than supportive care – available to infected people or animals.<sup>26</sup> It was first identified in 1998-9, when the virus killed 105 people following an outbreak in Nipah, Malaysia, which subsequently spread to Singapore.<sup>27</sup> Most recently, cases of Nipah virus were reported in Kerala, India in 2018.<sup>28</sup> The location of the Kerala Nipah cases were in a region supported by the WHO's Regional Office for South-East Asia (SEARO). However, the possibility of travel-associated transmission to countries which form member states of the WHO's Eastern Mediterranean Regional Office (EMRO) meant that management of the disease and its potential spread extended globally.<sup>29</sup>

Research on the virus has included a One Health approach that began with national clusters that transformed into international research communities over time.<sup>30</sup>

##### Mental health needs after the 2004 tsunami: Sri Lankan perspectives

Assumptions about the mental health needs of Sri Lankans affected by the 2004 tsunami included the perception that trauma counselling would be a necessary part of the medical response to the disaster. Subsequently an 'army' of trauma counsellors were sent from countries including the US, Australia, New Zealand, France, and the UK. However, the demand for this type of support was extremely low: Sri Lankans affected by the tsunami preferred to get support from traditional healers such as Ayurvedic practitioners. This highlighted the importance of understanding and valuing "the cultural and traditional coping mechanisms and resources available in local settings, particularly before providing psychological treatments to non-Western disaster survivors."<sup>31</sup>

##### Syrian refugees and non-communicable diseases

The displacement of Syrians to countries such as Lebanon, Turkey, and Jordan leads to refugees' ongoing medical needs associated with non-communicable diseases (NCDs) crossing borders into host states. The levels of pre-conflict NCDs is high among displaced Syrians, particularly among older people.<sup>32</sup> For host countries – and the NGOs, and other humanitarian actors who work in those countries – this raises the importance of not overlooking long-term, slowly-developing medical requirements of refugees related to NCDs.<sup>33</sup>

<sup>26</sup> WHO (2018) *Nipah virus factsheet*, available at: <https://www.who.int/news-room/fact-sheets/detail/nipah-virus>.

<sup>27</sup> Looi LM, and Chua KB (2007) Lessons from the Nipah virus outbreak in Malaysia *Malaysian Journal of Pathology* **29(2)**: 63-7.

<sup>28</sup> WHO (7 August 2018) *Nipah virus - India*, available at: <https://www.who.int/csr/don/07-august-2018-nipah-virus-india/en/>.

<sup>29</sup> WHO Regional Office for the Eastern Mediterranean (2018) *Weekly epidemiological monitor: current major event - Nipah virus: risk of importation to the countries of EMR*, available at: [http://applications.emro.who.int/docs/epi/2018/Epi\\_Monitor\\_2018\\_11\\_23.pdf?ua=1](http://applications.emro.who.int/docs/epi/2018/Epi_Monitor_2018_11_23.pdf?ua=1).

<sup>30</sup> STEPS Centre (2014) *Towards One Health: evolution of international collaboration networks on Nipah virus research from 1999-2011*, available at: <http://steps-centre.org/wp-content/uploads/Networks-wp2.pdf>, at 6.2.2.

<sup>31</sup> Sumathipala A (2014) When relief comes from a different culture: Sri Lanka's experience of the Asian tsunami, in *Disaster bioethics: normative issues when nothing is normal*, O'Mathúna D, Clarke M, and Gordijn B (Editors) (Dordrecht: Springer), at 5.4.6.1.

<sup>32</sup> Akik C, Ghattas H, Mesmar S *et al.* (2019) Host country responses to non-communicable diseases amongst Syrian refugees: a review *Conflict and Health* **13(1)**: 8.

<sup>33</sup> Emergency Nutrition Network (2019) *Field articles: tackling non-communicable disease about Syrian refugees and vulnerable host communities in Jordan*, available at: [https://www.ennonline.net/attachments/2982/diseasejordan\\_FA\\_FEX54.pdf](https://www.ennonline.net/attachments/2982/diseasejordan_FA_FEX54.pdf).



- 1.9 We note here two further points on the scope of this report and the descriptive, rather than definitional, approach we have taken to what constitutes a ‘global health emergency’. First, our analysis is not predicated on the need for a formal process of ‘declaring’ an emergency, such as that used by the Director-General of the WHO to designate a PHEIC (and hence does not rely on the ethically and politically highly-charged question of who should be entitled to make such a declaration). Rather, the implications both for research policy in general, and for any specific research project proposed in circumstances similar to those described above, will need to be considered within relevant governance systems. These could include independent systems of scrutiny and organisations’ own operational approaches. Our aim is to offer ethical analysis that may help guide and support those dealing with the competing tensions identified in paragraph 1.8: it is not to establish a distinct set of ethical requirements that come into play when an emergency has been ‘declared’. Our analysis will also inform recommendations targeted at the wide range of policy-makers (including funders, regulators, and employers) whose policies and actions determine and constrain the options open to those on the ground (see Chapters 5–10). This report is thus concerned both with the ethics of policy making, and with ethics policy: considering what procedures need to be in place in order to ensure that ethical issues, once identified, are addressed in practice in ways that add to, and do not detract from, the quality and value of research.
- 1.10 Second, it may also be the case that the issues we are considering, in this exceptionally challenging research context, may also be of wider relevance for research in other contexts: not least for research during domestic emergencies that do not involve external actors.<sup>34</sup> While making recommendations for ethical research conduct in general is not our focus, we note here that what is learnt in challenging circumstances may usefully inform standard practice.

## Role of research in emergency response

- 1.11 A good evidence base from a wide variety of disciplines is essential to support the core functions of effective emergency preparedness and response efforts.<sup>35</sup> Research is needed, for example, to understand: the nature of particular threats and their impacts; how individual and community perspectives shape the course of the emergency and its aftermath; how services are to be provided in highly challenging circumstances; and what interventions, whether biomedical or psychosocial, are most effective in meeting people’s needs. By its nature, much of this research can only be conducted in an emergency setting.
- 1.12 However, despite significant strides in recent decades, the evidence base for many health interventions provided in emergencies is still lacking: much of what is regarded as best practice is unsupported by evidence.<sup>36</sup> While research to develop experimental therapies for new and emerging diseases is the most likely to generate headlines, evidence is lacking for many health conditions that routinely and predictably affect large numbers of people in emergencies. We were told, for example, that lack of surveillance data and research means that healthcare workers responding to a famine still do not know how best to rehydrate children with cholera who are also suffering from severe

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<sup>34</sup> See, for example, Kohrt BA, Mistry AS, Anand N *et al.* (2019) Health research in humanitarian crises: an urgent global imperative *BMJ Global Health* **4(6)**: e001870 who discuss research strategies specific to humanitarian crises, and strategies for conducting research in LMICs that are especially important in humanitarian crises.

<sup>35</sup> See, for example, Waldman RJ, and Toole MJ (2017) Where is the science in humanitarian health? *The Lancet* **390(10109)**: 2224-6.

<sup>36</sup> *ibid.* See also: Kohrt BA, Mistry AS, Anand N *et al.* (2019) Health research in humanitarian crises: an urgent global imperative *BMJ Global Health* **4(6)**: e001870.

malnutrition.<sup>37</sup> Evidence is particularly poor for the effective provision of services in emergencies for people with non-communicable diseases ((NCDs) despite the rise of such diseases in low- and middle-income settings) and for how best to provide water, sanitation, and hygiene (WASH) services in humanitarian crises.<sup>38</sup> The essential role played by observational and social science research in understanding the way people affected by emergencies engage with health and other services, and the consequences for trust, behaviour, and community well-being, is only beginning to be adequately recognised.<sup>39</sup>

- 1.13 Box 1.5 illustrates the diverse ways in which health-related research from different disciplines may contribute to the effectiveness of emergency response, and better meet the needs both of people affected by the emergency, and those affected by similar emergencies in the future. It is not viable to see research as an optional extra;<sup>40</sup> and yet as we explore further in Chapter 2, there are real tensions with how research practice fits in the specific context of an emergency.

### Box 1.5: Examples of types of research conducted during global health emergencies

After the 2011 Great East Japan Earthquake and Tsunami, a team of Japanese researchers undertook a study that assessed the **mental health** – in particular symptoms of depression, anxiety, and post-traumatic stress disorder (PTSD) – among adolescents whose school was hit by the tsunami. The young people participated in annual **mental health surveys** for three years after the disaster. The researchers suggested that students who scored poorly in the psychological tests might require support from hospitals' paediatric psychiatry departments.<sup>41</sup>

**Qualitative interviews and focus group discussions** were carried out with people living in two Ebola 'hotspots' in Sierra Leone in 2015. The research aimed "to actively include the community in the **development of a set of actionable Ebola messages** that responded directly to their needs and concerns."<sup>42</sup>

<sup>37</sup> Data and samples roundtable, 3 December 2018. See also: Houston KA, Gibb JG, and Maitland K (2017) Intravenous rehydration of malnourished children with acute gastroenteritis and severe dehydration: a systematic review *Wellcome Open Research* 2: 65.

<sup>38</sup> Blanchet K, Ramesh A, Frison S *et al.* (2017) Evidence on public health interventions in humanitarian crises *The Lancet* 390(10109): 2287-96.

<sup>39</sup> See, for example, House of Commons Science and Technology Committee (2016) *Science in emergencies: UK lessons from Ebola - second report of session 2015-16*, available at: <https://publications.parliament.uk/pa/cm201516/cmselect/cmsctech/469/469.pdf>, at paragraph 40; Institute of Development Studies (1 June 2017) *A 'real-time' and anthropological response to the Ebola crisis*, available at: <https://www.ids.ac.uk/opinions/a-real-time-and-anthropological-response-to-the-ebola-crisis/>; and Wellcome (6 December 2018) *Social science research: a much-needed tool for epidemic control*, available at: <https://wellcome.ac.uk/news/social-science-research-much-needed-tool-epidemic-control>.

<sup>40</sup> See, for example, WHO (22 August 2019) *Ebola then and now: eight lessons from West Africa being applied in the Democratic Republic of the Congo*, available at: <https://www.who.int/news-room/feature-stories/detail/ebola-then-and-now>, which highlights 'putting research at the heart of the response' at the top of its list of essential developments. For a discussion of the very wide range of forms of interdisciplinary research that play a valuable role in effective emergency preparedness and response, see also: The Academy of Medical Sciences, the Medical Research Council (part of UK Research and Innovation (UKRI)), and the Interacademy Partnership (forthcoming) *Interdisciplinary research in epidemic preparedness and response*.

<sup>41</sup> Okuyama J, Funakoshi S, Tomita H *et al.* (2017) Mental health and school-based intervention among adolescent exposed to the 2011 Great East Japan Earthquake and Tsunami *International Journal of Disaster Risk Reduction* 24: 183-8.

<sup>42</sup> Kinsman J, de Bruijne K, Jalloh AM *et al.* (2017) Development of a set of community-informed Ebola messages for Sierra Leone *PLOS Neglected Tropical Diseases* 11(8): e0005742.

**Epidemiological research** was undertaken in order to identify **characteristics of an outbreak of plague** in urban settings in Madagascar.<sup>43</sup>

Children living in a long-term refugee settlement in Uganda took part in **workshops** to map out their broad perspectives and focus on aspects of the refugee protection process. The aim of these workshops – and related interviews with the refugee children – was **to explore what might constitute a more child-friendly, child-specific, and participatory refugee protection process for children.**<sup>44</sup>

The **efficacy and effectiveness of a vaccine for Ebola** was the subject of a **cluster-randomised trial** that took place in Guinea.<sup>45</sup> The trial – and the vaccine it studied (rVSV-ZEBOV – recombinant vesicular stomatitis virus–Zaire Ebola virus) – informed the response, via a ring vaccination strategy, to the Ebola outbreak that emerged in Democratic Republic of the Congo (DRC) in 2018.<sup>46</sup>

**Community-based participatory research** was carried out with ‘linguistically isolated’ people in Houston, Texas (specifically members of Vietnamese, Chinese, Somali, and Spanish-speaking communities) to investigate their **disaster-preparedness needs.**<sup>47</sup>

Adolescents affected by the Syria crisis in Egypt and Lebanon were included in **participatory action research** organised by Save the Children, the Issam Fares Institute, and the American University of Beirut. One of the project’s core aims was **“to generate credible evidence and critical learning on the situation of Syrian and host community adolescent girls and boys** through their own eyes and their self-identified responses, to inform programming”<sup>48</sup>.

**Ethnographic research** was conducted in Belize to assess **how perspectives of Zika-related health consequences are shaped.**<sup>49</sup>

After Hurricane Sandy hit in 2012, a **survey** was carried out to take account of the ways that networks of community-based organisations, in partnership with public health departments, **contribute to community recovery from disaster.**<sup>50</sup>

## What counts as research?

- 1.14 The issue of what activities are, or should be, counted as ‘research’ is as contested as the question of what constitutes a global health emergency. Clear distinctions can be hard to draw between, for example, academic health systems research that aim to improve the wider evidence base for service delivery, and the service evaluations and

<sup>43</sup> Randraemanana R, Andrianaivoarimanana V, Nikolay B *et al.* (2019) Epidemiological characteristics of an urban plague epidemic in Madagascar, August–November, 2017: an outbreak report *The Lancet Infectious Diseases* **19(5)**: 537-45.

<sup>44</sup> Save the Children (2013) *Guidelines for children’s participation in humanitarian programming*, available at: [https://resourcecentre.savethechildren.net/node/7718/pdf/children\\_participation\\_humanitarian\\_guidelines.pdf](https://resourcecentre.savethechildren.net/node/7718/pdf/children_participation_humanitarian_guidelines.pdf), at page 34.

<sup>45</sup> Henao-Restrepo AM, Longini IM, Egger M *et al.* (2015) Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial *The Lancet* **386(9996)**: 857-66.

<sup>46</sup> WHO (2019) *Preliminary results on the efficacy of the rVSV-ZEBOV-GP Ebola vaccine using the ring vaccination strategy in the control of an Ebola outbreak in the Democratic Republic of the Congo: an example of integration of research into epidemic response*, available at: <https://www.who.int/csr/resources/publications/ebola/ebola-ring-vaccination-results-12-april-2019.pdf>.

<sup>47</sup> Nepal V, Banerjee D, Slentz M *et al.* (2010) Community-based participatory research in disaster preparedness among linguistically isolated populations: a public health perspective *Journal of Empirical Research on Human Research Ethics* **5(4)**: 53-63.

<sup>48</sup> Save the Children (2018) *Youth voices: participatory action research with adolescents affected by the Syria crisis in Egypt and Lebanon*, available at: [https://resourcecentre.savethechildren.net/node/13182/pdf/par\\_lessons\\_learned\\_report\\_how\\_to\\_guide.pdf](https://resourcecentre.savethechildren.net/node/13182/pdf/par_lessons_learned_report_how_to_guide.pdf), at page viii.

<sup>49</sup> Gray D, and Mishtal J (2019) Managing an epidemic: Zika interventions and community responses in Belize *Global Public Health* **14(1)**: 9-22.

<sup>50</sup> Acosta JD, Burgette L, Chandra A *et al.* (2018) How community and public health partnerships contribute to disaster recovery and resilience *Disaster Medicine and Public Health Preparedness* **12(5)**: 635-43.

audits that are routinely carried out by the humanitarian sector. We heard repeatedly of the temptation to ‘label’ evidence-generating activities as anything other than research – for example as evaluation, audit, or needs assessment – in order to avoid what are perceived as bureaucratic scrutiny and approval processes that may delay needed improvements in care.<sup>51</sup> Such an approach may mean that some forms of data collection are undertaken with little or no consideration of ethical implications, in particular the harms that may arise for participants.<sup>52</sup> It may also undermine the opportunity for important lessons, such as those deriving from evaluations, to be shared through wider publication. On the other hand, bringing routine needs assessments and evaluations within the scope of research regulation in its current form could place unrealistic burdens and unachievable time limitations on the work of the humanitarian sector.

- 1.15 Further definitional challenges arise through the way that ‘research’, ‘healthcare’ and ‘public health interventions’ are often treated as quite separate activities, governed by distinct ethical and regulatory codes. Yet in practice (as illustrated in Box 1.6), these boundary lines may be far from clear, raising difficult questions both for participants and practitioners on the ground, and for regulators and policy-makers.

#### Box 1.6: Views on distinctions between research and response

“From a professional perspective, the activities of researchers, healthcare providers and public health workers are different and are governed or guided by different codes of practice. However, in reality, the boundaries become blurred because of the multiple roles each of them could have and which may overlap at different moments in time during and/or after the emergency.” *Jihad Makhoul, American University of Beirut*

“Researchers sometimes collect data with research in mind, avoid the review process and appropriate consent processes by claiming the data was collected for an audit or for surveillance.” *Dr Anuradha Rose*

“The line between research and response is more blurred than it is often represented and the circumstances in certain contexts, such as the Ebola outbreak in West Africa, make it much harder to seek out consent. The research and response communities are often quite separate and need to be clearer on how they can work together, and how data can be used and shared.” *Wellcome*

“In cases where there is overlap between research, health care and public health it is important to clarify that the three can have different aims, and loyalties.” *Myriam Henskens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“Many research participants, especially from low-income countries do not understand the difference between treatment and research. This confusion blurs their ability to engage rationally with researchers, on issues related to their right to participate in the study as well as to refuse or/and withdraw from the research.” *The Ethics, Community Engagement and Patient Advisory (ECEPAS) Working Group of the Global Emerging Pathogens Treatment (GET) Consortium*

<sup>51</sup> For example at RECAP meeting, American University of Beirut, 15-16 January 2019; and seminar with the Faculty of Health Sciences, American University of Beirut, 17 January 2019.

<sup>52</sup> The lack of formal procedures does not, of course, mean that such practice is necessarily unethical: in many cases those involved in data collection may be highly thoughtful and reflective in their practice (there is no way of knowing either way).

“I don’t think that the lack of separation between research and public health intervention is related to logistical or resource constraints; but just due to the fact that it is not possible to distinguish well between these sub-categories; and different ethics committees may apply different rules how they handle this issue.” *Anonymous respondent*

“Too much time is spent on trying to make clear-cut distinctions between terms or concepts that have blurry boundaries. What should motivate all these activities is a concern for the respect and dignity of the people involved. This means thinking critically and ethically about how the data could be used or abused. If the personal data could be misused, then mechanisms to anonymise should be introduced as soon as possible.” *Dónal O’Mathúna, PhD*

“Although distinctions between the above activities may be blurred in some contexts, research staff and participants must be equipped with information necessary for them to understand the distinction between experimental interventions and interventions whose efficacy has been demonstrated.” *Humanitarian Health Ethics Research Group*

### **Indistinct boundaries: research and treatment**

- 1.16 Traditionally, ethical guidance has distinguished sharply between ‘research’ (understood as the endeavour to generate knowledge for future benefit) and ‘treatment’ (concerned with immediate individual benefit with a focus on the care of the patient).<sup>53</sup> However, elements of research interventions may have the *potential* for therapeutic effect – for example, where novel treatments provided in the context of research turn out to be more effective than existing alternatives – even though the primary aim of the research is not to provide direct care.<sup>54</sup> Developments in ‘learning healthcare systems’,<sup>55</sup> and in new genomic medicines services that are an explicit hybrid of clinical and research practices,<sup>56</sup> challenge this distinction, although there remains a clear consensus on the importance of transparency for all concerned as to what elements of data collection or procedures are undertaken solely for research purposes.<sup>57</sup> This complex intersection between research and treatment may be further complicated in emergencies where unproven interventions are made available outside of research under a system of ‘monitored emergency use of unregistered and investigational interventions’ (MEURI), as long as clinical data are systematically collected and shared<sup>58</sup> (see also paragraph 1.27).
- 1.17 In circumstances where there is a sense of urgency, and there are no existing effective treatments, it is important to recognise that participants are very likely to give consent in order to access what they hope may be the best available treatment.<sup>59</sup> Despite concerns

<sup>53</sup> See, for example, Miller F (2006) Revisiting the Belmont report: the ethical significance of the distinction between clinical research and medical care *APA Newsletters* **5(2)**: 10-4.

<sup>54</sup> This is explicitly recognised in the governance of research, for example in the concept of research that offers ‘prospect of direct’ benefit’ (US Federal regulations) or ‘prospect of direct health-related benefit’ (CIOMS).

<sup>55</sup> Faden R, Kass N, Goodman S *et al.* (2013) An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics *Hastings Center Report* **43(s1)**: S16-S27.

<sup>56</sup> Dheensa S, Samuel G, Lucassen AM *et al.* (2018) Towards a national genomics medicine service: the challenges facing clinical-research hybrid practices and the case of the 100,000 genomes project *Journal of Medical Ethics* **44(6)**: 397-403.

<sup>57</sup> Helgesson G (2019) Can and should the research–therapy distinction be maintained? Reflections in the light of innovative last-resort treatment *Research Ethics* **15(2)**: 1-14.

<sup>58</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, at chapter 9.

<sup>59</sup> See, for example, Folayan MO, Haire B, Allman D *et al.* (2018) Research priorities during infectious disease emergencies in West Africa *BMC Research Notes* **11(1)**: 159. Parallels in the Global North include where parents move their children from clinical trial to clinical trial for experimental treatments for Duchenne muscular dystrophy if they believe that they have been allocated to the placebo, as they have “no time to waste”: Nature (13 November 2018) *How Facebook and Twitter could be*



about ‘therapeutic misconception’ (where research-related procedures are believed to have a therapeutic aim where this is not the case), in some cases, decisions to participate in research may be based on accurate perceptions of benefit, for example through access to ancillary or better quality care.<sup>60</sup> Even without ancillary care benefits, such a decision may still be a rational choice on the basis that participation may appear to offer the only source of hope, however uncertain – for example where there is no evidence of any kind of benefit from ‘standard’ care. This role of hope (described by one author as an “important community value”<sup>61</sup>) also highlights the need to clarify the responsibilities of those who offer such hope. We explore the implications of these difficulties in disentangling research and treatment options in Chapter 6.

- 1.18 Even where research participation may offer some prospect of direct benefit, however, it may also involve extra procedures (such as research-related blood draws, and data collection) in addition to the novel intervention itself. In other cases, research will involve such features, and their associated risks, without the possible immediate benefit of a novel intervention. There is thus an inherent tension for front-line workers when responding to a situation where there are high levels of suffering, and of also taking time to conduct research. This is an issue both for the workers themselves in how they prioritise their time; and for those involved in making funding decisions, including how funding is prioritised between care and research.

### ***Indistinct boundaries: research and public health***

- 1.19 Just as ‘research’ and ‘treatment’ are traditionally treated as separate domains of practice, ‘research’ and ‘public health’ practice are also commonly conceptualised as distinct activities.<sup>62</sup> WHO guidance states, for example, that individual informed consent for the collection and use of data for public health surveillance is not always required, including where this would be prohibitively costly, unfeasible, or unwarranted because the risks are low.<sup>63</sup> Such data may, however, at times need to be identifiable to meet particular public health needs: for example to avoid double-counting in surveillance, and to enable contact tracing in responding to infectious disease.<sup>64</sup> The collection of the same (identifiable) data for purposes described as ‘research’, would, in contrast, be subject to ethical review processes and require individual consent.<sup>65</sup> Such different approaches

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*the next disruptive force in clinical trials*, available at: <https://www.nature.com/articles/d41586-018-07351-8>; and the removal of a cap on the number of participants in a UK trial in recognition of the demand for the HIV prevention drug PrEP: National Health Executive (8 July 2019) *NHS England recommends uncapped PrEP trial access*, available at: <http://www.nationalhealthexecutive.com/Robot-News/nhs-england-prep-trial-access>.

<sup>60</sup> See, for example, Mfutso-Bengo J, Ndebele P, Jumbe V *et al.* (2008) Why do individuals agree to enrol in clinical trials? A qualitative study of health research participation in Blantyre, Malawi *Malawi Medical Journal: The Journal of Medical Association of Malawi* **20(2)**: 37-41; Mwangi R, Ndebele P, and Mongoven A (2017) Understanding, therapeutic misconceptions and perceptions, and enrollment decision-making: a pediatric preventive malaria trial in rural Tanzania *IRB: Ethics & Human Research* **39(5)**; and Tengbeh AF, Enria L, Smout E *et al.* (2018) “We are the heroes because we are ready to die for this country”: participants’ decision-making and grounded ethics in an Ebola vaccine clinical trial *Social Science & Medicine* **203**: 35-42.

<sup>61</sup> Folayan MO, Haire B, Allman D *et al.* (2018) Research priorities during infectious disease emergencies in West Africa *BMC Research Notes* **11(1)**: 159.

<sup>62</sup> See, for example, WHO (2015) *Ethics in epidemics, emergencies and disasters: research, surveillance and patient care - training manual*, available at: [http://apps.who.int/iris/bitstream/handle/10665/196326/9789241549349\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/196326/9789241549349_eng.pdf?sequence=1) which identifies, at page 20, what it describes as the “shortcomings and controversies” inherent in the way these two spheres of activity have been treated as distinct in guidance and regulation.

<sup>63</sup> WHO (2017) *WHO guidelines on ethical issues in public health surveillance*, available at: <https://www.who.int/ethics/publications/public-health-surveillance/en/>, at page 40. See also: Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/project/public-health>, at page xxi.

<sup>64</sup> WHO (2017) *WHO guidelines on ethical issues in public health surveillance*, available at: <https://www.who.int/ethics/publications/public-health-surveillance/en/>, at page 38.

<sup>65</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guideline 12.

may contribute to difficulties in data sharing in emergencies despite the clear guidance issued by the WHO in 2016 that “all individuals and entities involved in these [data generating] efforts should cooperate by sharing relevant and accurate data in a timely manner”.<sup>66</sup>

- 1.20 Even outside the emergency context, it has been argued that population-based research has far more in common with public health practice than with medical research, and that the “ethical challenges presented in population-based research need to be considered within a less individualist ethical framework because requirements such as informed consent and privacy, which have an important place in medical research ethics, may not be sufficient or appropriate to provide guidance.”<sup>67</sup> Such a shift, however, would require serious rethinking of whether the current demarcations between public health practice and research are sustainable.<sup>68</sup>

### **Working group approach**

- 1.21 In the same way that we have decided not to be prescriptive in defining an ‘emergency’, we aim to be similarly inclusive in our consideration of what constitutes research and research-like activities, recognising that there are diverse and complex ways in which evidence may be gathered in emergency settings. We therefore support the view that, instead of focusing on achieving a ‘correct’ classification for any particular evidence-gathering activity, it is more valuable to consider first the nature of the ethical concerns raised in the particular circumstances, and then what oversight would be most appropriate to identify and respond to them.<sup>69</sup> One example of such an approach is found in Public Health Ontario’s *Framework for the ethical conduct of public health initiatives*.<sup>70</sup> The document identifies ten guiding questions for investigators, reviewers, and decision-makers in public health to consider for *all* initiatives that involve the systematic collection of data about individuals or communities, whether or not such data collection is considered to be ‘research’. The framework thus separates out the regulatory question (which may depend on jurisdiction – see below) of what kind of external scrutiny is required before research, or other data initiatives, may legitimately take place, from the question of ethical conduct. In a similar way, we aim to distinguish where necessary between an exploration of what is ethically at stake (which may apply to many uses of data) and what might be an appropriate, proportionate, and flexible approach to scrutiny and/or regulation. We return to our consideration of what is ‘ethically at stake’ in Chapter 4.

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<sup>66</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, at page 38.

<sup>67</sup> Lignou S (2018) Informed consent in cluster randomised trials: new and common ethical challenges *Journal of Medical Ethics* **44**(2): 114-20, at page 117. See also: Ballantyne A, and Schaefer GO (2018) Consent and the ethical duty to participate in health data research *Journal of Medical Ethics* **44**(6): 392-6.

<sup>68</sup> See: Mbutia D, Molyneux S, Njue M *et al.* (2019) Kenyan health stakeholder views on individual consent, general notification and governance processes for the re-use of hospital inpatient data to support learning on healthcare systems *BMC Medical Ethics* **20**(1): 3 who echo this point in their conclusion.

<sup>69</sup> GFBR (2017) *Ethics of alternative clinical trial designs and methods in low- and middle-income country research: 28-29 November, Bangkok*, available at: [https://www.wellcomevents.org/WELLCOME/media/uploaded/EVWELLCOME/event\\_535/GFBR\\_Bangkok\\_summary\\_slides.pdf](https://www.wellcomevents.org/WELLCOME/media/uploaded/EVWELLCOME/event_535/GFBR_Bangkok_summary_slides.pdf).

<sup>70</sup> Public Health Ontario (2012) *A framework for the ethical conduct of public health initiatives*, available at: <https://www.publichealthontario.ca/en/eRepository/PHO%20%20Framework%20for%20Ethical%20Conduct%20of%20Public%20Health%20Initiatives%20April%202012.pdf>, particularly pp11-5. See also the proposed guidance tool in Luyckx V, Biller-Andorno N, Saxena A *et al.* (2017) Health policy and systems research: towards a better understanding and review of ethical issues *BMJ Global Health* **2**: e000314.



## The regulatory patchwork

### Sources of ethical requirements or guidance

1.22 We have noted above how research and other evidence-gathering activities cannot always be neatly separated out from other areas of practice in emergencies, including direct care and public health surveillance. Yet the ways in which ethical concerns in these various fields have been analysed and codified include significant differences of emphasis and approach. In very general terms:

- ethical concerns in **clinical care** focus primarily on the needs and interests of the particular patient, and the duties of the health professional to that patient;
- **public health** ethics are concerned with the needs and interests of communities, and hence touch on wider questions such as equity and access to care (recognising that at times community interests may trump individual interests or preferences), as well as political questions such as the relationship between the individual and the state; and
- **research ethics** are concerned with factors including the social value of the research, the protection of participants (for example by reference to risks and burdens and effective consent processes), and the need for independent scrutiny.<sup>71</sup>

1.23 This means that the many different professional groups and academic disciplines that may be involved, whether directly or indirectly, in conducting research or other evidence-gathering activities during an emergency are potentially working to different codes of ethics and different sources of procedural guidance, with divergent emphases and focus. Such codes and procedural guidance may be developed by a range of different bodies, including national professional regulatory bodies,<sup>72</sup> funders,<sup>73</sup> regional or international institutions,<sup>74</sup> or by individual employing institutions such as universities. They also vary in status, from being purely advisory, to professionally encouraged and/or mandated (with potential consequences for those found not to comply). In some cases, elements of ethical codes may become enforceable through law, by being incorporated into national legislation: a common example being the requirement for independent ethical scrutiny of certain forms of research.

1.24 Influential international sources of ethical guidance for research include the Declaration of Helsinki,<sup>75</sup> the Council for International Organizations of Medical Sciences (CIOMS) guidelines,<sup>76</sup> and the more recent *Global code of conduct for research in resource-poor*

<sup>71</sup> See, for example, WHO (2015) *Global health ethics: key issues*, available at: [https://apps.who.int/iris/bitstream/handle/10665/164576/9789240694033\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/164576/9789240694033_eng.pdf?sequence=1) for an overview.

<sup>72</sup> For example doctors registered in the UK are bound professionally to act by ethical guidance issued by the General Medical Council, including: General Medical Council (2010) *Good practice in research and consent to research*, available at: [https://www.gmc-uk.org/-/media/documents/good-practice-in-research-and-consent-to-research\\_pdf-58834843.pdf?la=en](https://www.gmc-uk.org/-/media/documents/good-practice-in-research-and-consent-to-research_pdf-58834843.pdf?la=en); and General Medical Council (2013) *Good medical practice*, available at: [https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215\\_pdf-51527435.pdf?la=en](https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215_pdf-51527435.pdf?la=en).

<sup>73</sup> For example, European Commission (2018) *Ethics in social science and humanities*, available at: [https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020\\_ethics-soc-science-humanities\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020_ethics-soc-science-humanities_en.pdf), published to support beneficiaries of EU grant funding. A total of 27 national standards for social-behavioural research standards are listed by the Office for Human Research Protections: HHS.gov (2019) *International compilation of human research standards*, available at: <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>.

<sup>74</sup> For example, WHO (2017) *WHO guidelines on ethical issues in public health surveillance*, available at: <https://www.who.int/ethics/publications/public-health-surveillance/en/>.

<sup>75</sup> World Medical Association (2013) *Declaration of Helsinki*, available at: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.

<sup>76</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>.

*settings*.<sup>77</sup> While, of these three sources, only the CIOMS guidelines make specific reference to disaster / emergency settings, there are also a number of sources of guidance aimed at those conducting research in disasters settings, including: guidance documents produced by the WHO and by the IASC;<sup>78</sup> by an expert working group established in the aftermath of the 2004 tsunami;<sup>79</sup> and by individual humanitarian organisations to guide their own employees' conduct<sup>80</sup> (for further details, see Appendix 4). There is also a growing literature of academic ethical reflection and commentary in this field, which, while not having the force of organisational guidance, reflects on, and is likely to influence, the conduct of academics in the field.<sup>81</sup>

- 1.25 While there are many common themes in these guidance documents, a qualitative review undertaken in 2016 of 14 sources of guidance noted how many of them focused on particular research activities in particular emergency settings, rather than providing a comprehensive overview on how to proceed ethically in all types of research.<sup>82</sup> The review authors highlighted the tension between the need for such comprehensive guidance to support researchers working in highly-challenging situations, and the fact that disaster research is unavoidably context- and time-sensitive. We return to the implications of this patchwork of ethical requirements and guidance in Chapter 4.

### ***Additional ethical and scientific guidelines and procedures for clinical trials of novel medicines or vaccines***

- 1.26 The *Good clinical practice* (GCP) guidelines, developed by the International Conference on Harmonisation, set internationally recognised ethical and scientific quality requirements for use in clinical trials, with the aim of setting common standards for the registration and licensing of new pharmaceuticals by national regulatory bodies.<sup>83</sup> These guidelines are therefore highly influential for research during emergencies that involves novel medicines or vaccines, and potentially (but not uncontroversially) also for other forms of clinical trial. They also inform many national regulatory requirements (see below).<sup>84</sup>

<sup>77</sup> TRUST (2018) *Global code of conduct for research in resource-poor settings*, available at: <http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf>.

<sup>78</sup> IASC (2014) *Recommendations for conducting ethical mental health and psychosocial research in emergency settings*, available at: [https://interagencystandingcommittee.org/system/files/1\\_iasc\\_recommendations\\_for\\_ethical\\_mhpss\\_research\\_in\\_emergency\\_settings\\_0.pdf](https://interagencystandingcommittee.org/system/files/1_iasc_recommendations_for_ethical_mhpss_research_in_emergency_settings_0.pdf).

<sup>79</sup> Sumathipala A, Jafarey A, Castro L *et al.* (2010) Ethical issues in post-disaster clinical interventions and research: a developing world perspective. Key findings from a drafting and consensus generation meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007 *Asian Bioethics Review* **2(2)**: 124-42.

<sup>80</sup> See, for example, MSF (2018) *MSF research ethics framework: guidance document*, available at: [http://fieldresearch.msf.org/msf/bitstream/10144/305288/5/MSF+Research+Ethics+Framework\\_Guidance+document+%28Dec2013%29.pdf](http://fieldresearch.msf.org/msf/bitstream/10144/305288/5/MSF+Research+Ethics+Framework_Guidance+document+%28Dec2013%29.pdf).

<sup>81</sup> See, for example, Bruno W, Parmar P, and Haar R (2019) *A systematic literature review of the ethics of conducting research in the humanitarian setting: poster presentation, PREA Conference (25-26 March 2019), Columbus, Ohio*, available at: <https://kb.osu.edu/handle/1811/87676>; and Bruno W, Parmar P, and Haar R (2020) A systematic literature review of the ethics of conducting research in the humanitarian setting *Conflict and Health* (forthcoming).

<sup>82</sup> Mezinaska S, Kakuk P, Mijaljica G *et al.* (2016) Research in disaster settings: a systematic qualitative review of ethical guidelines *BMC Medical Ethics* **17(1)**: 62.

<sup>83</sup> International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016) *Integrated addendum to ICH E6(R1): guideline for good clinical practice*, available at: [https://database.ich.org/sites/default/files/E6\\_R2\\_Addendum.pdf](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf); and Health Research Authority (2018) *Good clinical practice*, available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/>.

<sup>84</sup> While originally developed for regulators and pharmaceutical companies to support the testing and licensing of new drugs, they have become increasingly widely applied to other kinds of clinical trial. At the time of writing, a Joint Initiative on Good Practice in Clinical Research is being led by Wellcome, the African Academy of Sciences, and the Bill & Melinda Gates Foundation. The initiative will develop new such guidelines for health interventions that will not be licensed, and will advocate for these new guidelines, once available, to be widely adopted. See: Wellcome (2019) *This is a pivotal moment for clinical*

- 1.27 The WHO has also developed an ‘emergency use assessment and listing procedure’ (EUAL) to expedite the availability of as-yet-unlicensed medicines, vaccines, or diagnostics during public health emergencies.<sup>85</sup> The aim of this procedure is not to undermine the standard clinical trial process, but rather to determine the minimum levels of information needed about the safety and efficacy of new products to justify making them available for a time-limited period, while continuing to collect and evaluate further data. The WHO emphasises that the EUAL is intended to support countries in determining the acceptability of novel products, and that it is the sole prerogative of national regulatory bodies whether to permit the use of products listed in this way in their own countries.<sup>86</sup> It is also possible for the WHO to ‘pre-qualify’ a vaccine, meaning that WHO standards for quality, safety, and efficacy are assured and that the vaccine can be procured by UN agencies and Gavi, the Vaccine Alliance (see paragraph 3.22) for use in at-risk countries.<sup>87</sup>

## Adding complexity: the role of national and international law

### *National law*

- 1.28 In addition to the jigsaw of ethical codes, procedures, and sources of advice described above, those involved in research are self-evidently required to abide by the law of the country or countries where they are working. Relevant national law may include general regulations with respect to certain kinds of research (potentially incorporating issues also covered by ethical guidance); the regulation of medicines and medical devices (including the circumstances in which national regulatory bodies may permit unlicensed products to be imported and used); further requirements for clinical trials, such as clinical trial registries; requirements relating to data protection and privacy; and provisions with respect to human biological materials.
- 1.29 A regularly updated compilation of all such regulations worldwide, including reference to ethical guidance as well as to legal requirements, includes more than one thousand such instruments, illustrating the complexity facing researchers.<sup>88</sup> This is particularly the case for research that involves participants in more than one country. Researchers may face potentially conflicting demands – and may sometimes have to deal with regulatory gaps – as a result of the intersection of different countries’ legal requirements with ethical codes of practice and guidance.<sup>89</sup>

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*trial regulations*, available at: <https://wellcome.ac.uk/news/pivotal-moment-clinical-trial-regulations>. See also: Wellcome (2019) *Good clinical practice guidelines*, available at: <https://wellcome.ac.uk/what-we-do/our-work/good-clinical-practice-guidelines>.

<sup>85</sup> WHO (2015) *WHO emergency use assessment and listing procedures for medical products during public health emergencies*, available at: [https://www.who.int/medicines/news/public\\_consult\\_med\\_prods/en/](https://www.who.int/medicines/news/public_consult_med_prods/en/).

<sup>86</sup> WHO (2015) *Emergency use assessment and listing procedure (EUAL) for candidate vaccines for use in the context of a public health emergency*, available at: <http://apps.who.int/medicinedocs/documents/s21987en/s21987en.pdf>.

<sup>87</sup> WHO (12 November 2019) *WHO prequalifies Ebola vaccine, paving the way for its use in high-risk countries*, available at: <https://www.who.int/news-room/detail/12-11-2019-who-prequalifies-ebola-vaccine-paving-the-way-for-its-use-in-high-risk-countries>.

<sup>88</sup> HHS.gov (2019) *International compilation of human research standards*, available at: <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>.

<sup>89</sup> See, for example, challenges arising in the context of different approaches to data sharing: Science (20 February 2019) *A new law was supposed to protect South Africans’ privacy. It may block important research instead*, available at: <https://www.sciencemag.org/news/2019/02/new-law-was-supposed-protect-south-africans-privacy-it-may-block-important-research>.

### Box 1.7: Examples of conflicting obligations

Tensions between clinical care and research ethics, lack of consensus on how to handle the ethical aspects of research that focuses on communal rather than individual benefit, and incompatible lines of accountability and responsibility leave researchers working in these contested spaces with unanswered issues. These include:

- Negotiating between individual patient preferences for access to new treatments or strategies of care, and the need for scientific soundness of research and strict inclusion / exclusion criteria.<sup>90</sup>
- Managing participant and worker safety requirements in inherently dangerous research situations – for example where it is impossible to ensure adherence to laboratory safety protocols that would be the norm in HICs.<sup>91</sup>
- Managing conflicting lines of accountability – including to the communities they are working with, national governments, their funders and employers, and their own professional standards – for example on issues such as sharing data appropriately in an emergency.

### International law

- 1.30 The **International Health Regulations** 2005 set out an agreement between 196 countries (including all WHO member states) to work together for global health security, including requirements to share data between countries in timely ways.<sup>92</sup> The Regulations include commitments by all signatories to build their capacities to detect, assess, and report public health events, with coordination and support from the WHO. They also set out clear obligations for member states to notify the WHO of any events in their territory that might constitute a ‘public health emergency of international concern’ (see Box 1.3 and paragraph 3.5).
- 1.31 **Four ‘humanitarian principles’ of humanity, neutrality, impartiality, and independence** (see Box 1.8) underpin the work of the UN Office for the Coordination of Humanitarian Affairs (OCHA) and those working in emergency response in humanitarian organisations. Originally developed from the core principles guiding the work of the International Committee of the Red Cross (ICRC) and the national Red Cross / Red Crescent societies, the principles are now enshrined in two UN General Assembly resolutions, and hence form part of international law.<sup>93</sup> They are also at the heart of the *Code of conduct for the International Red Cross and Red Crescent movement and non-*

<sup>90</sup> See, for example, Calain P (2018) The Ebola clinical trials: a precedent for research ethics in disasters *Journal of Medical Ethics* **44(1)**: 3-8 who discusses this potential tension between individual interests (which may be to access unproven treatments if they seem the best source of hope) and communal interests.

<sup>91</sup> See, for example, Maehira Y, and Spencer RC (2019) Harmonization of biosafety and biosecurity standards for high-containment facilities in low- and middle-income countries: an approach from the perspective of occupational safety and health *Frontiers in Public Health* **7(249)**.

<sup>92</sup> WHO (2016) *International Health Regulations: third edition*, available at: <http://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf>. See also: WHO (2019) *About IHR*, available at: <https://www.who.int/ihr/about/en/>.

<sup>93</sup> OCHA (2012) *What are humanitarian principles?*, available at: [https://www.unocha.org/sites/dms/Documents/OOM-humanitarianprinciples\\_eng\\_June12.pdf](https://www.unocha.org/sites/dms/Documents/OOM-humanitarianprinciples_eng_June12.pdf).

governmental organizations (NGOs) in disaster relief,<sup>94</sup> supported by nearly 500 humanitarian organisations.<sup>95</sup>

### Box 1.8: Humanitarian principles

- **Humanity:** human suffering must be addressed wherever it is found. The purpose of humanitarian action is to protect life and health and ensure respect for human beings.
- **Neutrality:** humanitarian actors must not take sides in hostilities or engage in controversies of a political, racial, religious or ideological nature.
- **Impartiality:** humanitarian action must be carried out on the basis of need alone, giving priority to the most urgent cases of distress and making no distinctions on the basis of nationality, race, gender, religious belief, class or political opinions.
- **Independence:** humanitarian action must be autonomous from the political, economic, military or other objectives that any actor may hold with regard to areas where humanitarian action is being implemented.

1.32 While these principles clearly overlap with the ethical obligations of humanitarian health workers, it has been suggested that in practice humanitarian organisations and workers may view and use these two concepts differently – for example seeing humanitarian principles more as motivating ideals, while regarding ethical obligations as specifically action-guiding.<sup>96</sup> A 2019 systematic review of the literature exploring challenges to the humanitarian principles and to ethical obligations for humanitarian workers operating in armed conflicts identified both tensions and mutual reinforcement in how these concepts were used and understood (see Box 1.9).<sup>97</sup>

### Box 1.9: Challenges to ethical obligations and humanitarian principles in armed conflict – and the relationship between the two concepts

#### Ethical obligations for humanitarian workers

Given the nature of their engagement, humanitarian workers quite naturally adopt a wide range of ethical obligations in their practice.<sup>98</sup> The following were identified in a recent literature review: providing the highest quality of care; supporting a locally-led response; distributing benefits and burdens equally; respecting cultural norms; honesty in communication; and protecting response workers. Some of these seem to arise straightforwardly from the guiding humanitarian principles. Others may be in tension.

#### Examples of tensions

- The obligation to address suffering (which is again an aspect of the principle of humanity) can come into conflict with the principle of neutrality. There may be times when the best way to address suffering would be to expose an aggressor – explicitly to

<sup>94</sup> ICRC (1994) *Code of conduct for International Red Cross and Red Crescent movement and non-governmental organizations (NGOs) in disaster relief*, available at: <https://www.icrc.org/en/doc/assets/files/publications/icrc-002-1067.pdf>.

<sup>95</sup> OCHA (2012) *What are humanitarian principles?*, available at: [https://www.unocha.org/sites/dms/Documents/OOM-humanitarianprinciples\\_eng\\_June12.pdf](https://www.unocha.org/sites/dms/Documents/OOM-humanitarianprinciples_eng_June12.pdf). See also: Sphere (2018) *The Sphere handbook: humanitarian charter and minimum standards in humanitarian response*, available at: <https://spherestandards.org/wp-content/uploads/Sphere-Handbook-2018-EN.pdf>.

<sup>96</sup> Broussard G, Rubenstein LS, Robinson C *et al.* (2019) Challenges to ethical obligations and humanitarian principles in conflict settings: a systematic review *Journal of International Humanitarian Action* **4(1)**: 15.

<sup>97</sup> *ibid.*

<sup>98</sup> The authors of the review note that they were not, in this review, considering questions of clinical ethics, although these clearly come into play in direct patient care by humanitarian health workers. The ethical considerations identified in the review map rather onto public health concerns.



surrender neutrality. This is an enduring tension in humanitarian response and some regard neutrality as an operational principle – often necessary to ensure access but not in the same order of importance as, say, impartiality in the provision of services.

- ‘The ethical obligation to support a locally-led response’ could be in tension with the humanitarian principle of independence when local community members are aligned with a particular side of the conflict. Some humanitarian organisations will anticipate these accusations by ensuring that support is offered on all sides of a conflict. Similarly, the principle of independence can come into tension with the desire to reach vulnerable groups during conflicts as it may be necessary to negotiate with a particular armed actor in order to gain access.

#### **Examples where concepts are mutually supportive**

- In other instances, this intersection was found to be mutually supportive. For example, the ethical obligation of ensuring a fair distribution of the benefits and burdens of aid supports fulfilling the humanitarian principle of impartiality. Similarly, providing the highest quality of care and respecting cultural norms look like aspects of the overarching principle of ‘humanity’.

1.33 A third important area of international law for those working in emergency settings is **human rights law**: both in the form of the Universal Declaration of Human Rights, adopted unanimously by the UN in 1948; and in subsequent instruments, including the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). Rights protected through these frameworks that are relevant to research and evidence-gathering in emergencies include:

- Articles 1-3 of the Universal Declaration, which recognise the **inherent dignity and equal and inalienable rights of all members of the human family**; and the derived **prohibition on experimenting on human beings without their consent**, set out in Article 7 of the ICCPR.
- Article 12 of the Universal Declaration, which protects people from arbitrary interference with their **privacy**, and states that everyone has the right to the protection of the law against such interference.
- Article 2 of the ICESCR which **prohibits any discrimination on the ground of status**, including (among others) ethnicity, gender, national origin, or religion.
- Article 15 of the ICESCR which recognises that all individuals have a **right to enjoy the benefits of scientific progress and its applications**, while states must respect the freedom indispensable for scientific research and activity.
- Article 12 of the ICESCR which projects the **right of everyone to the enjoyment of the highest attainable standard of physical or mental health**.

1.34 A number of reasons have been identified for why the language of human rights can be helpful in the context of health research, particularly in the global context. These include:

- Global legitimacy, given that every country in the world has signed and ratified at least one major human rights treaty;
- Recognition of both individual and communal rights;
- Articulation of the obligations of governments, both towards each other and to those living within their jurisdiction; and

- Means of resolving the tensions that arise between rights and rightsholders, both through identifying a hierarchy of rights, and through emphasis on prioritising the rights of the most powerless and vulnerable.<sup>99</sup>
- 1.35 Under human rights law, so-called ‘non derogable’ rights are rights that cannot be limited or infringed under any circumstances, not even under a declaration of a state of emergency.<sup>100</sup> These include rights such as the right to life (Article 3 of the Universal Declaration), freedom from torture, or cruel, inhuman or degrading treatment or punishment (Article 5 of the Universal Declaration), and freedom from medical or scientific experimentation without consent (Article 7 of the ICCPR). These rights prevail over all other human rights such as the right to the highest attainable standard of health. Under international human rights law, all the other human rights are not absolute and so they may legitimately be restricted in order to advance a larger societal objective or rights for the whole; for example the state may curtail (but not extinguish) citizens’ right to privacy in order to secure the security of all citizens.
- 1.36 All human rights are considered indivisible, interrelated, and interdependent. Thus, the improvement of one right facilitates advancement of another, and likewise, the deprivation of one right adversely affects others. Nevertheless, as illustrated above, there are inevitable tensions between the exercise of rights, whether between individuals, or between individuals and the wider public good. International human rights law leaves it to nation states to make determinations on such conflicting rights. In addition to the principle that rights cannot be extinguished or voided, it has also been argued that “the historic mission of ‘contemporary’ human rights is to give voice to human suffering, to make it visible, and to ameliorate it.”<sup>101</sup>

### ***Implications for those engaged in research during global health emergencies***

- 1.37 As the complex picture of regulation and ethical guidance described above illustrates, while regulation and guidance are very important for those engaged in research during global health emergencies, it will often be the case that they do not provide definitive answers to the challenges encountered. Even the best and clearest rule requires interpretation in practice and in context. We return to this issue throughout our report, in particular in Chapter 4, in our presentation of an ‘ethical compass’ to guide both policy and practice, and in our discussion in Chapters 7 and 10 of the important role played by professional attitudes and personal dispositions of researchers in filling the gap between high level principle and the reality on the ground.

<sup>99</sup> Harris TL, and Wyndham JM (2015) Data rights and responsibilities: a human rights perspective on data sharing *Journal of Empirical Research on Human Research Ethics* **10(3)**: 334-7.

<sup>100</sup> UN Human Rights Committee (2001) *CCPR General Comment no.29: Article 4 - derogations during a state of emergency: CCPR/C/21/Rev.1/Add.11*, available at: <https://www.refworld.org/docid/453883fd1f.html>.

<sup>101</sup> Baxi U (2006) *The future of human rights* (Oxford: Oxford University Press), at page 6.





# Chapter 2

Research in context:  
experience of participants  
and researchers

## Chapter 2 – Research in context: experience of participants and researchers

### Chapter 2: overview

#### Community leadership and agency

Narratives from those with personal experience of being affected by emergencies, whether infectious disease outbreaks, or human-made or natural disasters, are an essential part of the evidence base when exploring the ethical challenges of effective emergency response and research. Although the features of emergencies described in Chapter 1 undermine and disrupt everyday life and institutions, affected communities nevertheless take a leading role themselves in emergency response. This has important consequences for the ethical conduct of research associated with that response, including questions of legitimacy and accountability of external actors to those communities.

Studies and evaluations of the 2004 Indian Ocean tsunami, Hurricane Katrina, the Syrian conflict, and the compound disaster at Fukushima, provide a rich source of examples of emergency response initiated and owned by affected communities. Many of these involve active roles by those who in ordinary circumstances would not have had influence in their communities, including young people and women. Such active engagement and ownership of emergency response by local communities and civil society organisations has been associated with longer-term benefits and sustainability. In contrast, failure on the part of some international organisations to engage meaningfully with local populations has led to needs being overlooked or not well understood. While the response to infectious disease outbreaks tends to be more institution-led and dominated by external actors, there is an increasing awareness of the importance of international actors supporting and enabling community health services and community responders in taking the lead.

#### Participant experiences

Insight into the experiences of people directly affected by emergencies is an essential first step in understanding potential sensitivities in standard research practices and minimising scope for misunderstanding about the role of research. It illustrates how closely interwoven research and response in humanitarian crises are, and how it may be unrealistic to expect people to trust in the good intentions of researchers if their basic needs are not being met. The primary motivation for taking part in intervention-based studies is often the hope of regaining health, and the invitation to take part may be perceived as an 'empty choice' with few if any apparent alternatives. Past experience with external organisations, whether related to research or other initiatives, affects participant expectations and can lead to significant misunderstandings, for example about possible future benefits, and consequent distrust.

#### Researcher experiences

Researchers in global health emergencies work in highly complex, rapidly changing, and often uncoordinated environments. Challenges include the multiplicity of organisations and structures involved in response and research; the diversity of people working in the field, including different motivations and lines of accountability, and rapid turnover; and tension between knowledge generation and the immediate emergency response, particularly for those with clinical skills.

## Community agency and community experience

*“Local structures are already in place and more often than not the ‘first responders’ to a crisis. The way the international community goes about providing relief and recovery assistance must actively strengthen, not undermine, these local actors.”<sup>102</sup>*

*“Across the world, communities have great agency and ability to act, and we must support them to do so – this is what it means to have communities at the centre of preparedness and response.”<sup>103</sup>*

- 2.1 The immediate image triggered by the concept of a ‘global health emergency’ may for many constitute a flurry of international activity descending on a disaster site.<sup>104</sup> However, although our description of a global health emergency emphasises the involvement of a range of external actors and all the associated challenges of coordination and legitimacy (see Box 1.2), it is crucial to keep in view the primary role of nation states and of communities at the local level, both with respect to emergency preparedness and risk reduction, and in immediate response.
- 2.2 The leading role taken by affected communities themselves in emergency response emerged very strongly in the many different forms of evidence available to the working group: in roundtable meetings held with contributors with on-the-ground experience of emergency response;<sup>105</sup> in a community engagement workshop co-hosted with partners in Dakar;<sup>106</sup> and in illustrative literature reviews conducted for us that focused on community agency and engagement during and after natural and human-made disasters.<sup>107</sup> These narratives from those with personal experience of being affected by emergencies provide an essential part of the context in which research may take place, contrasting with the disempowering aspects of the factors associated with emergencies identified earlier (see paragraph 1.8).
- 2.3 In order to ensure that our ethical analysis in Chapter 4 is soundly based on the experiences of those most affected by emergencies, this chapter draws on the input of many contributors to our project to provide, first, a snapshot of the role of communities in responding to various kinds of emergencies, and second, insights into the experiences of being involved in research during an emergency, from both participant and researcher perspectives. These insights help to illustrate the complex ways in which response and research are closely interwoven, and the implications of this complexity for an ethical approach to research in these challenging circumstances, particularly with respect to issues of legitimacy and ownership of decision-making (see Chapter 5). While the first part of this chapter focuses on the experiences of communities in emergency *response* (i.e., not specifically research associated with that response), this focus derives directly

<sup>102</sup> Tsunami Evaluation Coalition (2006) *Joint evaluation of the international response to the Indian Ocean tsunami*, available at: [https://www.sida.se/contentassets/f3e0fbc0f97c461c92a60f850a35daddb/joint-evaluation-of-the-international-response-to-the-indian-ocean-tsunami\\_3141.pdf](https://www.sida.se/contentassets/f3e0fbc0f97c461c92a60f850a35daddb/joint-evaluation-of-the-international-response-to-the-indian-ocean-tsunami_3141.pdf), at page 3.

<sup>103</sup> IFRC (2019) *From words to action: towards a community-centred approach to preparedness and response in health emergencies*, available at: [http://apps.who.int/gpmb/assets/thematic\\_papers/tr-5.pdf](http://apps.who.int/gpmb/assets/thematic_papers/tr-5.pdf), at page 6.

<sup>104</sup> YouTube (11 March 2019) *Lunch hour lecture: disaster - it's not like a Hollywood movie*, available at: <https://www.youtube.com/watch?v=FYP18remj5o>.

<sup>105</sup> On-the-ground roundtable, 25 June 2018; and Data and samples roundtable, 3 December 2018 (see Appendix 1).

<sup>106</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>107</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: literature reviews*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.

from contributions at the Dakar workshop, where leaders of Ebola survivors' movements emphasised how crucial it is for researchers to start from a real understanding of the experiences of those whose lives have been turned upside down by the emergency.<sup>108</sup> Further details of the methods we used in gathering the evidence and experiences presented below are given in Appendices 1 and 2.

## Community response in natural and human-made disasters

*"The Fukushima disaster also shows us that yet again, the most effective humanitarian response happens when there is a partnership with affected communities and coordination with relevant authorities. Thus, local, national and international actors all must play an essential role in scaling up preparedness, response and recovery activities."*<sup>109</sup>

*"In displacement, humanitarianism treats children as dependent subjects, but at the same time, Za`tari's NGO programming [in Jordan] instils in children a sense that they can exercise agency as independent beings in the camp."*<sup>110</sup>

*"We watched as the levees broke. We watched as the flood waters rose. We watched as New Orleanians were stranded on their rooftops, in the Superdome, the Convention Center, and on the interstate. Now, we come together with a plan, to prevent what happened in 2005 from ever happening again."*<sup>111</sup>

### Individual and community-led initiatives

- 2.4 The many studies and evaluations of the response to the 2004 Indian Ocean tsunami provide a rich source of examples of community-initiated and community-owned emergency response in a major natural disaster. Local citizens, including children and young people, were active in all forms of immediate response, including evacuating the injured, delivering medicines, gathering and burning debris, and providing emotional and practical support.<sup>112</sup> In some camps, survivors formed committees to run the camp, rather than relying on outside management.<sup>113</sup> Involvement both in practical tasks, such as clearing up after the destruction, and in peer support, such as sharing stories of grief, accompanying each other to the health post, and looking after each other's children, helped people recover psychologically from the impact of the disaster.<sup>114</sup> More generally, informal social resources such as networks of families, friends, and neighbours were

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<sup>108</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>109</sup> OCHA (2016) *Fukushima: five years on*, available at: <https://www.unocha.org/story/fukushima-five-years>.

<sup>110</sup> Gatter MN (2017) Restoring childhood: humanitarianism and growing up Syrian in Za`tari refugee camp *Contemporary Levant* **2(2)**: 89-102.

<sup>111</sup> Evacuteer (2019) *Homepage*, available at: <http://evacuteer.org/>.

<sup>112</sup> See, for example, UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf).

<sup>113</sup> Archer D, and Boonyabancha S (2011) Seeing a disaster as an opportunity – harnessing the energy of disaster survivors for change *Environment and Urbanization* **23(2)**: 351-64.

<sup>114</sup> Humanitarian Practice Network (2010) *Making space for community-based protection in the humanitarian protection landscape*, available at: <https://odihpn.org/magazine/making-space-for-community-based-protection-in-the-humanitarian-protection-landscape/>.

central in helping people cope with the emotional and practical consequences of the tsunami.<sup>115</sup>

- 2.5 Similar accounts emerge in the other literature reviews of experiences after the Fukushima disaster and Hurricane Katrina, and in the context of the current conflict in Syria. After Fukushima, for example, residents produced their own maps of radioactive contamination and used them to avoid / reduce their own exposure;<sup>116</sup> and through citizen science initiatives that provided data otherwise unavailable to scientists through their involvement in data collection, technical measurement, and analysis in fields as diverse as ecology, biodiversity, and astronomy.<sup>117</sup> Cooperative efforts to revitalise the fishing industry destroyed by the tsunami were initiated by individuals.<sup>118</sup> Initiatives such as knitting circles set up by older people not only provided mutual social support for members, but were also described as a form of ‘informal insurance’ where members shared resources with each other in the absence of standard supplies from the authorities or the private sector.<sup>119</sup>
- 2.6 The role of young people emerged particularly strongly in the illustrative review of how communities have been, and continue to be, engaged in the humanitarian crisis resulting from the Syrian conflict (both inside Syria and in displaced populations in other countries). Examples of young people’s activity are cited in many different contexts, including providing material support such as textbooks<sup>120</sup> and clothes for children from more disadvantaged families within the community (see Box 2.1 below); leading sports<sup>121</sup> and arts<sup>122</sup> projects; and being active in entrepreneurial initiatives.<sup>123</sup> There are also numerous examples of young people participating in youth-led peacebuilding projects such as creating a radio station within Syria to ‘spread peaceful values’,<sup>124</sup> and establishing the Berlin-based Syrian Youth Assembly.<sup>125</sup> Other initiatives by community groups combined meeting immediate needs for food with peacebuilding: rooftop

<sup>115</sup> Ekanayake S, Prince M, Sumathipala A *et al.* (2013) “We lost all we had in a second”: coping with grief and loss after a natural disaster *World Psychiatry: Official Journal of the World Psychiatric Association (WPA)* **12(1)**: 69-75.

<sup>116</sup> European Joint Programme for the Integration of Radiation Protection Research (2018) *Report on key challenges, best practices and recommendations for stakeholder engagement*, available at: [http://www.engage-concert.eu/-/media/Files/ENGAGE/publications/deliverables/D9\\_82\\_Report\\_on\\_key\\_challenges-best\\_practices\\_and\\_recomm\\_stakeholder\\_engagement\\_submitted29082018.pdf](http://www.engage-concert.eu/-/media/Files/ENGAGE/publications/deliverables/D9_82_Report_on_key_challenges-best_practices_and_recomm_stakeholder_engagement_submitted29082018.pdf), at page 49.

<sup>117</sup> Aldrich DP (2012) *Post-crisis Japanese nuclear policy: from top-down directives to bottom-up activism*, available at: <https://www.eastwestcenter.org/sites/default/files/private/api103.pdf>, pp7-8. It was noted that these were “results that lone researchers in highly funded laboratories would not be able to accomplish” because of access issues. See also: Safecast (2019) *About Safecast*, available at: <https://blog.safecast.org/about/>.

<sup>118</sup> CNN (28 February 2012) *Fisherman’s battle to revive tsunami-devastated industry*, available at: <https://edition.cnn.com/2012/02/26/world/asia/rebuilding-japan-urato-islands/index.html>.

<sup>119</sup> Aldrich DP (2015) Social capital in post disaster recovery: strong networks and communities create a resilient East Asian community, in *Resilience and recovery in Asian disasters: community ties, market mechanisms, and governance*, Aldrich DP, Oum S, and Sawada Y (Editors) (Tokyo: Springer Japan), at page 23.

<sup>120</sup> Norwegian Refugee Council (2016) *A future in the balance*, available at: [http://wos-education.org/uploads/reports/Final\\_youth\\_research\\_doc\\_-\\_April2016.pdf](http://wos-education.org/uploads/reports/Final_youth_research_doc_-_April2016.pdf), at page 24.

<sup>121</sup> The Change Foundation (14 February 2018) *Empowering young sports leaders in refugee camps in Lebanon*, available at: <https://www.thechangefoundation.org.uk/empowering-young-sports-leaders-in-refugee-camps-in-lebanon/>.

<sup>122</sup> RET (2019) *Bridging the cultural gaps through music and dance. An initiative led by the youth to the young people of Turkey*, available at: <https://www.theret.org/bridging-the-cultural-gaps-through-music-and-dance-an-initiative-led-by-the-youth-to-the-young-people-of-turkey/>.

<sup>123</sup> UNICEF (15 July 2019) *UNICEF builds the entrepreneurial skills of Syrian youth to create new opportunities*, available at: <https://www.unicef.org/syria/stories/unicef-builds-entrepreneurial-skills-syrian-youth-create-new-opportunities>.

<sup>124</sup> Swiss Peace Foundation (2016) *Inside Syria: what local actors are doing for peace*, available at: <http://cdint.org/documents/Inside-Syria-What-Local-Actors-Are-Doing-for-Peace.pdf>.

<sup>125</sup> Syrian Youth Assembly (2019) *Homepage*, available at: <https://syrian-youth.org/>.



agriculture projects, for example, have enabled people living within Syria “to come together to grow their own food, which eases tensions between them.”<sup>126</sup>

- 2.7 In the aftermath of Hurricane Katrina, community-led initiatives worked to clear up devastated neighbourhoods and develop a community healthcare network, described as “an important source of care for a population that historically had relied on the public hospital and emergency rooms for primary care”.<sup>127</sup> Umbrella groups were formed to coordinate the many active community groups, avoid competition or conflict, and facilitate learning from each other,<sup>128</sup> and in one neighbourhood a network of ‘block captains’ emerged to ensure that in every block there was someone who had volunteered to be the central point of information for that block.<sup>129</sup> A common theme in many of the initiatives reported was that of the absence of government support, both in the past, through neglect and marginalisation of impoverished communities, and through ongoing failings in emergency response and rebuilding.<sup>130</sup>

### Box 2.1: Examples of individual and community-initiated response in different forms of emergency

- “After the tsunami struck on 26 December 2004, a call went out in the Maldives – “Whoever can help, please come.” Each volunteer was given an age-appropriate task. Many adults stayed away. Many young people came forward. When a psychosocial counsellor was sent to concentrate on possible problems with young people, she couldn’t find anyone. “They were all working,” she said.”<sup>131</sup>
- After Fukushima, in the absence of government support, community leaders and volunteers organised a beach-clearing project “to fulfil the dreams of our children”. Realising that the government had different priorities for disaster recovery, “the attitude of the community leaders was not to wait for official plans to be put into operation but to find a bottom-up solution and do things themselves with the resources available in the community.”<sup>132</sup>
- A group of girls in Aleppo used skills gained from a United Nations Children’s Fund (UNICEF) tailoring project to make clothes to help 300 children from disadvantaged families in their community. These were distributed at a clothing fair: families showed their invitations at the door, and were free to choose whatever items they wanted for

<sup>126</sup> Swiss Peace Foundation (2016) *Inside Syria: what local actors are doing for peace*, available at: <http://cdint.org/documents/Inside-Syria-What-Local-Actors-Are-Doing-for-Peace.pdf>, at page 22. See also: Syria Deeply (28 October 2014) *Greening the rubble: Syrians embrace urban farming to stave off starvation*, available at: <https://www.newsdeeply.com/syria/articles/2014/10/28/greening-the-rubble-syrians-embrace-urban-farming-to-stave-off-starvation>.

<sup>127</sup> DeSalvo K (2011) Delivering high-quality, accessible health care: the rise of community centers, in *Resilience and opportunity: lessons from the US Gulf Coast after Katrina and Rita*, Liu A, Anglin R, Mizelle R, and Plyer A (Editors) (Washington DC: Brookings Institution Press), at page 50.

<sup>128</sup> Campanella R, and Koritz A (2009) “Bring your own chairs”: civic engagement in postdiluvial New Orleans in *Civic engagement in the wake of Katrina*, Koritz A, and Sanchez G (Editors) (Ann Arbor, Michigan: University of Michigan Press).

<sup>129</sup> Weil F (2011) Rise of community organizations, citizen engagement, and new institutions, in *Resilience and opportunity: lessons from the US Gulf Coast after Katrina and Rita*, Liu A, Anglin R, Mizelle R, and Plyer A (Editors) (Washington DC: Brookings Institution Press), at page 208.

<sup>130</sup> See, for example, Nelson M, Ehrenfeucht R, and Laska S (2007) Planning, plans, and people: professional expertise, local knowledge, and governmental action in post-hurricane Katrina New Orleans *Cityscape* **9(3)**: 23-52, at page 41; Weil F (2011) Rise of community organizations, citizen engagement, and new institutions, in *Resilience and opportunity: lessons from the US Gulf Coast after Katrina and Rita*, Liu A, Anglin R, Mizelle R, and Plyer A (Editors) (Washington DC: Brookings Institution Press); and Ebony (9 May 2012) *Jungleland? New Orleans community activist rejects NY Times depiction of 9th Ward*, available at: <https://www.ebony.com/news/jungleland-new-orleans-community-activist-rejects-ny-times-depiction-of-9th-ward/>.

<sup>131</sup> UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicefemergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicefemergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf), at page 9.

<sup>132</sup> Lin Y, Kelemen M, and Kiyomiya T (2017) The role of community leadership in disaster recovery projects: tsunami lessons from Japan *International Journal of Project Management* **35(5)**: 913-24.



their children. One of the girls who took part in the project – Sabah – observed, “We didn’t want families to feel like we were handing out clothes to them, we wanted to maintain their dignity and freedom to choose whatever they liked!”<sup>133</sup>

- “From tiny storefront congregations to deep-pocketed denominations, the communities of faith arrived first. In the harrowing hours and days after Hurricane Katrina, when survivors roamed the desolate streets in search of water, food and medicine, (religious) groups – not FEMA, not the [American] Red Cross, not the National Guard – provided dazed residents with their first hot meal, their first clean water, their first aspirin.”<sup>134</sup>
- Sivaperumal Manimekalai, based in the tsunami-affected Nagapattinam district of Sri Lanka, set up a fish-vendors’ federation for female members of her community despite the resistance of male members. The federation was able to repay substantial loans, “contradicting the post-tsunami climate in which communities were being showered with grants.”<sup>135</sup>

### **Role of local services and civil society organisations**

- 2.8 Alongside these examples of activity initiated by individuals and families, existing health services and local civil society organisations played an important role in response to the 2004 tsunami. Psychosocial support programmes in war-affected parts of Sri Lanka, for example, were adapted to the needs of those affected by the tsunami,<sup>136</sup> and the village health post played a central role in programmes addressing child malnutrition in Indonesia.<sup>137</sup> Organisations such as CARE and World Vision were commended for ensuring their field offices, rather than international headquarters, took the lead in determining appropriate forms of response,<sup>138</sup> and a UNICEF evaluation of its own response to the tsunami recommended positively discriminating in favour of grassroots and advocacy organisations as the most effective implementers.<sup>139</sup>
- 2.9 In emergencies caused by civil conflict and the associated widescale displacement of large parts of the population, the role of government-provided services is inevitably more complex, although the role played by Local Administrative Councils in opposition-held areas of Syria has been noted as providing a route for citizens to have a stake in local services.<sup>140</sup> The key role of local humanitarian organisations in providing local services,

<sup>133</sup> UNICEF (19 August 2018) *The young women of rural Aleppo support their community with help from UNICEF*, available at: <https://www.unicef.org/syria/stories/young-women-rural-aleppo-support-their-community-help-unicef>.

<sup>134</sup> National Disaster Interfaith Network (2014) *Working with US faith communities during crises, disasters and public health emergencies*, available at: [http://www.n-din.org/ndin\\_resources/FGS/FieldGuide-HighRes.pdf](http://www.n-din.org/ndin_resources/FGS/FieldGuide-HighRes.pdf), at page 39, citing Philadelphia Inquirer (23 August 2006) *Faith in action: faith-based groups early and enduring: before agencies aided Katrina’s victims, religious groups did*.

<sup>135</sup> UNISDR (2007) *Acting with common purpose: proceedings of the first session of the Global Platform for Disaster Risk Reduction: Geneva, 5-7 June 2007*, available at: [https://www.unisdr.org/files/1464\\_GPActingwithcommonpurpose.pdf](https://www.unisdr.org/files/1464_GPActingwithcommonpurpose.pdf), at page 25.

<sup>136</sup> Plan (2005) *Children and the tsunami* (Bangkok: Plan), at page 25.

<sup>137</sup> Care Australia (2010) *Tsunami report*, available at: [https://www.care.org.au/wp-content/uploads/2014/12/Tsunami-Report\\_2010\\_web-quality.pdf](https://www.care.org.au/wp-content/uploads/2014/12/Tsunami-Report_2010_web-quality.pdf), at page 15.

<sup>138</sup> Tsunami Global Lessons Learned Project Steering Committee (2009) *The tsunami legacy: innovation, breakthroughs and change*, available at: <https://www.alnap.org/system/files/content/resource/files/main/aprc-cpr-2009-tsunamilegacyreport.pdf>, at page 12.

<sup>139</sup> UNICEF (2009) *Children and the 2004 Indian Ocean tsunami: evaluation of UNICEF’s response in Indonesia, Sri Lanka and Maldives (2005-2008)*, available at: [https://www.unicef.org/evaldatabase/files/FINAL\\_Tsunami\\_Overall\\_Synthesis\\_29\\_March.pdf](https://www.unicef.org/evaldatabase/files/FINAL_Tsunami_Overall_Synthesis_29_March.pdf), recommendation 6.

<sup>140</sup> Local Administrative Councils were formed in opposition-held areas of Syria. They began as relief agents and “evolved over time, attempting to fill the vacuum left when the Syrian government retreated from certain areas of the country.” See: Swiss

especially health services, within Syria, has been highlighted, alongside concern that it is difficult for them to access financial support from overseas.<sup>141</sup> The role of Syrians, particularly young Syrians, in active volunteering in projects initiated by local or international NGOs, both within Syria and in displaced populations outside Syria, was cited in many of the studies and commentaries covered in the review.<sup>142</sup>

- 2.10 The role of local faith-based communities, such as the Salvation Army and individual church communities, in providing key support is particularly emphasised in accounts of the aftermath of Hurricane Katrina. This is ascribed both to the overall inability of government and organisations such as the American Red Cross to take care of all the problems,<sup>143</sup> and to hesitancy on the part of these agencies to venture into 'harder-to-reach' areas, because of safety concerns.<sup>144</sup> Faith-based organisations thus played a crucial role in meeting the basic needs of the most disenfranchised groups. A degree of disillusionment with the likelihood of timely support being provided by the state, and hence the need to develop locally-driven alternatives, was also expressed in studies after Fukushima.<sup>145</sup> Indeed, experiences in the aftermath of Fukushima and Katrina were reported as prompting citizens to challenge the information given to them by government and other authorities and to protest against existing policies (see also paragraphs 2.13 and 2.15).<sup>146</sup>

### **Collaborative approaches between communities and NGOs**

- 2.11 In all four of the reviews, there were also many examples of the way in which local and national organisations, including NGOs, universities, and church-based organisations worked collaboratively with grassroots communities to meet needs and rebuild communities. These included projects to establish peer-to-peer support and health information networks, with university students or NGOs providing initial training;<sup>147</sup> the creation of children's parliaments and youth advisory councils to promote children's and young people's rights and promote advocacy;<sup>148</sup> and an initiative by a university architecture department to work with communities to 'recover, rebuild, and renew' their neighbourhoods.<sup>149</sup> In some cases, initiatives established by development agencies were subsequently taken over by local communities, including, for example, by young

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Peace Foundation (2017) *The experience of Local Administrative Councils in opposition-held Syria*, available at: [https://www.swisspeace.ch/fileadmin/user\\_upload/pdf/Mediation/WOTRO\\_Report\\_The\\_Experience\\_of\\_Local\\_Administrative\\_Councils\\_in\\_Oppositionheld\\_Syria.pdf](https://www.swisspeace.ch/fileadmin/user_upload/pdf/Mediation/WOTRO_Report_The_Experience_of_Local_Administrative_Councils_in_Oppositionheld_Syria.pdf), at page 3.

<sup>141</sup> Elrha (2019) *Dr Rola Hallam: accountability to people affected by humanitarian crises*, available at: <https://www.elrha.org/researchdatabase/dr-rola-hallam-accountability-to-people-affected-by-humanitarian-crises/>; and CanDo (2019) *Meet our local partners*, available at: <https://www.candoaction.org/our-partners#meet-our-local-partners>.

<sup>142</sup> See, for example, UNHCR (11 June 2017) *Volunteer work helps refugee in Syria make a difference*, available at: <https://www.unhcr.org/sy/10574-volunteer-work-help-refugee-in-syria-make-a-difference.html>; and GIZ (2019) *Turkey: schools and sports are forging bonds between Syrians and local people*, available at: <https://www.giz.de/en/mediacenter/76847.html>.

<sup>143</sup> National Disaster Interfaith Network (2014) *Working with US faith communities during crises, disasters and public health emergencies*, available at: [http://www.n-din.org/ndin\\_resources/FGS/FieldGuide-HighRes.pdf](http://www.n-din.org/ndin_resources/FGS/FieldGuide-HighRes.pdf), at page 54.

<sup>144</sup> Government Accountability Office (2005) *Hurricanes Katrina and Rita*, available at: <https://www.gao.gov/new.items/d06297t.pdf>, at page 9.

<sup>145</sup> See, for example, Goulding C, Kelemen M, and Kiyomiya T (2018) Community based response to the Japanese tsunami: a bottom-up approach *European Journal of Operational Research* **268(3)**: 887-903.

<sup>146</sup> See, for example, Aldrich DP (2012) *Post-crisis Japanese nuclear policy: from top-down directives to bottom-up activism*, available at: <https://www.eastwestcenter.org/sites/default/files/private/api103.pdf>, at page 10.

<sup>147</sup> Plan (2005) *Children and the tsunami* (Bangkok: Plan), at page 28; and UNICEF (7 January 2019) *Young people in rural Hama, Syria join UNICEF's efforts to raise awareness on skin diseases*, available at: <https://www.unicef.org/syria/stories/young-people-rural-hama-syria-join-unicefs-efforts-raise-awareness-skin-diseases>.

<sup>148</sup> Save the Children (2006) *Child rights perspective in response to natural disasters in South Asia: a retrospective study* (Kathmandu: Save the Children); and The Jordan Times (1 November 2017) *UNICEF appoints 60 youth for local advisory council*, available at: <http://www.jordantimes.com/news/local/unicef-appoints-60-youth-local-advisory-council>.

<sup>149</sup> Evans-Cowley J, and Zimmerman Gough M (2009) Citizen engagement in post-Hurricane Katrina planning in Harrison County, Mississippi *Cityscape* **10(3)**: 21-37.

people initiating new activities and priorities in services for children in response to their own awareness of children's needs.<sup>150</sup>

- 2.12 The role of local culture and art played an important role in many of these participatory initiatives. Music-based projects are cited across the range of emergencies studied, but played a particularly powerful role in the aftermath of Hurricane Katrina, through community initiatives such as the establishment of community choirs, a marching band, and support to reinstate children's music lessons;<sup>151</sup> and through active support for struggling musicians from well-known musicians through the creation of a 'musicians' village'.<sup>152</sup> Other ways in which local cultural traditions could be deployed in collaborative projects between NGOs and affected communities included 'picture-letter' drawing,<sup>153</sup> writing haikus,<sup>154</sup> and 'manzai' stand-up comedy<sup>155</sup> as means of self-expression and healing after Fukushima. The valuable role played by neighbourhood storytelling and community theatre also emerged in very different settings.<sup>156</sup> Other examples include art, music, and dance in projects in Lebanon, Syria, and Turkey;<sup>157</sup> and theatre in Thailand.<sup>158</sup>
- 2.13 Despite recognition that the humanitarian sector tends to lack incentives to put in place feedback loops and measure performance based on beneficiary feedback,<sup>159</sup> a variety of examples were cited of ways in which service-providers engaged with communities to ensure that they had a better understanding of the needs they were seeking to meet (see Box 2.2 below).<sup>160</sup> Strikingly, however, it has been suggested that official plans for responding to Katrina did not involve community groups,<sup>161</sup> and indeed in some cases

<sup>150</sup> UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf).

<sup>151</sup> See, for example, Harvey R, Smith M, Abraham N *et al.* (2007) The hurricane choir: remote mental health monitoring of participants in a community-based intervention in the post-Katrina period *Journal of Health Care for the Poor and Underserved* **18**(2): 356-61; Gambit (20 July 2018) *The Roots of Music education program moves into the Marigny*, available at: [https://www.nola.com/gambit/music/article\\_66fe326e-faa5-598a-888e-00ab72ffe427.html](https://www.nola.com/gambit/music/article_66fe326e-faa5-598a-888e-00ab72ffe427.html); and The Roots of Music (2019) *Homepage*, available at: <https://therootsofmusic.org/>.

<sup>152</sup> Ellis Marsalis Center (2019) *About: Musicians' Village*, available at: <https://ellismarsaliscenter.org/musicians-village>.

<sup>153</sup> Chiba N (2015) *Voices of women from the city of Ishinomaki, Miyagi prefecture*, available at: [https://jdardrupal.s3.amazonaws.com/3\\_11women\\_2210.pdf](https://jdardrupal.s3.amazonaws.com/3_11women_2210.pdf), at page 8.

<sup>154</sup> Goulding C, Kelemen M, and Kiyomiya T (2018) Community based response to the Japanese tsunami: a bottom-up approach *European Journal of Operational Research* **268**(3): 887-903, at page 895.

<sup>155</sup> Japan Disasters Digital Archive (23 May 2017) *In Fukushima, children are being taught to laugh out loud*, available at: <http://jdarchive.org/en/item/2228684>.

<sup>156</sup> See, for example, Brenner L (2010) Storming the nation: post-Katrina New Orleans, documentary theatre, and civic responsibility *Transformations: The Journal of Inclusive Scholarship and Pedagogy* **20**(2): 15-38, at page 29; Jung J-Y, Toriumi K, and Mizukoshi S (2013) Neighborhood storytelling networks, internet connectedness, and civic participation after the Great East Japan Earthquake *Asian Journal of Communication* **23**(6): 637-57; and Michna C (2013) Performance and cross-racial storytelling in post-Katrina New Orleans: interviews with John O'Neal, Carol Bebel, and Nicholas Slie *TDR/The Drama Review* **57**(1): 48-69.

<sup>157</sup> Vice (27 March 2014) *How Syrian children are drawing and using art therapy to heal the trauma from war*, available at: [https://www.vice.com/en\\_au/article/xd5wva/syrian-children-are-drawing-to-heal-the-trauma-from-war](https://www.vice.com/en_au/article/xd5wva/syrian-children-are-drawing-to-heal-the-trauma-from-war); and RET (2019) *Bridging the cultural gaps through music and dance. An initiative led by the youth to the young people of Turkey*, available at: <https://www.theret.org/bridging-the-cultural-gaps-through-music-and-dance-an-initiative-led-by-the-youth-to-the-young-people-of-turkey/>.

<sup>158</sup> UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicefinemergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf), at Box 11.

<sup>159</sup> Red Barnet (2016) *The listen learn act project*, available at: <https://redbarnet.dk/eu-fonde-og-ministerier/the-listen-learn-act-project/>.

<sup>160</sup> In some cases, this evolved further into fully participatory 'collaborative community-based research': see, for example, Kleiner AM, and Walker SD (2012) Lifting spirits and changing lives: analysis of outcomes from one organization's journey with community-based research *Journal of Rural Social Sciences* **27**(2): 12-31.

<sup>161</sup> Community and Regional Resilience Initiative (2008) *Community resilience: lessons from New Orleans and Hurricane Katrina*, available at: [http://www.emergencyvolunteering.com.au/docs/CR\\_Lessons\\_Hurricane\\_Katrina.pdf](http://www.emergencyvolunteering.com.au/docs/CR_Lessons_Hurricane_Katrina.pdf), at page 14. Subsequent guidance from FEMA on whole community approaches to emergency management makes no reference to Katrina: FEMA (2011) *A whole community approach to emergency management: principles, themes, and pathways for action*, available at: [https://www.fema.gov/media-library-data/20130726-1813-25045-0649/whole\\_community\\_dec2011\\_\\_2\\_.pdf](https://www.fema.gov/media-library-data/20130726-1813-25045-0649/whole_community_dec2011__2_.pdf).

communities had to fight to demonstrate that utilities such as water and electricity could be reconnected because they were back in residence and repairing their housing.<sup>162</sup> According to an account from a survivor, attempts to build a playground in ‘Renaissance Village’ (temporary accommodation for survivors of Katrina) were blocked by the Federal Emergency Management Agency (FEMA) on the grounds they did not wish to encourage people to stay – until a local company providing other services “poured a concrete slab and built a basketball court in the middle of the night, and dared FEMA to tear it down... [it] quickly became a cherished community gathering place.”<sup>163</sup>

### Box 2.2: Community engagement for service provision

- **Services for older people in Ofunato – an area of Japan significantly damaged by the tsunami:** the Ibasho Café was built by HelpAge International after 18 months’ consultation with older people living in the area, and aimed to improve older people’s well-being, building on “people’s strengths not their physical weaknesses.” The café provided a space for older people “to connect with each other and pass on their experience and knowledge to other generations.”<sup>164</sup>
- **Children’s clubs established by the United Nations Refugee Agency (UNHCR) in the Damascus area** sought to enable young people to express the challenges and obstacles they face in their communities or schools, in addition to submitting ideas to UNHCR that might improve their surrounding environment.<sup>165</sup>
- **Community involvement in infrastructure planning in Lebanon:** a joint project between the Qatar Red Crescent Society and Elrha’s Humanitarian Innovation Fund sought to engage Syrian refugees and their views on how sanitation services at four Syrian refugee camps could be enhanced.<sup>166</sup>
- **Art and research in Sri Lanka:** participants from a village in eastern Sri Lanka took part in an arts-based research workshop and evaluation exercise. Participants were asked to present images of their most important needs, and their presentations were subsequently translated for international aid providers.<sup>167</sup>

## Benefits and challenges

- 2.14 A common theme in the reviews of all four emergencies was the increased sense of personal confidence and control on the part of community members who took an active role in responding. This was varyingly expressed as agency, empowerment, or pride by those whose homes, neighbourhoods, and livelihoods were affected. At the individual level, this was expressed in terms of ‘having a voice’ or being able to hope again in the future, whether because of improved mental well-being, or through skills acquired to help

<sup>162</sup> Patterson O, Weil F, and Patel K (2010) The role of community in disaster response: conceptual models *Population Research and Policy Review* 29(2): 127-41, at page 138.

<sup>163</sup> Alabama Possible (30 September 2011) *Community at the center of the storm*, available at: <http://alabamapossible.org/2016/01/29/community-at-the-center-of-the-storm/>.

<sup>164</sup> HelpAge International (16 March 2015) *Ibasho Café: a space for older people*, available at: <https://www.helpage.org/blogs/jane-scobie-35/ibasho-caf-a-space-for-older-people-831/>.

<sup>165</sup> UNHCR (8 August 2016) *Children’s Club: children find a new environment for innovation and creativity*, available at: <https://www.unhcr.org/sy/172-childrens-club-children-find-a-new-environment-for-innovation-and-creativity.html>.

<sup>166</sup> QRCS (27 November 2018) *QRCS concludes WATSAN project for Syrian refugees in Lebanon*, available at: <https://reliefweb.int/sites/reliefweb.int/files/resources/QRCS%20concludes%20WATSAN%20project%20for%20Syrian%20refugees%20in%20Lebanon.pdf>.

<sup>167</sup> Huss E, Kaufman R, Avgar A *et al.* (2016) Arts as a vehicle for community building and post-disaster development *Disasters* 40(2): 284-303.



regain independence.<sup>168</sup> At the community level, this took the form of greater community cohesion and sense of shared purpose and pride (even, it was suggested in the case of Japan, “awaken[ing] a civil society that for decades has been seen as weak and non-participatory”<sup>169</sup>) alongside greater sustainability of communities as they were rebuilt.<sup>170</sup> Experience of being directly affected by a disaster in some cases translated into increased community involvement in future emergency preparedness, such as the development of youth-led radio stations in Thailand that could act as early warning stations;<sup>171</sup> and the launch of ‘Disaster risk reduction notes’ by mothers affected by Fukushima.<sup>172</sup> The “new sense of we-ness” described in the aftermath of Hurricane Katrina<sup>173</sup> was accompanied by an upsurge in volunteering, with examples of people prioritising community work in their evenings, or building a ‘week of service’ each year into their lives.<sup>174</sup> In places, the sustainability of existing civil society organisations was strengthened, with the experience gained enhancing their ability to initiate projects and advocate for funds independently.<sup>175</sup>

2.15 In contrast, however, where international organisations did not properly recognise the role of local civil society in mobilising the response, the capacity and potential of those local initiatives could be undermined.<sup>176</sup> After Hurricane Katrina, for example, it was suggested that “at times, engaged residents felt as if they were working against the city,”<sup>177</sup> and distrust was compounded by misunderstandings about the amount of federal funds available and associated disparities between community-led recovery plans and affordability.<sup>178</sup> Reviews of all four emergencies identified examples of frustration on the part of affected populations where failure by authorities or service-providers to engage meaningfully with them led to needs being overlooked and not well understood (an issue

<sup>168</sup> See, for example, McKinsey & Co (2015) *Improving disaster recovery: lessons learned in the United States*, available at: [https://www.mckinsey.com/~media/mckinsey/business%20functions/risk/our%20insights/improving%20disaster%20recovery/improving\\_disaster\\_recovery\\_280615\\_final.ashx](https://www.mckinsey.com/~media/mckinsey/business%20functions/risk/our%20insights/improving%20disaster%20recovery/improving_disaster_recovery_280615_final.ashx), at page 20; and Turkish Red Crescent Society (2018) *Community engagement and accountability (CEA) assessment report: Community Based Migration Programme*, available at: <https://media.ifrc.org/ifrc/wp-content/uploads/sites/5/2019/07/Community-Based-Migration-Programme-Turkish-Red-Crescent-Society-CEA-Assessment-Report.pdf>, at page 28.

<sup>169</sup> Aldrich DP (2012) *Post-crisis Japanese nuclear policy: from top-down directives to bottom-up activism*, available at: <https://www.eastwestcenter.org/sites/default/files/private/api103.pdf>, at page 10.

<sup>170</sup> See, for example, Archer D, and Boonyabanha S (2011) Seeing a disaster as an opportunity – harnessing the energy of disaster survivors for change *Environment and Urbanization* **23(2)**: 351-64; Goulding C, Kelemen M, and Kiyomiya T (2018) Community based response to the Japanese tsunami: a bottom-up approach *European Journal of Operational Research* **268(3)**: 887-903; and Refugees International (2019) *An uncertain future: fragility and humanitarian priorities in northeast Syria*, available at: <https://reliefweb.int/sites/reliefweb.int/files/resources/Northeast%2BSyria%2BReport%2B-%2BJuly%2B2019%2B-%2Bfinal.pdf>, at page 6.

<sup>171</sup> UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicef emergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicef emergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf), at page 24.

<sup>172</sup> Japan Women’s Network for Disaster Risk Reduction and Japan Association for Women’s Education (2015) *Gender equality and disaster risk reduction: women as a force for change*, available at: [http://jwndrr.org/main/wp-content/uploads/2015/08/Report\\_qatar\\_final.pdf](http://jwndrr.org/main/wp-content/uploads/2015/08/Report_qatar_final.pdf), at page 24.

<sup>173</sup> Michna C (2013) Performance and cross-racial storytelling in post-Katrina New Orleans: interviews with John O’Neal, Carol Bebel, and Nicholas Slie *TDR/The Drama Review* **57(1)**: 48-69, at page 49.

<sup>174</sup> Bates S (2014) ‘Just another hurricane’: the lived experiences of everyday life in Plaquemines Parish, Louisiana in the aftermath of Hurricane Katrina and the BP oil spill *University of Glasgow*. PhD thesis, at page 219.

<sup>175</sup> Tsunami Evaluation Coalition (2006) *Impact of the tsunami response on local and national capacities*, available at: [https://www.sida.se/contentassets/a4ff43a5202d468c9d3eb2a9dc547661/impact-of-the-tsunami-response-on-local-and-national-capacities\\_3142.pdf](https://www.sida.se/contentassets/a4ff43a5202d468c9d3eb2a9dc547661/impact-of-the-tsunami-response-on-local-and-national-capacities_3142.pdf); and Tsunami Global Lessons Learned Project Steering Committee (2009) *The tsunami legacy: innovation, breakthroughs and change*, available at: <https://www.alnap.org/system/files/content/resource/files/main/aprc-cpr-2009-tsunami-legacyreport.pdf>, at page 55.

<sup>176</sup> Tsunami Evaluation Coalition (2006) *Impact of the tsunami response on local and national capacities*, available at: [https://www.sida.se/contentassets/a4ff43a5202d468c9d3eb2a9dc547661/impact-of-the-tsunami-response-on-local-and-national-capacities\\_3142.pdf](https://www.sida.se/contentassets/a4ff43a5202d468c9d3eb2a9dc547661/impact-of-the-tsunami-response-on-local-and-national-capacities_3142.pdf), pp31-2.

<sup>177</sup> Nelson M, Ehrenfeucht R, and Laska S (2007) Planning, plans, and people: professional expertise, local knowledge, and governmental action in post-hurricane Katrina New Orleans *Cityscape* **9(3)**: 23-52, at page 41.

<sup>178</sup> McKinsey & Co (2015) *Improving disaster recovery: lessons learned in the United States*, available at: [https://www.mckinsey.com/~media/mckinsey/business%20functions/risk/our%20insights/improving%20disaster%20recovery/improving\\_disaster\\_recovery\\_280615\\_final.ashx](https://www.mckinsey.com/~media/mckinsey/business%20functions/risk/our%20insights/improving%20disaster%20recovery/improving_disaster_recovery_280615_final.ashx), at page 19.

to which we return in Chapter 5).<sup>179</sup> The particular challenges of engaging communities in emergency response in a conflict zone were highlighted in the review of the Syrian conflict, with public gatherings limited by security concerns<sup>180</sup> and by restrictive laws controlling the existence of associations and private societies.<sup>181</sup> Practical logistical challenges also arise in working with people with scattered living patterns and little community structure,<sup>182</sup> or in the absence of reliable power supplies or mobile phone networks.<sup>183</sup>

- 2.16 Finally, there was a mixed picture across the reviews for the ways that both community-initiated action, and non-governmental organisation (NGO) engagement of communities in response, reflected the experiences and concerns of all parts of the community. Many evaluations of the response to the 2004 tsunami, for example, highlighted the way in which children's and women's rights and standing in their own communities were enhanced as a result of taking an active role in emergency response and reconstruction (see Box 2.3). World Vision, for example, highlighted how women took extremely active roles, despite the initial reservations of local community leaders and concern among international NGO workers that it was not their place to try to change practices and beliefs within the local culture.<sup>184</sup>
- 2.17 In Japan and in communities affected by the Syrian conflict, however, the picture was more mixed. While the women involved in creating 'disaster risk reduction notes' in Japan (see paragraph 2.14) were described as going on speaking tours to introduce their booklet to other mothers and developing into "full-fledged women leaders",<sup>185</sup> another study from Japan comments how women were treated only as victims, with their role "assumed to be housework and childminding only".<sup>186</sup> Similarly, in the review of the Syrian conflict, there were both examples of women and girls being very actively engaged,<sup>187</sup> while also reports that women felt excluded from appropriate service provision, including as a result of ignorance of cultural norms.<sup>188</sup> More generally, the way in which women are at increased risk of harm in emergencies – for example through sexual and gender-based violence and through disrupted access to basic healthcare for

<sup>179</sup> Oxfam (2008) *Deepening community engagement*, available at: <https://www.oxfamamerica.org/static/oa3/files/deepening-community-engagement.pdf>; Reich MR, and Goto A (2015) Towards long-term responses in Fukushima *The Lancet* **386(9992)**: 498-500; and Norwegian Refugee Council (2016) *A future in the balance*, available at: [http://wos-education.org/uploads/reports/Final\\_youth\\_research\\_doc\\_-\\_April2016.pdf](http://wos-education.org/uploads/reports/Final_youth_research_doc_-_April2016.pdf), at page 24.

<sup>180</sup> Swiss Peace Foundation (2017) *The experience of Local Administrative Councils in opposition-held Syria*, available at: [https://www.swisspeace.ch/fileadmin/user\\_upload/pdf/Mediation/WOTRO\\_Report\\_The\\_Experience\\_of\\_Local\\_Administrative\\_Councils\\_in\\_Oppositionheld\\_Syria.pdf](https://www.swisspeace.ch/fileadmin/user_upload/pdf/Mediation/WOTRO_Report_The_Experience_of_Local_Administrative_Councils_in_Oppositionheld_Syria.pdf), at page 17.

<sup>181</sup> OCHA and UNICEF (2016) *Reaching adolescents and youth inside Syria: 2016 HRP mapping report*, available at: [https://reliefweb.int/sites/reliefweb.int/files/resources/hrp\\_adol\\_youth\\_mapping\\_report\\_oct\\_20\\_ocha\\_v2.pdf](https://reliefweb.int/sites/reliefweb.int/files/resources/hrp_adol_youth_mapping_report_oct_20_ocha_v2.pdf), at page 11.

<sup>182</sup> Turkish Red Crescent Society (2018) *Community engagement and accountability (CEA) assessment report: Community Based Migration Programme*, available at: <https://media.ifrc.org/ifrc/wp-content/uploads/sites/5/2019/07/Community-Based-Migration-Programme-Turkish-Red-Crescent-Society-CEA-Assessment-Report.pdf>, at page 5

<sup>183</sup> Xu Y, Holzer A, Maitland C *et al.* (2017) Community building with co-located social media: a field experiment with Syrian refugees *Proceedings of the Ninth International Conference on Information and Communication Technologies and Development*. 1-11.

<sup>184</sup> The Brookings Institution (2008) *Moving beyond rhetoric: consultation and participation with populations displaced by conflict or natural disasters*, available at: <https://www.alnap.org/system/files/content/resource/files/main/10-internal-displacement.pdf>, at appendix A.

<sup>185</sup> Japan Women's Network for Disaster Risk Reduction and Japan Association for Women's Education (2015) *Gender equality and disaster risk reduction: women as a force for change*, available at: [http://jwndrr.org/main/wp-content/uploads/2015/08/Report\\_qatar\\_final.pdf](http://jwndrr.org/main/wp-content/uploads/2015/08/Report_qatar_final.pdf), at page 24.

<sup>186</sup> *ibid.*

<sup>187</sup> See, for example, the account of the young women in Syria challenging the role of militants in their city: Swiss Peace Foundation (2016) *Inside Syria: what local actors are doing for peace*, available at: <http://cdint.org/documents/Inside-Syria-What-Local-Actors-Are-Doing-for-Peace.pdf>, at page 9; and girls' access to suitable facilities to play football: USAID (5 July 2017) *As Jordan hosts Syrian refugees, youth find security in recreation*, available at: <https://www.usaid.gov/results-data/success-stories/refuge-recreation>.

<sup>188</sup> Oxfam (2014) *Refugee perceptions study: Za'atari Camp and host communities in Jordan*, available at: <http://www.cdacnetwork.org/contentAsset/raw-data/41ed4a54-388b-4605-8287-7614bdd5221c/attachedFile>; and USAID (2016) *USAID community engagement project: baseline assessment*, available at: <https://data2.unhcr.org/en/documents/download/43323>, at page 4.



pregnancy and childbirth – is well documented.<sup>189</sup> In infectious disease outbreaks, to which we turn below, women are also put at particular risk because they commonly take on much of the burden of family care.<sup>190</sup> Commentary after Hurricane Katrina, by contrast, focused less on questions of age or gender, but rather on the particular impact on marginalised ethnic minority communities (see also paragraph 2.10).

### Box 2.3: Examples of children’s and women’s empowerment after the 2004 tsunami

- “In the weeks following the tsunami, these women could barely speak in front of their husbands... But look at them now – they are sharing the same platform with their menfolk. And when they speak, the men listen.”<sup>191</sup> (Tamil Nadu)
- “Some enterprising young people set up small local businesses while others with second language skills took on roles of negotiating with outsiders on behalf of their community. These activities earned them respect from adults and thus gained them a place in community meetings. Where adults were also trained in children’s rights, young people were offered opportunities. In a tsunami-affected area of Thailand, for example, a teenage girl became the accountant for a community housing group.”<sup>192</sup>
- “Moken young people in Thailand have represented their community in discussions with outside agencies. When external developers wanted to take Moken-owned property after the tsunami, young people took on an important role in the struggle against their land grabbing. Older girls involved themselves in that struggle and gained a degree of empowerment from it that they had not experienced before.”<sup>193</sup>

## Community experience and response in infectious disease outbreaks

*“Seeing victims as leaders was so powerful.”*<sup>194</sup>

2.18 It was suggested to us that there are important differences between experiences of natural and human-made disasters where, as described above, communities might be expected to take the lead, demand information, and mobilise themselves, and infectious disease outbreaks, where the response tends to be both much more expert- and institution-led and more dominated by external actors.<sup>195</sup> Reasons suggested for these differences include the fact that international involvement in infectious disease response is generally associated with the inability of local health services to respond to a growing outbreak; concerns on the part of external actors as to the health threats posed to other countries; the way in which the (often unavoidable) use of separate health structures to

<sup>189</sup> See, for example, Criado Perez C (2019) *Invisible women: exposing data bias in a world designed for men* (London: Chatto & Windus).

<sup>190</sup> Harman S (2016) Ebola, gender and conspicuously invisible women in global health governance *Third World Quarterly* **37(3)**: 524-41.

<sup>191</sup> Tsunami Global Lessons Learned Project Steering Committee (2009) *The tsunami legacy: innovation, breakthroughs and change*, available at: <https://www.alnap.org/system/files/content/resource/files/main/aprc-cpr-2009-tsunamilegacyreport.pdf>, at page 49.

<sup>192</sup> UNICEF (2007) *The participation of children and young people in emergencies*, available at: [http://unicefemergencies.com/downloads/eresource/docs/Adolescents/the\\_participation\\_of\\_children\\_and\\_young\\_people\\_in\\_emergencies.pdf](http://unicefemergencies.com/downloads/eresource/docs/Adolescents/the_participation_of_children_and_young_people_in_emergencies.pdf), at page 16.

<sup>193</sup> *ibid.*, at box 29.

<sup>194</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>, at page 4.

<sup>195</sup> *ibid.*

respond to the highly infectious outbreak disease may add to the experience of disempowerment associated with the whole response ‘apparatus’; and very ‘top-down’ approaches to communities via local hierarchies.<sup>196</sup> It was also suggested to us that this tendency towards a top-down approach to intervention by external experts was a consequence of past lack of appreciation of the extent to which social factors, in the form of local cultural norms, values, and practice (including, for example, compassionate care for the sick and ceremonial burial of the dead), was directly relevant to patterns of disease transmission.<sup>197</sup> The central importance of working with local communities, and researchers with local knowledge, in order to achieve successful breakthroughs in both response and research efforts, has thus historically been underestimated.

- 2.19 Despite this general picture, contributions by leaders of Ebola survivors’ movements in Sierra Leone and Liberia to the workshop on community engagement held in Dakar clearly demonstrated the important role played by community leadership and initiative, even in the face of a highly infectious disease where patients are routinely cared for in full protective clothing (see Boxes 2.4 and 2.5 below and Box 5.6 in Chapter 5). Survivors of Ebola are particularly well-placed to be engaged in the response effort: because of their acquired immunity, they are the only people who can have direct physical contact with those currently infected with the virus without the need for protective clothing.<sup>198</sup> These individuals’ very survival showed that it was possible to emerge from the Ebola treatment units (ETUs) alive, at a time when death was assumed from the point when the ambulance arrived to take a sick person away (see Box 2.5). Survivors of the West African Ebola outbreak in 2014–16 subsequently self-organised into active survivors’ movements in Sierra Leone, Liberia, and Guinea, and continue to work in an advocacy role. A similar pattern is emerging in the Democratic Republic of the Congo (DRC).<sup>199</sup>

#### Box 2.4: Patient- and survivor-led action in Sierra Leone<sup>200</sup>

- Organising improvised theatre and talent competitions in ETUs to help maintain hope among patients (described as “these talented friends”).
- Coaxing fellow patients in ETUs to eat, to maximise chance of recovery.
- Once recovered, volunteering as staff members in ETUs and acting as community mobilisers.
- Acting as advocates for the needs of other survivors, including capturing and documenting the impacts of Ebola, such as joint pain, concern about miscarriages, and the need for eye care. Such advocacy contributes to the ongoing research agenda: for example concerns about high miscarriage rates led to this factor being investigated and the causes (anxiety about accessing health services rather than physical consequences of Ebola) to be recognised and addressed.<sup>201</sup>

<sup>196</sup> *ibid.*; On-the-ground roundtable, 25 June 2018; and Roundtable with funders, 8 March 2019.

<sup>197</sup> Comments submitted by external reviewers.

<sup>198</sup> See, for example, National Geographic (23 May 2019) *Life amid an Ebola outbreak: combating mistrust - and saving lives*, available at: <https://www.nationalgeographic.com/culture/2019/05/ebola-democratic-republic-congo/>.

<sup>199</sup> UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo’s 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf), at page 43; and WHO Regional Office for Africa (2019) *Local leaders help turn the tide on Ebola*, available at: <https://afro.who.int/news/local-leaders-help-turn-tide-ebola>.

<sup>200</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>201</sup> See also: James PB, Wardle J, Steel A *et al.* (2019) Pattern of health care utilization and traditional and complementary medicine use among Ebola survivors in Sierra Leone *PLoS One* **14(9)**: e0223068.

- Working alongside other peer-led initiatives (for example supporting groups of people living with HIV in developing techniques for maintaining self-esteem) after the outbreak ended.

### Box 2.5: Yusuf's story

*A personal account provided to the working group by Yusuf Kabba, President, Sierra Leone Association of Ebola Survivors*

"7 November 2015 was the day that most of the world breathed a sigh of relief as the Ebola outbreak in Sierra Leone was officially declared over. But for those of us that survived Ebola, this was no sign of relief, it was yet another reminder of how easily we were forgotten once the virus ran its course. We had our belongings burned, for fear they would be infectious. We lost our loved ones, either to the virus or to the stigma our families forced upon us, blaming us for the tragedy. For us, the end of the Ebola outbreak was far from the end of the battle.

As we, the Ebola survivors of Sierra Leone, look to Democratic Republic of Congo we cannot help but imagine what every one of those people in the Ebola treatment units are thinking – that they have entered something just short of hell. We know because we too sat in those sweltering, crowded treatment centres and waited for our death sentence.

Yusuf Kabba is the President of the Sierra Leone Association of Ebola Survivors (SLAES). He became infected with the Ebola virus on 6 October 2014, as the outbreak began to reach its peak. As he watched five family members in his home die of the virus, he knew that the fever and chills he was feeling was more than just a flu. On 10 October, an ambulance was called to his home to pick him up and take him to the holding centre, where anyone suspected of Ebola was being held. The doors of the red and white ambulance opened up and he stepped in, knowing he would be stepping into his death like so many people before him who entered the ambulance, never to return.

Yusuf was taken four miles from his home to tents haphazardly held up, he was driven past gunmen with automatic weapons, and was greeted by someone covered from head to toe in gloves, boots, goggles, and a face mask. They never once made eye contact with him. In fact, not a single person did except the other patients he laid across from, most of whom did not survive. Yusuf watched as the health workers walked past them as they cried out for water and as patients wept in both pain and horror as they waited to hear if they were positive for the Ebola virus. Yusuf was but a young schoolteacher at the time, but knew that more than anything the Ebola treatment needed hope. Yusuf began bringing water to the other patients, began a prayer group, and eventually put on theatre plays.

Unlike so many of those around him who met their fate in the scorching walls of those Ebola treatment units, Yusuf survived. He survived Ebola, walked out of the treatment centre declared Ebola-free in what should be the most triumphant day of his life, but was told he couldn't return home because his village feared him. No employer would hire him. So he walked right back into the Ebola treatment unit, the very place he had faced his own mortality, and he began volunteering. Eventually, he organised Ebola survivors into support groups and began what would later become the Sierra Leone Association of Ebola Survivors.

Yusuf's story is no different than most of our stories – like all survivors, being infected with Ebola was excruciatingly painful, terrifying, and one of the most harrowing experiences of our life. And like Yusuf, every survivor returned to the community only to

be rejected, to be blamed for the outbreak, to face complex medical complications like blindness.

But not all survivors have to face that. The outbreak in the Democratic Republic of the Congo presents the world with the opportunity to fight outbreaks in ways that respect the dignity of the people who are suffering the most. We learned a tremendous amount about the science of Ebola in West Africa's outbreak – the Ebola vaccine being the most prominent example – but we call on the world to also draw lessons from the human experience of the Ebola outbreak.

As we look to DR Congo, we must remember that those suspected with Ebola are also people, not simply specimens, and they must be treated as such in their communities and in the treatment centres. We urge the world to remember the impact of the virus does not end when someone walks out of the Ebola treatment unit. In fact, that is when much of the impact begins and resources must be allocated to support survivors' reintegration in a comprehensive and systematic way that addresses the psychosocial and economic elements that lead to their social exclusion.

So before the world celebrates how much better of a response it is this time around, we encourage you to ask the survivors, the ones that waited for their death sentence in the haphazard tents, and see if they would agree. That will be the true test to how well the lessons of the 2014 Ebola outbreak have been learned.”

2.20 In the ninth and tenth outbreaks of Ebola in the DRC which followed the West African outbreak, the respective roles of international responders and local health systems / communities in combating infectious disease outbreaks have continued to be debated vigorously. A UNICEF review of the (successfully contained) ninth outbreak in 2018 in Equateur province called for a 'grassroots model for epidemic response', involving:

- A 'whole society' approach, attending not only to those individuals directly affected by the outbreak but also to their broader communities;
- A commitment to inclusivity that appreciates that 'communities' are not homogenous, and prioritises the engagement of marginalised and vulnerable populations;
- Attending to local perspectives, helping responders appreciate why Ebola epidemics are understood through alternative lenses and broader issues, such as politics, economics, and religion; and
- Utilising pre-existing epidemic response capacity, ensuring that interventions build on the social and cultural resources of the communities they seek to support.<sup>202</sup>

2.21 This emphasis on using existing response capacity and building on local social and cultural resources has been reiterated and reinforced as a result of the difficulties experienced in responding in the tenth outbreak in the DRC.<sup>203</sup> This outbreak (ongoing at the time of writing) emerged in a conflict zone, where the challenges of political instability and violence have been compounded by widespread distrust in the work of disease responders.<sup>204</sup> Representatives of leading response organisations in the field,

<sup>202</sup> UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo's 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf), at page 7.

<sup>203</sup> WHO (2019) *Ebola in the Democratic Republic of the Congo: health emergency update*, available at: <https://www.who.int/emergencies/diseases/ebola/drc-2019>. See also: WHO (2019) *Social science research projects for the Ebola response in the DRC and neighbouring countries*, available at: <https://www.who.int/risk-communication/social-science-research-for-ebola/en/>.

<sup>204</sup> The Ebola Global Research Group (2019) Responding to the Ebola virus disease outbreak in DR Congo: when will we learn from Sierra Leone? *The Lancet* **393**(10191): 2647-50. See also: Vinck P, Pham PN, Bindu KK *et al.* (2019) Institutional trust and misinformation in the response to the 2018–19 Ebola outbreak in North Kivu, DR Congo: a population-based survey *The Lancet Infectious Diseases* **19**(5): 529-36.

including Médecins Sans Frontières (MSF), The Alliance for International Medical Action (ALIMA), and the International Rescue Committee (IRC) have made public statements calling for a 'reset' of the approach to enable closer working with communities and to build trust.<sup>205</sup> These calls have been accompanied by robust arguments from some leading researchers to "let locals lead",<sup>206</sup> and for an increasing emphasis on providing the tools to enable local health services to respond to the outbreak<sup>207</sup> (see also Box 2.6). A World Health Organization (WHO) spokesperson was quoted as commenting that "in areas of the DRC where response efforts have successfully meshed with existing community structures and expectations, 'we have seen outbreaks end'".<sup>208</sup> At the same time, the UNICEF review of the 2018 outbreak in Equateur province highlighted the important role of 'non-local' workers in helping protect confidentiality with respect to potentially stigmatising conditions.<sup>209</sup>

**Box 2.6: Challenges to the response to the tenth Ebola outbreak in the DRC: recommendations of the Ebola Gballo Research Group<sup>210</sup>**

"Recognising differences between settings, we believe, nevertheless, that it is urgent that the lessons from Sierra Leone help international responders to rethink their response to the worsening outbreak in north-eastern DR Congo. These lessons are:

- 1 to work closely with the different forms of local authority, including recognising heterogeneity and different capacities among those authorities, with a commitment to allowing local authorities to shape the response;
- 2 to allow local front-line health workers to advise international responders on the best means to reach, and encourage cooperation from, affected communities;
- 3 to disperse resources and basic life-saving equipment (including gloves, boots, and chlorine) to communities, particularly in remote locations beyond formal health systems (front-line health workers and distant community leaders should also be provided with communication tools to expand the surveillance area beyond those reached by formal health systems); and
- 4 to recognise that in the highly politicised context of the Ebola virus disease outbreak in DR Congo, securitisation of response is problematic and will require reflection. If international agencies are to provide effective support to local responders, then serious efforts need to be given to peace negotiations and brokering a ceasefire or securing safe corridors for aid delivery. But even if an improvement in security conditions does not

<sup>205</sup> ALIMA (10 May 2019) *Interview d'Augustin Augier sur RFI avec Christophe Boisbouvier sur la situations d'Ebola en RDC*, available at: <https://www.alima-ngo.org/fr/interview-d-augustin-augier-sur-rfi-avec-christophe-boisbouvier-sur-la-situation-d-ebola-en-rdc>; NPR (10 May 2019) *Threats by text, a mob outside the door: what health workers face in the Ebola zone*, available at: <https://www.npr.org/sections/goatsandsoda/2019/05/10/721020887/threats-by-text-a-mob-outside-the-door-what-health-workers-face-in-the-ebola-zone?t=1574684433852>; and The Guardian (15 May 2019) *'Terrifying' Ebola epidemic out of control in DRC, say experts*, available at: <https://www.theguardian.com/world/2019/may/15/terrifying-ebola-epidemic-out-of-control-in-drc-say-experts>.

<sup>206</sup> The Guardian (18 July 2019) *More of the same won't solve Congo's Ebola crisis - let locals lead*, available at: <https://www.theguardian.com/global-development/2019/jul/18/congo-ebola-crisis-let-locals-lead-world-health-organization-public-health-emergency>.

<sup>207</sup> National Geographic (18 July 2019) *The world's second-biggest Ebola outbreak is still raging. Here's why.*, available at: <https://www.nationalgeographic.co.uk/science-and-technology/2019/07/worlds-second-biggest-ebola-outbreak-still-raging-heres-why>.

<sup>208</sup> *ibid.*

<sup>209</sup> UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo's 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf), at page 42.

<sup>210</sup> The Ebola Gballo Research Group (2019) *Responding to the Ebola virus disease outbreak in DR Congo: when will we learn from Sierra Leone? The Lancet* **393(10191)**: 2647-50.



happen, the situation could be transformed if international agencies, including WHO, let go of their control and trust community responders to take the lead.

While acknowledging the enormous courage, commitment, and hard work shown by responders to date, we share these reflections in the hope that new ways can urgently be found to support communities to tackle the devastating outbreak in north-eastern DR Congo.”

*The Ebola Global Research Group is a partnership between the London School of Hygiene and Tropical Medicine, UK, and Njala University, Sierra Leone*

- 2.22 The overview in this chapter of the ways in which communities are, and wish to be, involved in actively responding to the emergencies affecting their lives is inevitably illustrative and incomplete. However, it provides convincing support for the arguments put to us (both in Dakar and in roundtable meetings held as part of our evidence-gathering) that **exploration of what constitutes ethical research has to start from an understanding of people’s experiences, rather than with abstract principles or from assumptions that expertise is found primarily in external agencies**. In drawing on this material, our purpose is to embed our approach in lived experience, and to stress the importance of local agency. We return to these themes in Chapter 4 (see in particular paragraphs 4.34–4.35) .

## Experiences of research during global health emergencies

### Participant experiences

*“Dear sir, this may be your project, but this is my life.”<sup>211</sup>*

*“You will leave when Ebola does,” I have heard, “but we will still be here, slowly dying from the diseases that have always killed us.”<sup>212</sup>*

*[Researchers collecting data on gender-based violence] “often cited study participants who expressed gratitude that people were taking an interest in their suffering”.<sup>213</sup>*

- 2.23 Several research studies have explored the experiences of those participating in various forms of research during the 2014–16 West African Ebola outbreak, including people involved in clinical trials using plasma, clinical trials of drugs and vaccines, and observational studies. A study following up the experiences of 70 participants from Sierra Leone, Guinea, and Liberia, for example, highlighted how the main motivation for their participation in interventional studies was that of wanting to survive and regain their health, with access to free healthcare or services such as screening particularly

<sup>211</sup> Cited by a contributor to: On-the-ground roundtable, 25 June 2018 (see Appendix 1). See also: Al Jazeera (24 February 2018) *Humanitarian aid system is a continuation of the colonial project*, available at: <https://www.aljazeera.com/indepth/opinion/humanitarian-aid-system-continuation-colonial-project-180224092528042.html>.

<sup>212</sup> Nguyen V-K (2019) An epidemic of suspicion — Ebola and violence in the DRC *New England Journal of Medicine* **380**: 1298-9. Similarly: “The view was – you’re only here for Ebola, and when that is over you’ll go and we will have all the same problems as before”: The Guardian (25 June 2019) *‘Most complex health crisis in history’: Congo struggles to contain Ebola*, available at: <https://www.theguardian.com/global-development/2019/jun/25/most-complex-health-crisis-congo-struggles-ebola-drc>. See also: NPR (10 September 2019) *In Congo, Ebola is just one more thing to worry about*, available at: <https://www.npr.org/sections/goatsandsoda/2019/09/10/759343232/in-congo-ebola-is-just-one-more-thing-to-worry-about?t=1570116847487>.

<sup>213</sup> Personal communication, Stefan Jansen PhD, Ag. Deputy Director, Center for Medical Health; Research Coordinator, Directorate of Research and Innovation, College of Medicine and Health Sciences, University of Rwanda (26 November 2019). See also: Box 10.3 in Chapter 10.



valued.<sup>214</sup> Such decisions have been described in other contexts as “empty choices”, where the lack of alternative options open to potential participants means that, however well-informed a person’s decision to take part, refusal will in practice not be an option.<sup>215</sup>

- 2.24 However, people also spoke of a strong desire to help others, particularly in the context of those survivors who took part in plasma studies, expressed in terms of feeling a deep solidarity with those who were still ill with Ebola in Ebola treatment centres (ETCs – see Box 2.7). Some also spoke of wanting to help find a cure or of leading by example so that others might benefit, for example where they had been vaccinated and believed that this had helped protect them. A third motivation cited was that of trust in God or destiny: they had faith that this was the right thing for them to do.
- 2.25 The issue of trust emerged as a particular theme around participants’ decisions and experiences: trust in the healthcare system underpinned decisions to agree to take part, while existing distrust meant that concerns expressed by family or neighbours might be more influential. Trust in survivors’ associations meant that participants were more likely to take part in studies endorsed by association representatives; and personal or community ties between research workers and prospective participants were also influential (see Box 2.7). The way in which personal relationships between researchers and prospective participants can influence decisions about participation has also been highlighted in other research in diverse settings, including in HIV studies in London and ethnographic fieldwork in Tanzania and Uganda,<sup>216</sup> and is discussed later in the context of consent practice (see paragraph 7.23).
- 2.26 Participants also identified some very positive aspects of being involved in research in these difficult circumstances. These included the respect with which they were treated by researchers, the psychosocial care that they received, and the greater understanding that some obtained with respect to their present and future health. Some participants were subsequently hired as research assistants, which gave them the opportunity to improve their knowledge of research and, in some cases, offered possible future career benefits (see also paragraph 2.27, which describes an example of where this was not an option).<sup>217</sup>

### Box 2.7: Taking part in research: explanations from participants

“... since I am an Ebola survivor, I know what was going on in the ETC, I could not just stay there like that, standing idly by with my arms crossed, refusing to give life to other people who were still suffering.”

<sup>214</sup> Humanitarian Health Ethics (2018) *Participants’ perceptions of Ebola research: report to participants*, available at: [https://humethnet.files.wordpress.com/2018/06/hherg\\_perceptions\\_ebola\\_research\\_participants\\_report\\_draft.pdf](https://humethnet.files.wordpress.com/2018/06/hherg_perceptions_ebola_research_participants_report_draft.pdf).

<sup>215</sup> Kingori P (2015) The ‘empty choice’: a sociological examination of choosing medical research participation in resource-limited Sub-Saharan Africa *Current Sociology* **63(5)**: 763-78. See also: Tindana P, Bull S, Amenga-Etego L *et al.* (2012) Seeking consent to genetic and genomic research in a rural Ghanaian setting: a qualitative study of the MalariaGEN experience *BMC Medical Ethics* **13(1)**: 15; and Mfutso-Bengo J, Manda-Taylor L, and Masiye F (2014) Motivational factors for participation in biomedical research: evidence from a qualitative study of biomedical research participation in Blantyre District, Malawi *Journal of Empirical Research on Human Research Ethics* **10(1)**: 59-64.

<sup>216</sup> Parker M, and Allen T (2013) Questioning ethics in global health *Ethics in the Field: Contemporary Challenges* **7**: 24-41.

<sup>217</sup> Humanitarian Health Ethics (2018) *Participants’ perceptions of Ebola research: report to participants*, available at: [https://humethnet.files.wordpress.com/2018/06/hherg\\_perceptions\\_ebola\\_research\\_participants\\_report\\_draft.pdf](https://humethnet.files.wordpress.com/2018/06/hherg_perceptions_ebola_research_participants_report_draft.pdf); ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>; and external reviewers’ comments.

“[The nurse said] ‘I am not here to harm you, I’m not here to kill you. I am your relative. I am your sister. So take it in.’ So I said OK, and I took it in.”<sup>218</sup>

- 2.27 Aspects of research involvement described by the 70 informants taking part in the follow-up study as unpleasant or unacceptable included reliving painful memories, stigmatisation, poor communication, lack of confidentiality and lack of follow-up, including not getting the compensation promised.<sup>219</sup> Many of these issues also emerged in a different follow-up study, undertaken with participants in a West African Ebola vaccine trial, which found that the dominant reasons for participating were hope for direct health benefit, and need for money, alongside the expectation that participation would lead to long-lasting improvement in their socioeconomic situation.<sup>220</sup> Problems described by informants centred on poor communication and unfulfilled expectations, alongside stigma. These expectations arose in the context of a history of reintegration projects after civil war that were designed to support future employment. In the study, systems designed to support recruitment and to reward participants, including workshops providing information (described as ‘studying’) and ‘graduation’ when they completed a study, generated false hope that participation could lead to longer-term employment in research (whether as ‘professional’ participants, or as research assistants). Others working in this field have echoed the need for researchers to be alert to how past experiences of the actions of NGOs, or of research, will affect present-day expectations and fears in a study, and can lead to substantial misunderstandings.<sup>221</sup>
- 2.28 The participant experiences described above draw heavily on studies associated with recent Ebola outbreaks. We recognise that this can only offer a very partial snapshot of research experiences, especially given the wide range of emergencies covered by this report. Similar themes, both positive and negative, do however emerge in a small sample of studies with participants traumatised by very different emergencies. Bosnian refugee families, for example, who had previously taken part in in-depth interviews about the question of repatriation after arriving in a new country, were later asked for feedback on their experience. While “painful to talk about all the bad memories” inevitably involved, informants appreciated the interest shown in them as individuals; felt relieved after sharing their stories; and wanted to help others with their information.<sup>222</sup> A similar follow-up study exploring the experiences of those participating in research after devastating bushfires in Australia concluded that participants perceived the benefits to outweigh the costs of taking part. Some, however, refused to take part in the follow-up, either because they had “moved on” and did not want to think about it anymore, or felt it would be “too distressing”.<sup>223</sup>
- 2.29 In addition to concerns about how alien research may seem during an emergency, the challenges of disentangling research and response emerged as a strong theme in our community engagement workshop in Dakar, as illustrated in Box 2.8. Workshop

<sup>218</sup> Humanitarian Health Ethics (HHE) research, presented by Nouvet E (26 March 2019) *Consent complexities, Ebola, and the fine line between collaboration and exploitation in research conducted during public health emergencies: presentation to PREA conference, Ohio State University*, available at: [https://kb.osu.edu/bitstream/handle/1811/87662/PREA\\_Nouvet\\_2019\\_presentation.pdf](https://kb.osu.edu/bitstream/handle/1811/87662/PREA_Nouvet_2019_presentation.pdf).

<sup>219</sup> Humanitarian Health Ethics (2018) *Participants’ perceptions of Ebola research: report to participants*, available at: [https://humethnet.files.wordpress.com/2018/06/hherg\\_perceptions\\_ebola\\_research\\_participants\\_report\\_draft.pdf](https://humethnet.files.wordpress.com/2018/06/hherg_perceptions_ebola_research_participants_report_draft.pdf).

<sup>220</sup> Alenichev A, and Nguyen V-K (2019) Precarity, clinical labour and graduation from Ebola clinical research in West Africa *Global Bioethics* **30**(1): 1-18.

<sup>221</sup> Pringle J (17 July 2017) *Lessons in research ethics: experiences of clinical research participation during the West Africa Ebola crisis* (Kebble College, Oxford: Oxford Global Health and Bioethics International Conference).

<sup>222</sup> Dyregrov K, Dyregrov A, and Raundalen M (2000) Refugee families’ experience of research participation *Journal of Traumatic Stress* **13**(3): 413-26.

<sup>223</sup> Gibbs L, Molyneaux R, Whiteley S *et al.* (2018) Distress and satisfaction with research participation: impact on retention in longitudinal disaster research *International Journal of Disaster Risk Reduction* **27**: 68-74, at page 70.

discussions illustrated the interdependence of the humanitarian health response to emergencies and research and suggested that it may not be realistic to expect people to trust in the good intentions of researchers if their basic needs are not being met.<sup>224</sup>

**Box 2.8: Experiences of being involved in research: examples of participants' perspectives cited in Dakar workshop<sup>225</sup>**

- Research can feel very intrusive: for example one experience in the ETU of researchers wanting to know “what we eat, how we sleep, how we are” when patients are very unwell.
- Researchers may be seen as being responsible for people’s suffering: why are they not concerned with patients’ / survivors’ well-being and support? Why are researchers only concerned with Ebola when there are so many other pressing needs?
- Research does not benefit participants now, so why participate? People have lost relatives and are grieving.
- Research brings back what happened to them: being in hospital for a research study may be like being back in the ETU.
- The perception that researchers should compensate people heavily before they participate: if this research is important, why shouldn’t they benefit?

2.30 Building on this theme, some workshop participants argued strongly that it is not enough for an emergency response effort to respond only to the specific disease at the heart of the outbreak: this may not be the only, or even main, concern of affected populations. In the middle of an Ebola outbreak, for example, people will still be suffering from other serious conditions, such as malaria, and may also be experiencing extreme poverty, lack of access to the basics of life, and exposure to violence.<sup>226</sup> An emergency response that focuses solely on the outbreak disease may reinforce the belief that external organisations are only interested in limiting harm to other (richer) countries (see Box 2.9).<sup>227</sup>

**Box 2.9: Example of the need to respond to more than the outbreak condition**

“The standard “isolate and test” model often leads to expectant management for such patients – the tendency is to “cover” patients with antimalarials and broad-spectrum antibiotics, wait for EVD [Ebola virus disease] test results, and then discharge patients without Ebola. We instead took a more active approach, treating severe cerebral malaria, typhoid, sepsis, and even cholera. I have witnessed how such active clinical management for all patients, along with MSF’s long-term presence in North Kivu, has contributed to the community’s acceptance of our Ebola unit. Having patients emerge

<sup>224</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>225</sup> *ibid.*

<sup>226</sup> Nguyen V-K (2019) An epidemic of suspicion — Ebola and violence in the DRC *New England Journal of Medicine* **380**: 1298-9. In July 2019, the number of deaths from measles in the DRC, for example, was higher than that from Ebola: The Guardian (12 July 2019) *Measles vaccination begins in Ebola-hit Congo amid fears of ‘massive loss of life’*, available at: <https://www.theguardian.com/global-development/2019/jul/12/measles-vaccination-begins-in-ebola-hit-congo-amid-fears-of-massive-loss-of-life>. See also: Al Jazeera (11 June 2019) *DR Congo declares measles epidemic as cases up 700 percent*, available at: <https://www.aljazeera.com/news/2019/06/dr-congo-declares-measles-epidemic-cases-700-percent-190611113925436.html>.

<sup>227</sup> Devex (21 May 2019) *The activists trying to ‘decolonize’ global health*, available at: <https://www.devex.com/news/the-activists-trying-to-decolonize-global-health-94904>.

from isolation in improved health is powerful evidence that we aim to make everyone better, not just to stop Ebola's spread."<sup>228</sup>

2.31 In emergencies, contributing to research may not be seen as a priority – and indeed focusing only on the outbreak condition may also reinforce beliefs that the disease has been imported precisely in order to test new treatments,<sup>229</sup> or that the response operations are simply a “money-making business for foreigners”.<sup>230</sup> The feasibility and acceptability of research may therefore depend on a sufficiently broad and effective response effort by national and external actors, involving a wide range of essential services, including primary health services. Clearly these are not services that researchers, and research institutions and funders, are well-placed to provide – but the feasibility of research may depend on other organisations doing so. Indeed, as we explore at the start of Chapter 3, the weakness of existing healthcare systems may play a significant role in how particular emergencies develop (see paragraph 3.1).<sup>231</sup>

## Researcher perspectives

2.32 Researchers responding to our call for evidence, and contributing to roundtable meetings, similarly highlighted the highly complex and often uncoordinated situation on the ground, and the associated challenges in creating the trusting and trustworthy relationships necessary for research to take place. The multiple lines of accountability and challenges of coordination inherent in the response effort inevitably have a direct effect on researchers' ability to work effectively (see further Chapter 8 with respect to cooperation and collaboration, and Chapter 10 for discussion of the personal experiences of front-line workers). Key challenges for researchers described to us at a roundtable exploring practical experiences on the ground in a variety of humanitarian contexts<sup>232</sup> included:

- **The diversity of actors involved, and the impact on forming working relationships** including, for example, workers with no knowledge of the area, or the local language, and no adjustment period on arrival; rapid turnover leading to the constant need to reform relationships; the co-option of non-health workers; and people working ‘remotely’, not only from other countries, but also from laboratories or hotels in-country with no contact with patients or participants.
- **Different motivations and responsibilities of external actors** whether in response or research, including direct responsibilities to the welfare of the people of the country; responsibility and accountability to sources of finance; diplomatic and political considerations including biosecurity; responsibilities to future people (gaining knowledge to benefit future populations); and individual motivations such as career enhancement, curiosity, and financial benefit.

<sup>228</sup> Nguyen V-K (2019) An epidemic of suspicion — Ebola and violence in the DRC *New England Journal of Medicine* **380**: 1298-9. See also: The Conversation (4 July 2019) *Context matters in fighting Ebola: lessons from West Africa for the DRC*, available at: <https://theconversation.com/context-matters-in-fighting-ebola-lessons-from-west-africa-for-the-drc-119242>.

<sup>229</sup> See, for example, The Conversation (4 July 2019) *Context matters in fighting Ebola: lessons from West Africa for the DRC*, available at: <https://theconversation.com/context-matters-in-fighting-ebola-lessons-from-west-africa-for-the-drc-119242>.

<sup>230</sup> The New Humanitarian (30 May 2019) *Aid community raises highest alert on Ebola*, available at: <https://www.thenewhumanitarian.org/news/2019/05/30/aid-community-raises-highest-alert-ebola-congo>.

<sup>231</sup> For discussion on the relationship between global preparedness and universal health coverage, see: Wenham C, Katz R, Birungi C *et al.* (2019) Global health security and universal health coverage: from a marriage of convenience to a strategic, effective partnership *BMJ Global Health* **4**(1): e001145. See also: Stat News (19 August 2019) *Containing the Ebola outbreak means addressing its root causes: a weak health system and insecurity*, available at: <https://www.statnews.com/2019/08/19/ebola-containment-address-root-causes/>.

<sup>232</sup> On-the-ground roundtable, 25 June 2018; Data and samples roundtable, 3 December 2018 (see Appendix 1).

- The **interactivity of research and response**: recognising how research depends on response infrastructure and is limited by the constraints of that infrastructure, such as laboratory capacity, the diversity of actors described above and so forth. The way in which research is perceived by affected populations may also affect perceptions of response, and vice-versa.
- **Tensions between knowledge generation and the focus on responding to the immediate emergency**: in addition to the sometimes blurred boundaries between response and research (see paragraphs 1.16–1.20), in practice situations will arise where researchers with relevant skills take on response roles on a temporary basis because of the level of need.





# Chapter 3

Emergency  
preparedness: key actors

## Chapter 3 – Emergency preparedness: key actors

### Chapter 3: overview

This chapter provides an overview of the major actors and institutions whose capacities and priorities with respect to emergency preparedness, response, and research have a powerful influence on the way in which research can be conducted during emergencies. Consideration of the structural and technical factors that affect how health threats become (or are prevented from becoming) global health emergencies is an important precursor for analysing the ethical concerns arising in associated research.

#### Influential actors and institutions

The way in which research can be conducted during emergencies is influenced by the capacities and priorities of many actors and institutions. These include:

- **national governments** in developing the resilience both of their healthcare systems (both in general, and in their ability to respond in emergencies) and of their health research systems;
- **intergovernmental organisations** – both in supporting national governments, and in coordinating emergency planning and emergency response and research at local, regional, and head office level;
- the **humanitarian sector** which, alongside national health systems, can play a central part in direct response to emergencies, in influencing what health research can take place, and increasingly in conducting research themselves;
- the **military (foreign and domestic)**, which can play a sometimes-controversial role both in direct clinical care and research, and in logistical and technical support;
- **private sector actors**, both in their role in funding emergency preparedness through partnerships with intergovernmental agencies and others, and through direct funding of research through the pharmaceutical and biotech sectors;
- **major non-commercial research funders** whose priorities, policies, and processes directly control much of the research that takes place in an emergency, and may either facilitate or limit the ethical options open to researchers seeking funding; and
- **regional and international research networks** focusing on emergency preparedness.

#### Role of technology and surveillance in supporting preparedness

Technological developments also play an essential part in providing the information necessary to inform the actions and decisions of the institutions listed above. These include monitoring and modelling techniques to inform emergency preparedness for both natural disasters and infectious disease outbreaks, and to help support effective response. These technologies complement the important role of local communities and health services in being alert to the early signs of emergencies, and initiating local action plans.

## Introduction

- 3.1 A dominant theme in the numerous international reports produced in the light of the 2014–16 West African Ebola outbreak has been that of the need for a greater focus on

'preparedness' for emergencies: of ensuring that lessons have been learned and appropriate systems put in place so that 'next time' the world would be better prepared for disaster.<sup>233</sup> Much has changed in the intervening time, particularly with respect to the role and functioning of the World Health Organization (WHO – see paragraphs 3.12–3.16), and we explore in this chapter the critical role of many of the key actors in emergency preparedness, starting with that of nation states. However, concerns have also been expressed that this focus on preventing and managing emergencies can mask (and potentially reinforce) the underlying neglect that often exacerbates the effects, or is even the root cause, of what then becomes a health emergency.<sup>234</sup> It is widely recognised that those who are most vulnerable, for example through poverty, lack of access to healthcare, and lack of political voice, are disproportionately affected by health emergencies.<sup>235</sup> Thinking of preparedness primarily in terms of 'global health security',<sup>236</sup> rather than more broadly in terms of ensuring basic health and research infrastructure is in place, risks further prioritising more powerful global and transborder interests over those of the most marginalised communities.<sup>237</sup>

3.2 A comprehensive *Health emergency and disaster risk management (HEDRM) framework*, published by WHO in 2019, responds to some of these concerns.<sup>238</sup> Building on the Sendai Declaration<sup>239</sup> and Framework for Disaster Risk Reduction endorsed by the United Nations (UN) General Assembly in 2015,<sup>240</sup> it takes an 'all hazards' approach to risk management and risk reduction and includes within its scope emergencies associated with infectious disease outbreaks, conflicts, and natural, technological and other hazards.<sup>241</sup> It also explicitly makes connections between better preparation for emergencies and broader sustainable development, including universal access to healthcare. In doing so, it draws together major areas of global health policy, including not only the Sendai Declaration, but also the International Health Regulations (IHR), the Sustainable Development Goals (SDGs), the pathway to Universal Health Coverage (UHC), and the Paris Agreement on Climate Change. Outlining an extensive course of action for national governments – from national strategy, legislation, and planning

<sup>233</sup> See, for example, Moon S, Leigh J, Woskie L *et al.* (2017) Post-Ebola reforms: ample analysis, inadequate action *BMJ* **356**; and Leigh J, Fitzgerald G, Garcia E *et al.* (2018) Global epidemics: how well can we cope? *BMJ* **362**.

<sup>234</sup> Nunes J (2016) Ebola and the production of neglect in global health *Third World Quarterly* **37(3)**: 542-56. Nunes notes that neglect may arise at both national and global level, whether because issues are overlooked, noticed but not considered important, or considered important but not effectively addressed – with the result that the needs of some are systematically ignored in global or national health policy. See also: Stat News (19 August 2019) *Containing the Ebola outbreak means addressing its root causes: a weak health system and insecurity*, available at: <https://www.statnews.com/2019/08/19/ebola-containment-address-root-causes/>; and The Conversation (30 October 2019) *Decades neglecting an ancient disease has triggered a health emergency around the world*, available at: <http://theconversation.com/decades-neglecting-an-ancient-disease-has-triggered-a-health-emergency-around-the-world-121282>.

<sup>235</sup> Global Preparedness Monitoring Board (2019) *A world at risk: annual report on global preparedness for health emergencies*, available at: [https://apps.who.int/gpmb/assets/annual\\_report/GPMB\\_annualreport\\_2019.pdf](https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf). See also: Chan EYY (2017) *Building bottom-up health and disaster risk reduction programmes* (Oxford: Oxford University Press), at page 51.

<sup>236</sup> Defined as "concerned with preventing, detecting and responding to infectious disease threats of international concern to limit any socioeconomic impact of transborder disease": Wenham C, Katz R, Birungi C *et al.* (2019) Global health security and universal health coverage: from a marriage of convenience to a strategic, effective partnership *BMJ Global Health* **4(1)**: e001145, mirroring WHO definitions.

<sup>237</sup> Nunes points to the history of Ebola (recognised since 1976) to illustrate how the needs of some populations or communities are systematically ignored in global or national health policy. He argues further that such neglect "does not just happen; it is made to happen", as a result of a moral landscape where some issues are deemed not to matter: Nunes J (2016) Ebola and the production of neglect in global health *Third World Quarterly* **37(3)**: 542-56, at page 546.

<sup>238</sup> WHO (2019) *Health emergency and disaster risk management framework*, available at: <https://www.who.int/hac/techguidance/preparedness/health-emergency-and-disaster-risk-management-framework-eng.pdf?ua=1>.

<sup>239</sup> UNISDR (2015) *Sendai Declaration*, available at: [https://www.unisdr.org/files/43300\\_sendaideclaration.pdf](https://www.unisdr.org/files/43300_sendaideclaration.pdf).

<sup>240</sup> UNISDR (2015) *Sendai framework for disaster risk reduction 2015-2030*, available at: [http://www.unisdr.org/files/43291\\_sendaiframeworkfordrren.pdf](http://www.unisdr.org/files/43291_sendaiframeworkfordrren.pdf).

<sup>241</sup> WHO (2019) *Health emergency and disaster risk management framework*, available at: <https://www.who.int/hac/techguidance/preparedness/health-emergency-and-disaster-risk-management-framework-eng.pdf?ua=1>.

processes, to risk communication on the ground – the framework highlights the importance of promoting and protecting health through resilient health systems, through effective working across sectors and ministries, and planning ‘with’ (not ‘for’) communities to ensure that “no-one is left behind”.<sup>242</sup>

- 3.3 The focus of our report is on the ethical conduct of *research* in responding to emergencies. Broader policy with respect to emergency preparedness and response is, nonetheless, a crucial part of the jigsaw of factors that affect ethical research conduct. As those contributing evidence throughout the project repeatedly told us (see, for example, paragraphs 2.32 and 8.12–8.13), research and response are inevitably interdependent. Effective and sustainable health-related research relies on functioning health infrastructure; and the ethical challenges of conducting research in these particularly difficult contexts are rooted in concerns about equity and exploitation. Many emergencies are predictable to a degree, and recent reports have indicated how every country in the world could be better prepared.<sup>243</sup> Consideration of the structural and technical factors that affect how health threats become (or are prevented from becoming) global health emergencies is an important precursor for analysing the ethical concerns arising in associated research. It also helps to identify where responsibilities for action, particularly preventative action, may lie (see paragraphs 4.62–4.71).
- 3.4 With these provisos in mind, this chapter provides an overview of the major actors and institutions whose capacities and priorities with respect to emergency preparedness have a powerful influence on the way in which research can be conducted during emergencies. It concludes with a brief account of the research-driven technological developments that both underpin much emergency preparedness, and that can (through research and innovation ‘in peacetime’) make a significant contribution to the research landscape during emergencies.

## Role of influential actors

### National governments: health systems and research systems strengthening

- 3.5 The core role of nation states in strengthening their health systems so that they are better prepared to identify and manage infectious disease threats is clearly set out in the 2005 IHR.<sup>244</sup> As signatories to the IHR, 196 states have committed to developing their national health surveillance and response capacity to meet specified criteria, with technical support available on request from the WHO, including through a system of joint external evaluations.<sup>245</sup> More broadly, all UN member states have committed to try to achieve

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<sup>242</sup> *ibid.*, at page 5. See also: Wenham C, Katz R, Birungi C *et al.* (2019) Global health security and universal health coverage: from a marriage of convenience to a strategic, effective partnership *BMJ Global Health* **4**(1): e001145 for a critique of the argument that global health security and universal health coverage “are frequently regarded as two sides of the same coin”. Wenham *et al.* identify tensions between these goals, but also points of convergence, including the shared emphasis on health systems strengthening. Nevertheless, they point out how – even within health systems strengthening – in the context of tight budgets, UHC might prioritise direct clinical care, while global health security would prioritise surveillance.

<sup>243</sup> Security (28 October 2019) *Global Health Security Index finds gaps in preparedness for epidemics and pandemics*, available at: <https://www.securitymagazine.com/articles/91168-global-health-security-index-finds-gaps-in-preparedness-for-epidemics-and-pandemics>; and Global Preparedness Monitoring Board (2019) *A world at risk: annual report on global preparedness for health emergencies*, available at: [https://apps.who.int/gpmb/assets/annual\\_report/GPMB\\_annualreport\\_2019.pdf](https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf).

<sup>244</sup> WHO (2016) *International Health Regulations: third edition*, available at: <http://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf>.

<sup>245</sup> WHO (2005) *Joint external evaluations*, available at: <https://www.who.int/ihr/procedures/joint-external-evaluations/en/>.

UHC by 2030 as part of the SDGs, with a particular focus on quality primary care and strengthening the health systems required to deliver it.<sup>246</sup>

- 3.6 Adequate funding support for such programmes (both from each country's own budget and through external support) is clearly critical, and the Director-General of the WHO has been quoted as expressing frustration that donor funding tends to be crisis-led rather than long-term: "The problem is that [donors] refrain from paying until there is fear and panic. That has to change. We should not be funding by huge amounts when we panic, but should be funding to avoid panic."<sup>247</sup>
- 3.7 This frustration with a cycle of panic and neglect is also reflected in academic commentary, where some argue for enhanced accountability mechanisms when states fail to meet their obligations and commitments.<sup>248</sup> Since 2016, however, it has been noted that the pace of completion of joint external evaluations has been considerably increased, and that while many countries are yet to develop the action plans needed to close the gaps identified, African countries in particular have made substantial progress in preparedness.<sup>249</sup> The valuable role of regional or continental organisations such as the African Union (AU) and the Africa Centres for Disease Control and Prevention (Africa CDC) in supporting such preparedness is illustrated in Box 3.1.

### Box 3.1: WHO working with African Union on global health

A memorandum of understanding signed in November 2019 provided for closer working between the WHO and the AU on global health, including through:<sup>250</sup>

- providing technical expertise to the African Medicines Agency and creating an environment to foster local production of medicines;
- strengthening collaboration between WHO and the Africa CDC, with a focus on emergency preparedness to build defences against epidemics and other health emergencies; and
- supporting the implementation of the Addis Ababa Call to Action on UHC and the AU Declaration on Domestic Financing.

- 3.8 The connection between this focus on health system strengthening and the role of national health research systems was strongly emphasised to the working group at a roundtable meeting in December 2018.<sup>251</sup> Attendees argued that research cannot be conducted effectively and sustainably without resilient healthcare systems, nor can

<sup>246</sup> WHO (2019) *Universal Health Coverage (UHC)*, available at: [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)). Similar commitments may be made by states under the right to the highest attainable standard of physical or mental health protected by the ICESCR (see paragraph 1.34), and regional human rights agreements.

<sup>247</sup> The Guardian (9 July 2019) *Conflict and insecurity driving spread of diseases like Ebola, WHO chief warns*, available at: <https://www.theguardian.com/global-development/2019/jul/09/ebola-outbreak-global-wake-up-call-says-who-head-tedros-adhanom-ghebreyesus-congo>.

<sup>248</sup> Nature (12 November 2019) *World view: pandemic policy can learn from arms control*, available at: <https://www.nature.com/articles/d41586-019-03452-0>.

<sup>249</sup> Jonas O, Katz R, Yansen S *et al.* (2018) Call for independent monitoring of disease outbreak preparedness *BMJ* **361**. For an account of this process in one country, Nigeria, see: Medium (26 November 2019) *While we were sleeping: is Nigeria prepared for the next big global epidemic?*, available at: <https://medium.com/@nigeriahealthwatch/while-we-were-sleeping-is-nigeria-prepared-for-the-next-big-global-epidemic-70bf912a2c2>.

<sup>250</sup> The memorandum of understanding was signed by the WHO Director-General Tedros Adhanom Ghebreyesus and African Union Chair Moussa Faki Mahamat. See: UN News (18 November 2019) *UN, African Union make significant joint commitment to global health*, available at: <https://news.un.org/en/story/2019/11/1051571>. See also: African Risk Capacity (28 August 2019) *African Risk Capacity and Africa CDC sign partnership agreement to strengthen disease outbreak preparedness*, available at: [https://reliefweb.int/sites/reliefweb.int/files/resources/Draft\\_PR\\_ARC\\_Africa\\_CDC\\_FINAL.pdf](https://reliefweb.int/sites/reliefweb.int/files/resources/Draft_PR_ARC_Africa_CDC_FINAL.pdf).

<sup>251</sup> Data and samples roundtable, 3 December 2018.

healthcare systems flourish without research; and that states with poor health research systems need support to help them develop stronger ones.<sup>252</sup> The question of how governments can be encouraged to commit more to research was particularly highlighted: many international collaborations are between institutions rather than governments (see paragraphs 8.14–8.34), and the lack of government buy-in to research was described to us as problematic. A high-level meeting in February 2019 (see Box 3.2), convened by the Chair of the AU to leverage support for healthcare infrastructure and research within AU member states, brought in business and philanthropic support from within and beyond Africa, and was described by the Director of Africa CDC as a ‘game-changer’.<sup>253</sup>

3.9 Further initiatives developed with the aim of incentivising governments to commit to health research funding include novel funding mechanisms that offer matched funding (see Box 3.2); and the development of a national health research system (NHRS) ‘barometer’. This barometer, developed with the support of the African Regional Office of the WHO (AFRO), identifies essential components of a NHRS in the form of 17 indicators listed under four core functions:<sup>254</sup>

- **Governance** (including national policy and strategic plan, law governing research, and a national ethics review committee);
- **Developing and sustaining resources** (including availability of universities conducting health sciences research, numbers of researchers, a national research institute, a health research programme within the ministry of health, and research being conducted within NGOs);
- **Producing and using research** (including numbers of peer-reviewed publications and systems for knowledge translation); and
- **Financing** (a budget line in the health budget for research, with the aim of progressing towards allocation of two per cent of the national health budget on research for health).

3.10 The barometer has been used to produce ranked lists of research capacity within the 47 countries of the WHO African Region, providing an incentive for states to pay renewed attention to the importance of health research systems. While the barometer has been developed in Africa, it is clearly of potential value to other WHO Regions. The weakest reported indicators in African Region countries in 2016 were government spending on research, availability of institutions conducting health research, numbers of researchers, and publications in peer reviewed journals.<sup>255</sup> We return to these issues of institutional research capacity in Chapter 8 (see in particular paragraphs 8.25–8.34).

### Box 3.2: Future funding models?

- In February 2019, the AU Chair brought together the heads of the WHO and UN, heads of state and government across Africa, and private sector and philanthropic leaders. AU heads of state and government committed to increasing domestic

<sup>252</sup> See also: Kirigia JM, Ota MO, Senkubuge F *et al.* (2016) Developing the African national health research systems barometer *Health Research Policy and Systems* **14**(1): 53 who argue that “progress towards the goal of universal health coverage in the post-2015 sustainable development agenda will be difficult for African countries without strengthening of their NHRS [national health research system] to yield the required evidence for decision-making”. States also commit themselves under Article 44 of the IHR to “collaboration and assistance”.

<sup>253</sup> Nature (11 March 2019) *John N. Nkengasong: how Africa can quell the next disease outbreaks*, available at: <https://www.nature.com/articles/d41586-019-00789-4>.

<sup>254</sup> Kirigia JM, Ota MO, Senkubuge F *et al.* (2016) Developing the African national health research systems barometer *Health Research Policy and Systems* **14**(1): 53. See also: Pang T, Sadana R, Hanney S *et al.* (2003) Knowledge for better health: a conceptual framework and foundation for health research systems *Bulletin of the World Health Organization* **81**(11): 815-20.

<sup>255</sup> Kirigia JM, Ota MO, Senkubuge F *et al.* (2016) Developing the African national health research systems barometer *Health Research Policy and Systems* **14**(1): 53.



investment in healthcare infrastructure, and to working with the private sector to do so. In response, several private sector firms pledged \$200 million.<sup>256</sup>

- In July 2019, the Center for Global Development report, *Transforming the institutional landscape in sub-Saharan Africa*, recommended the establishment of a multi-stakeholder funding platform with matched funding by development partners (including African philanthropists and corporations) and sub-Saharan Africa governments. Under this proposal, funding would be made available, on a competitive basis, only to organisations in African countries whose governments contribute.<sup>257</sup>

### **Preparedness beyond the health sector**

3.11 As the WHO's HEDRM framework emphasises (see paragraph 3.2), emergency preparedness also requires multidisciplinary and multisectoral collaboration beyond the health sector. One aspect of this multisectoral approach includes recognising the impact of animal health and environmental factors on human health, particularly through disease passing from animals to humans. Cooperation between states at regional and global level is crucial, given the scope for disease to pass rapidly and without control between states, for example through migratory birds (see Box 3.3). Another aspect, in the context of natural hazards such as earthquakes and tsunamis, is the need for collaboration across sectors as diverse as engineering, urban planning, education, and the emergency services (see Box 3.4).

#### **Box 3.3: One Health initiatives: highly pathogenic avian influenza (HPAI) and Middle East respiratory syndrome (MERS)**

- The **Association of Southeast Asian Nations (ASEAN) HPAI Task Force** brought together the ten ASEAN countries (Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Laos, Myanmar, Cambodia, and Vietnam) with the Emergency Centre for Transboundary Animal Diseases, established by the FAO Regional Office for Asia and the Pacific (ECTAD-RAP). This led to endorsement by ASEAN Ministers of Agriculture and Forestry in 2010 of a roadmap for an 'HPAI-free ASEAN community by 2020'.<sup>258</sup>
- In 2018 the **WHO Eastern Mediterranean Regional Office (EMRO)** convened a training workshop in order to establish a pool of experts on MERS across the Middle East. Representatives of health ministries from Bahrain, Egypt, Jordan, Kuwait, Oman, Saudi Arabia, Sudan, and United Arab Emirates attended the workshop, along with representatives from EMRO, Centers for Disease Control and Prevention (CDC), the World Organisation for Animal Health (OIE), and the FAO. Attendees discussed how preparedness for MERS (including improving surveillance and field investigations)

<sup>256</sup> Nature (11 March 2019) John N. Nkengasong: *how Africa can quell the next disease outbreaks*, available at: <https://www.nature.com/articles/d41586-019-00789-4>.

<sup>257</sup> Center for Global Development (2019) *Transforming the institutional landscape in sub-Saharan Africa: considerations for leveraging Africa's research capacity to achieve socioeconomic development*, available at: <https://www.cgdev.org/publication/transforming-institutional-landscape-sub-saharan-africa-considerations-leveraging-africa>.

<sup>258</sup> Food and Agriculture Organization of the United Nations (2013) *Lessons from Hpai: a technical stocktaking of outputs, outcomes, best practices and lessons from the fight against highly pathogenic avian influenza in Asia 2005-2011*, available at: <http://www.fao.org/3/a-i3183e.pdf>, at page 9.

might be carried out under a One Health approach,<sup>259</sup> including through addressing gaps in knowledge through priority research.<sup>260</sup>

### Box 3.4: Tsunami preparedness and Caribe Wave

Tsunami preparedness can be increased through focusing on key elements such as:

- **defence structures:** constructing, for example, forest belts, tsunami-resistant buildings, or tsunami tide gates;
- **urban planning:** reducing damage through appropriate land use and moving important facilities to safer areas (for example, on higher ground) that are less likely to be affected by tsunamis; and
- **disaster organisation:** including governments acting to establish disaster mitigation plans, safety procedures, evacuation plans, and warning systems.<sup>261</sup>

Warning systems for tsunamis are tested as part of an annual simulation exercise in the Caribbean. The exercise – Caribe Wave – assists tsunami preparedness and coordination for Caribbean countries that could be affected by this type of natural disaster. It is a collaboration between the United Nations Educational, Scientific and Cultural Organization’s (UNESCO) International Oceanographic Commission and disaster coordination authorities / stakeholders from Caribbean member states.<sup>262</sup>

The most recent Caribe Wave exercise (in March 2019) considered two hypothetical scenarios. The first anticipated a 6.0 magnitude earthquake associated with an eruption of Kick ‘em Jenny (an active underwater volcano) and a subsequent tsunami. The second scenario focused on a tsunami generated by an 8.5 magnitude earthquake located on the Northern Panama deformed belt.<sup>263</sup>

Based on a survey of participants in Caribe Wave 17,<sup>264</sup> a report of the exercise – which simulated tsunamis affecting Costa Rica, Cuba, and the Northeast Antilles – indicated an improved level of tsunami preparedness in the region.<sup>265</sup>

## Role of intergovernmental organisations

3.12 The WHO is the lead coordinating body for international health within the UN system, and hence plays a key role at global level for health emergencies, alongside other UN bodies with relevant remits including:

- The UN Office for the Coordination of Humanitarian Affairs (OCHA), which coordinates humanitarian action through the work of the Inter-Agency Standing Committee (IASC) for humanitarian disasters (WHO being a member of that committee);

<sup>259</sup> The principal repository for Middle East respiratory syndrome (MERS) is dromedary camels. Contact with camels is a major risk factor for human infection, making the virus an ‘ideal example’ for developing One Health concepts. See: Hemida MG, and Alnaeem A (2019) Some One Health based control strategies for the Middle East respiratory syndrome coronavirus *One Health* 8: 100102.

<sup>260</sup> WHO Regional Office for the Eastern Mediterranean (2018) *Training workshop held on establishing pool of experts on Middle East respiratory syndrome (MERS)*, available at: <http://www.emro.who.int/pandemic-epidemic-diseases/news/training-workshop-held-on-establishing-pool-of-experts-on-middle-east-respiratory-syndrome-mers.html>.

<sup>261</sup> UNESCO (2008) *Tsunami preparedness: information guide for disaster planners*, available at: [http://iopic.ioc-unesco.org/images/xplod/resources/material/tsunami\\_preparedness\\_information\\_guide\\_for\\_disaster\\_planners\\_2008.pdf](http://iopic.ioc-unesco.org/images/xplod/resources/material/tsunami_preparedness_information_guide_for_disaster_planners_2008.pdf).

<sup>262</sup> The Tsunami Zone (2019) *Caribe Wave 2019*, available at: <https://www.tsunamizone.org/caribewave/>.

<sup>263</sup> UNESCO (2019) *Caribe Wave 19: tsunami warning exercise in the Caribbean and adjacent regions*, available at: <https://en.unesco.org/events/caribe-wave-19-tsunami-warning-exercise-caribbean-and-adjacent-regions>.

<sup>264</sup> Survey Monkey (2017) *Caribe Wave 17 evaluation*, available at: <https://www.surveymonkey.com/r/CaribeWave17>.

<sup>265</sup> UNESCO (2017) *Exercise Caribe Wave 17: a Caribbean and adjacent regions tsunami warning exercise - 21 March 2017 (Costa Rica, Cuba and Northeastern Antilles scenarios): final report*, available at: [https://www.weather.gov/media/ctwp/CaribeWave\\_17\\_Final\\_Report-UNESCO133.pdf](https://www.weather.gov/media/ctwp/CaribeWave_17_Final_Report-UNESCO133.pdf), at page 14.

- The UN Refugee Agency (UNHCR), which works to safeguard the rights and well-being of people who have been forced to flee;
- The United Nations Children's Fund (UNICEF), the UN's lead agency for children's welfare; and
- The Food and Agriculture Organization (FAO) which leads international efforts concerning hunger.

3.13 The WHO plays a pivotal role with respect to the IHR (see paragraph 3.5 on countries' responsibilities), providing technical and operational support for country readiness and response, alongside recommendations for travel and trade during outbreaks. In outbreaks, it can call on the support of Emergency Medical Teams (EMTs) from 25 countries;<sup>266</sup> and on the Global Outbreak Alert and Response Network (GOARN) – an international network of collaborating institutions and networks, which can quickly deploy relevant personnel in response to requests by host countries.<sup>267</sup> GOARN is also increasingly taking on a role regarding research in emergencies (see paragraph 3.15).<sup>268</sup> In humanitarian crises, the IASC is responsible for the 'humanitarian cluster' system: a coordinating system led by a designated emergency relief coordinator that aims to ensure collective action at local level during humanitarian crises (see paragraph 3.18).<sup>269</sup> WHO takes the lead within this system for the health cluster.<sup>270</sup>

3.14 Importantly, the role of the WHO is exercised at multiple levels: through its national offices; its six autonomous regional offices that are answerable to regional committees of member states in the region; and through its Geneva headquarters, accountable to all states through the World Health Assembly. Other UN agencies similarly have layered structures,<sup>271</sup> and, as the boxes throughout this chapter illustrate, regional offices of the WHO and other UN organisations play a key convening role across their regions for research and response, promoting collaboration, and supporting technical capacity. Strong criticism of the WHO's performance during the West African Ebola outbreak led to a major restructure of its functions in 2016: a Health Emergencies Programme was created; clearer reporting lines across the national, regional, and headquarters offices were established; a Global Coordination Mechanism for public health emergencies was introduced; and the WHO Contingency Fund for Emergencies was created, allowing for rapid release of funds.<sup>272</sup>

<sup>266</sup> WHO (2016) *WHO's new Health Emergencies Programme*, available at: <https://www.who.int/features/qa/health-emergencies-programme/en/>. See also: WHO (2013) *Classification and minimum standards for foreign medical teams in sudden onset disasters*, available at: [https://www.who.int/hac/global\\_health\\_cluster/fmt\\_guidelines\\_september2013.pdf](https://www.who.int/hac/global_health_cluster/fmt_guidelines_september2013.pdf); and WHO (2015) *Emergency Medical Teams and World Health Organization*, available at: [https://www.who.int/hac/techguidance/preparedness/foreign\\_medical\\_teams/en/](https://www.who.int/hac/techguidance/preparedness/foreign_medical_teams/en/).

<sup>267</sup> WHO (2018) *Global Outbreak Alert and Response Network (GOARN)*, available at: [http://www.who.int/ihr/alert\\_and\\_response/outbreak-network/en/](http://www.who.int/ihr/alert_and_response/outbreak-network/en/). In the UK context, for example, the UK Public Health Rapid Support Team (a partnership between Public Health England and the London School of Hygiene and Tropical Medicine) has deployed a number of times on behalf of GOARN: Department of Health & Social Care (2018) *UK Public Health Rapid Support Team annual review: global health security programme*, available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/754173/UK\\_PHRST\\_Annual\\_Review\\_1.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/754173/UK_PHRST_Annual_Review_1.pdf).

<sup>268</sup> GOARN (1-2 May 2018) *Workshop on integrating research into response* (WHO headquarters, Geneva: GOARN).

<sup>269</sup> Inter-Agency Standing Committee (2019) *The Inter-Agency Standing Committee*, available at: <https://interagencystandingcommittee.org/the-inter-agency-standing-committee>.

<sup>270</sup> See: WHO (2015) *Health cluster: the cluster system*, available at: <https://www.who.int/health-cluster/about/cluster-system/en/>; and WHO (2016) *Questions and answers about WHO's role in Humanitarian Health Action*, available at: <https://www.who.int/hac/about/faqs/en/index3.html>.

<sup>271</sup> See, for example, UN (2019) *Where we work*, available at: <https://www.un.org/en/sections/where-we-work/>. See also: UN (2019) *The United Nations system*, available at: [https://www.un.org/en/pdfs/18-00159e\\_un\\_system\\_chart\\_17x11\\_4c\\_en\\_web.pdf](https://www.un.org/en/pdfs/18-00159e_un_system_chart_17x11_4c_en_web.pdf).

<sup>272</sup> WHO (2016) *WHO's new Health Emergencies Programme*, available at: <https://www.who.int/features/qa/health-emergencies-programme/en/>.

3.15 On the research side, WHO has established a Research and Development Blueprint – a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics, including social science research supporting effective communication and response (see Box 3.5).<sup>273</sup> Draft standing operating procedures for integrating research into emergency response are currently being developed.<sup>274</sup> The WHO has identified the integration of research into response as being one of the key changes in its approach since 2016, citing the following eight lessons learned from West Africa that are being applied in the latest Ebola outbreak in the Democratic Republic of the Congo (DRC):

- “Putting research at the heart of the response;
- Getting test results quickly; (see paragraph 3.30 below)
- Saving lives with an experimental vaccine;
- Working to find an effective treatment for Ebola;
- Supporting survivors;
- Incorporating social science and engaging with communities;
- Changing WHO’s emergency response structure; and
- Creating a fast-acting funding mechanism.”<sup>275</sup>

### Box 3.5: The R&D Blueprint

The R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines, and medicines that can be used to save lives and avert large-scale crises. With WHO as convener, the broad global coalition of experts who have contributed to the Blueprint come from several medical, scientific, and regulatory backgrounds. WHO member states welcomed the development of the Blueprint at the World Health Assembly in May 2016.<sup>276</sup>

The Blueprint focuses on a list of identified priority diseases. For each disease an R&D roadmap is created, followed by target product profiles. WHO has developed a special tool for determining which diseases and pathogens to prioritise for research and development in public health emergencies. This tool seeks to identify those diseases that pose a public health risk because of their epidemic potential, and for which there are no, or insufficient, countermeasures. The diseases identified through this process are the focus of the work of the Blueprint.

The first list of prioritised diseases was released in December 2015, and has been regularly revised, using a published prioritisation methodology. The list includes ‘Disease X’ which represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease. The R&D Blueprint therefore explicitly seeks to enable cross-cutting R&D preparedness that is also relevant for an unknown ‘Disease X’ as far as possible.<sup>277</sup>

3.16 While the changes made by the WHO have been applauded, concerns remain that the institution is chronically underfunded, with funding provided by major donors increasingly

<sup>273</sup> WHO (2016) *An R&D Blueprint for action to prevent epidemics: plan of action*, available at: [http://www.who.int/blueprint/about/r\\_d\\_blueprint\\_plan\\_of\\_action.pdf](http://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf); and WHO (2018) *Annual review of the Blueprint list of priority diseases*, available at: <http://www.who.int/blueprint/en/>.

<sup>274</sup> GOARN (1-2 May 2018) *Workshop on integrating research into response* (WHO headquarters, Geneva: GOARN), at page 8.

<sup>275</sup> WHO (22 August 2019) *Ebola then and now: eight lessons from West Africa being applied in the Democratic Republic of the Congo*, available at: <https://www.who.int/news-room/feature-stories/detail/ebola-then-and-now>.

<sup>276</sup> WHO (2016) *About the R&D Blueprint*, available at: <https://www.who.int/blueprint/about/en/>.

<sup>277</sup> WHO (2019) *Prioritizing diseases for research and development in emergency contexts*, available at: <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-context>.

earmarked for particular projects, rather than provided as part of core funding.<sup>278</sup> The operation of other global emergency financing mechanisms, including the World Bank's pandemic emergency financing facility, has also been criticised.<sup>279</sup> Aside from questions of inadequate resources, the extent to which the WHO is equipped (or could be equipped) to work in conflict zones, in a context of instability and insecurity with attacks on health workers and emergency responders, has been queried.<sup>280</sup> The challenges facing public health responders in such situations have been highlighted by the tenth Ebola outbreak in the DRC: its location in a conflict zone has led to forced withdrawals from outbreak areas, putting progress in controlling the outbreak in jeopardy.<sup>281</sup>

### **Interaction between UN agencies and other research / response actors on the ground**

- 3.17 The challenges for WHO working in conflict zones illustrate inevitable tensions in the interdependence of the 'global health' approach of the WHO under the IHR (working with and through nation states) and the 'medical humanitarianism' approach of agencies coordinated by OCHA within the cluster system that operates under humanitarian principles of humanity and neutrality.<sup>282</sup> Critiques of the response to the West African Ebola outbreak highlight the way it was handled as a 'public health emergency' with emphasis on the role of nation states, rather than as a humanitarian crisis with local coordination provided through the cluster system.<sup>283</sup> Reported consequences of not using the cluster system include lack of strategic input by humanitarian organisations, and the overlooking of wider socioeconomic consequences of the outbreak, including other essential health needs such as maternal and newborn healthcare.<sup>284</sup> Despite these important conceptual differences in approach, the WHO relies on the humanitarian sector to provide direct clinical care during public health emergencies as well as in emergencies designated as humanitarian crises. The sector in return relies on the coordinating and directing role of the WHO.
- 3.18 The central role often occupied by the humanitarian agencies – including Médecins Sans Frontières (MSF), the International Committee of the Red Cross (ICRC), The Alliance for International Medical Action (ALIMA), Save the Children, and the International Rescue Committee (IRC) – in providing healthcare in all forms of health emergency is also important in the research context. As providers of care, they have an obligation to gather appropriate data to monitor the effectiveness of their interventions, and are increasingly initiating research themselves, conducting or commissioning studies in response to

<sup>278</sup> Twitter (8 May 2019) *Tweet: Jeremy Farrar*, available at: <https://twitter.com/JeremyFarrar/status/1126160567625031685>, where Dr Farrar states: "After West Africa 2013-2016 world asked @WHO to reform, to be active, engaged, impactful & to provide leadership. It is doing all that was asked of it & more. Now the world has to acknowledge that progress & back it with political support, funding & thanks. Now as matter urgency". See also: Clinton C, and Sridhar D (2017) Who pays for cooperation in global health? A comparative analysis of WHO, the World Bank, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance *The Lancet* **390(10091)**: 324-32.

<sup>279</sup> Financial Times (13 June 2019) *Ebola escalation keeps World Bank's 'pandemic bonds' in spotlight*, available at: <https://www.ft.com/content/30dc1a0c-8da4-11e9-a24d-b42f641eca37>; and Erikson S (2019) Global health futures? Reckoning with a pandemic bond *Medicine Anthropology Theory* **6(3)**: 77-108.

<sup>280</sup> Devex (15 May 2019) *WHO not equipped for conflict response, says former Ebola czar*, available at: <https://www.devex.com/news/who-not-equipped-for-conflict-response-says-former-ebola-czar-94900>.

<sup>281</sup> Stat News (28 November 2019) *Four Ebola-response workers killed in attacks, forcing withdrawal from critical DRC region*, available at: <https://www.statnews.com/2019/11/28/four-ebola-response-workers-killed-in-attacks-drc/>.

<sup>282</sup> Agencies include Médecins Sans Frontières (MSF) and the International Committee of the Red Cross (ICRC). See: Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* **15(3)**: 362-76.

<sup>283</sup> *ibid.*

<sup>284</sup> *ibid.*



needs identified on the ground.<sup>285</sup> Critical data about care in humanitarian crises are often sparse; yet it is vital that ineffective interventions are either weeded out or improved, while information about positive interventions needs to be critically assessed and widely disseminated. This, of course, extends beyond biomedical interventions to include studies aiming to evaluate and improve many other kinds of care, as well as practical and infrastructural support, such as logistics and water and sanitation. As providers of direct healthcare, humanitarian agencies can also be highly influential in the prioritisation and selection of potential research studies (both biomedical and other disciplines) by virtue of their ‘gatekeeping’ role for patients in their care.<sup>286</sup>

- 3.19 The role played by domestic or foreign military in humanitarian crises is similarly complex. Military medical services can play a significant role in supporting emergency preparedness and response capacity,<sup>287</sup> and research conducted by the military sector for its own purposes, for example in biodefence, can provide important evidence in improving emergency response.<sup>288</sup> However military involvement may elicit concerns about a ‘militarised’ response with risks of coercion and violence for affected populations,<sup>289</sup> and associated community distrust even when the primary function of the military is to protect health workers.<sup>290</sup> The international agreement governing the deployment of foreign military assets in humanitarian response requires that the military can only be used as a “last resort” when there is no “comparable civilian alternative”.<sup>291</sup> In the West African Ebola outbreak, the involvement of foreign militaries (from AU member states, Canada, China, France, Germany, Ireland, the UK, and the US, alongside those of Sierra Leone and Liberia) has been described as “controversial for some, and a much-needed game changer in the response for others”.<sup>292</sup>
- 3.20 Expectations of foreign militaries’ roles during emergencies (for example whether they are primarily offering technical and logistical support, or providing direct clinical care) can also be unclear and can result in frustration or misunderstanding.<sup>293</sup> The ‘military rules of eligibility’ that prioritise use of military health services for UK or allied forces created ethical challenges for some UK military health professionals deployed to Sierra Leone in Operation Gritrock when they were unable to use empty beds in their unit for local

<sup>285</sup> See, for example, Benelli P, and Low T (2019) Ethical primary research by humanitarian actors *Forced Migration Review* 61: 28-9; and Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* 43(4): 711-26.

<sup>286</sup> Rid A, and Antierens A (2017) How did Médecins Sans Frontières negotiate clinical trials of unproven treatments during the 2014–2015 Ebola epidemic?, in *The politics of fear*, Hofman M, and Au S (Editors) (Oxford: Oxford University Press).

<sup>287</sup> See, for example, the APORA partnership between the US military and over 20 African militaries: US Air Forces in Europe & Air Forces in Africa (22 November 2019) *APORA VII: knowledge sharing is contagious*, available at: <https://www.usafe.af.mil/News/Article-Display/Article/2023741/apora-viii-knowledge-sharing-is-contagious/>; and APORA (2019) *APORA manual guideline*, available at: [https://community.apan.org/cfs-file/\\_\\_key/docpreview-s/00-00-11-51-67/APORA-Manual\\_5F00\\_v1\\_5F00\\_18May2019\\_5F00\\_final.pdf](https://community.apan.org/cfs-file/__key/docpreview-s/00-00-11-51-67/APORA-Manual_5F00_v1_5F00_18May2019_5F00_final.pdf).

<sup>288</sup> WHO (2019) *Prioritizing diseases for research and development in emergency contexts*, available at: <https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-context>.

<sup>289</sup> See, for example, Chatham House and the British Red Cross (2018) *Civil-military relations: a focus on health emergencies and epidemics: conference report*, available at: <https://www.chathamhouse.org/sites/default/files/NMCG-conference-report-2018.pdf>; and Imperiale AJ, and Vanclay F (2019) Command-and-control, emergency powers, and the failure to observe United Nations disaster management principles following the 2009 L'Aquila earthquake *International Journal of Disaster Risk Reduction* 36: 101099.

<sup>290</sup> The New York Times (23 May 2019) *Attacks on Ebola health workers in the Democratic Republic of Congo*, available at: <https://www.nytimes.com/2019/05/23/opinion/letters/ebola-violence-congo.html>.

<sup>291</sup> OCHA (2007) *Guidelines on the use of foreign military and civil defence assets in disaster relief*, available at: <https://www.unocha.org/publication/oslo-guidelines-use-foreign-military-and-civil-defence-assets-disaster-relief>, at page 8. See also: Draper H, Jenkins S, Bernthal L *et al.* (2018) Preparing for Operation Gritrock: military medical ethics challenges encountered in the planning stages of the UK Ebola response mission, in *Ethical challenges for military health care personnel: dealing with epidemics*, Messelken D, and Winkler D (Editors) (London and New York: Routledge).

<sup>292</sup> Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* 15(3): 362-76, at page 369. See also: Devex (15 May 2019) *WHO not equipped for conflict response, says former Ebola czar*, available at: <https://www.devex.com/news/who-not-equipped-for-conflict-response-says-former-ebola-czar-94900>, making the case for “a white-helmeted security battalion” to provide security for responders in the DRC.

<sup>293</sup> Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* 15(3): 362-76.



patients despite significant pressures on other facilities.<sup>294</sup> Risk-averse policies, such as being confined to barracks, limited scope for local collaboration for deployed military health professionals, including in relation to research.<sup>295</sup>

## Role of private sector

- 3.21 While the role of governments, intergovernmental agencies, and the not-for profit sector (encompassing both philanthropic organisations and the academic sector) tends to be more visible in emergency preparedness and research, the private sector plays a significant part in a variety of ways. The pharmaceutical and biotech industries are key partners with the academic research community in developing novel pharmaceuticals and diagnostics, and also other technical innovations (see paragraph 3.30); and the associated commercial interests involved – for example the affordability of products and requirements of insurers (see paragraphs 5.17 and 6.10) – can add to the complexity of these collaborations.
- 3.22 The economic model that underpins much pharmaceutical development does not readily support the development of affordable vaccines and therapies for diseases prevalent mainly in low-income countries (LICs). The role of ‘public-private partnerships’ (PPP) such as the Coalition for Epidemic Preparedness Innovations (CEPI – see paragraph 3.24) and GAVI<sup>296</sup> is therefore key, particularly for vaccine development and supply.<sup>297</sup> A broader example of a PPP is the Global Health Security Agenda which brings together countries, international organisations, NGOs, and private sector companies to support the capacity of states to meet IHR requirements and other intergovernmental commitments.<sup>298</sup> As at September 2018, this coalition involved 65 countries and over 100 private companies, alongside international and regional multilateral organisations, NGOs, and academic institutions.<sup>299</sup> As illustrated in Box 3.6, emergency preparedness, response, and research also involve many other private sector actors, from social media companies to transport firms.

### Box 3.6: ‘Event 201’ pandemic planning, and reflections on the role of the private sector from Nigeria

In October 2019, the Johns Hopkins Center for Health Security, in partnership with the World Economic Forum and the Bill & Melinda Gates Foundation, hosted ‘Event 201’, a global pandemic planning exercise, based around a fictional disease and outbreak

<sup>294</sup> Draper H, and Jenkins S (2017) Ethical challenges experienced by UK military medical personnel deployed to Sierra Leone (operation Gritrock) during the 2014-2015 Ebola outbreak: a qualitative study *BMC Medical Ethics* **18(77)**: 1-13.

<sup>295</sup> Meeting with Andy Johnston, Lt Col RAMC, Consultant in Respiratory Medicine and Critical Care Royal Centre for Defence Medicine, Queen Elizabeth Hospital Birmingham, Birmingham, 21 September 2018; and Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* **15(3)**: 362-76. See also: Chatham House (2017) *The next Ebola: considering the role of the military in future epidemic response*, available at: <http://www.chathamhouse.org/sites/default/files/events/2017-03-31-next-ebola-role-of-military-meeting-summary.pdf>.

<sup>296</sup> Gavi (2019) *Homepage*, available at: <https://www.gavi.org/>.

<sup>297</sup> See, for example, Wellcome Trust and CIDRAP (2015) *Recommendations for accelerating the development of Ebola vaccines: report and analysis*, available at: [http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola\\_virus\\_team\\_b\\_report-final-021615.pdf](http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_virus_team_b_report-final-021615.pdf), at Appendix D.

<sup>298</sup> Global Health Security Agenda (2018) *Global Health Security Agenda (GHS) 2024 framework*, available at: <https://ghsa2024.files.wordpress.com/2019/11/ghsa-2024-framework.pdf>; and Global Health Security Agenda (2019) *Homepage*, available at: <https://ghsagenda.org/>.

<sup>299</sup> Global Health Security Agenda (2018) *Global Health Security Agenda (GHS) 2024 framework*, available at: <https://ghsa2024.files.wordpress.com/2019/11/ghsa-2024-framework.pdf>.

scenario.<sup>300</sup> Reflecting on the lessons for his country after the recent Lassa fever outbreak, a commentator from Nigeria highlighted the role of:

- The expertise and infrastructure of specialist courier companies, in transporting samples to labs for rapid diagnosis;
- The importance of working with social media companies in order to target messages in outbreak zones, and combat fake news;
- Leveraging private actors in communications to support the work of the national Centre for Disease Control;
- Working with businesses to ensure contingency planning in advance of any pandemic;
- Building up stockpiles of medical supplies; and
- Working with airlines, train services, and other public transport companies on handling an outbreak: from responding to infected passengers, to appropriate procedures at airports or stations.<sup>301</sup>

## Role of research funders

3.23 Research funders – a diverse group including large and small philanthropic funding bodies, government departments, and the private sector – have a direct influence on the way that research is conducted both during an emergency, and in support of emergency preparedness (see the discussion of ‘duty-bearers’ in the next chapter, at paragraphs 4.62–4.71). Their own priorities and procedures help steer what research and which research teams receive funding; and they exercise significant levers for researchers’ ethical conduct. These levers include the guidance they issue to institutions and to their own decision-making panels; and what they expect, or require, of applicants. We return to these opportunities to influence ethical research conduct in later chapters, particularly Chapters 5 and 8.

3.24 There is an increasingly collaborative approach across the research funding sector, alongside new initiatives to bring in more funding, especially from the private sector. Significant collaborations in the area of infectious diseases research include:

- the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) which brings together funding organisations with the aim of facilitating effective rapid response, research, and innovation in this sector;<sup>302</sup> and
- CEPI – an alliance between governments, industry, academia, intergovernmental organisations, and philanthropic organisations, with a remit to finance and coordinate the development of new vaccines<sup>303</sup> (see, for example, funding for a phase III-ready chikungunya vaccine<sup>304</sup>).

3.25 There is also increasing recognition of the influential role played by funders in setting research priorities, and in the associated challenges of equity, given the predominance

<sup>300</sup> Center for Health Security (17 October 2019) *Event 201 pandemic exercise underscores immediate need for global public-private cooperation to mitigate severe economic and societal impacts of pandemics*, available at: <http://www.centerforhealthsecurity.org/event201/191017-press-release.html>.

<sup>301</sup> The Guardian (Nigeria) (15 November 2019) *Preparing private sector for next pandemic*, available at: <https://guardian.ng/features/health/preparing-private-sector-for-next-pandemic/>. See also: The Cable (2 January 2020) *Private sector and public health collaboration for emergency preparedness in Nigeria*, available at: <https://www.thecable.ng/private-sector-and-public-health-collaboration-for-emergency-preparedness-in-nigeria>.

<sup>302</sup> GloPID-R (2018) *Homepage*, available at: <https://www.glopid-r.org/>.

<sup>303</sup> CEPI (2018) *Homepage*, available at: <http://cepi.net/>.

<sup>304</sup> BioSpace (4 June 2019) *CEPI awards up to US\$21 million to Themis Bioscience for phase 3 chikungunya vaccine development*, available at: <https://www.biospace.com/article/releases/cepi-awards-up-to-us-21-million-to-themis-bioscience-for-phase-3-chikungunya-vaccine-development/>.

of funders based in high-income countries (HICs). A four-year review of the funding of African researchers, for example, found that research publications from Africa-based scientists are funded mainly from Europe, the US and China, with only two Africa-based funders in the top ten.<sup>305</sup> In response, the African Academy of Sciences (AAS) commented that the role of foreign funders was “so pervasive that if they were to pull out, research on the continent would be seriously disrupted and in most countries, it would literally grind to a halt.”<sup>306</sup> This dominance of foreign funders inevitably shapes the research agenda, with big grants being awarded in fields corresponding to funders’ priorities, rather than necessarily in those regarded as more important by domestic research leaders.<sup>307</sup>

- 3.26 In response to these concerns, initiatives such as the India Alliance<sup>308</sup> (a collaboration between the Government of India and Wellcome), and the Alliance for Accelerating Excellence in Science (AESA) founded by the AAS and the New Partnership for Africa’s Development Agency,<sup>309</sup> have sought to move decision-making away from HICs towards the location of the research being funded. Wellcome has handed over two of its major research programmes in Africa to AESA with the aim of “shift[ing] the centre of gravity of our African science funding from the UK to Africa.”<sup>310</sup> The well-established European and Developing Countries Clinical Trials Partnership (EDCTP) similarly seeks to support South-South partnerships, as well as international partnerships connecting European and African research teams (see Box 3.7).

### Box 3.7: Role of the European and Developing Countries Clinical Trials Partnership

The EDCTP is a partnership between the European Union and national institutions in Europe and sub-Saharan Africa.<sup>311</sup> It funds clinical research to accelerate the development of new or improved drugs, vaccines, microbicides, and diagnostics against HIV/AIDS, tuberculosis, and malaria as well as other poverty-related infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials. In addition to funding two major new emergency preparedness networks (the African coalition for Epidemic Research, Response and Training (ALERT) and the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Disease Epidemics (PANDORA-ID-NET)), EDCTP-supported initiatives include ‘South-South’ collaborations such as:

<sup>305</sup> Nature (14 November 2018) *Africa’s science ‘millionaires’: survey spotlights top-funded researchers*, available at: <https://www.nature.com/articles/d41586-018-07418-6>, reporting African Minds (2018) *The next generation of scientists in Africa*, available at: <http://www.africanminds.co.za/wp-content/uploads/2018/10/AM-The-Next-Generation-of-Scientists-in-Africa-TEXT-WEB-11112018-1.pdf>.

<sup>306</sup> Nature (14 November 2018) *Africa’s science ‘millionaires’: survey spotlights top-funded researchers*, available at: <https://www.nature.com/articles/d41586-018-07418-6>.

<sup>307</sup> See, for example, the role of the Nigerian CDC in pushing back against “flashy academic studies in favour of meeting basic, pressing needs”: Nature (20 February 2019) *A new model for disease research in Africa*, available at: <https://www.nature.com/articles/d41586-019-00612-0>.

<sup>308</sup> India Alliance (2019) *Homepage*, available at: <https://www.indiaalliance.org/>.

<sup>309</sup> The African Academy of Sciences (2019) *AESA: shifting the centre of gravity for African science to Africa - overview*, available at: <https://www.aasciences.africa/aesa>.

<sup>310</sup> Wellcome (27 October 2016) *Shifting the centre of gravity for Africa research funding*, available at: <https://wellcome.ac.uk/news/shifting-centre-gravity-african-research-funding>.

<sup>311</sup> EDCTP (2019) *Homepage*, available at: <http://www.edctp.org/>; and Africa-News (8 July 2019) *Africa: sharing data can help prevent public health emergencies in Africa*, available at: <https://www.africa-news.info/health/2019/07/08/africa-sharing-data-can-help-prevent-public-health-emergencies-in-africa/>.

- The Coalition for African Research and Innovation, being developed by the AAS. This platform will foster collaboration on research and innovation in Africa. It will also address the under investment in scientific talent and research infrastructure.
- The Pan African Clinical Trials Registry (PACTR), hosted by the South African Medical Research Council. The registry provides access to contacts for researchers as well as trial sites. It also provides information on which organisation or institution funds various research projects. These data can be used to map clinical trial activity in several diseases relevant to the continent, such as Ebola.

## Role of academia: development of regional and international collaborative research networks

3.27 The key role academic research can play in supporting effective emergency preparedness for a range of health threats has been recognised in the past few years through the increasing number of regional and international research collaborations, across a wide range of disciplines. The WHO Thematic Platform for Health Emergency and Disaster Risk Management Research Network (TPRN) was established as a global research network in 2018 in response to substantial challenges facing the academic HEDRM community. Challenges include overlapping research activities, lack of a strategic research agenda, lack of coordination between key stakeholders, and lack of resources.<sup>312</sup> The TPRN has since held its first core group meeting in Kobe to identify and prioritise research questions with representatives of all six WHO Regional Offices and key stakeholders in the Asia Pacific area.<sup>313</sup> Future plans to develop the work of the network include providing funding through the Kobe office for research in a number of areas identified at the first core group meeting; publishing a research methods resource to support researchers (currently in development); and holding further annual meetings to review progress and update priorities as necessary.<sup>314</sup>

3.28 Discipline-specific international and regional networks, from longstanding to relatively new, play a critical role in both emergency preparedness and in effective emergency response. These range from technical monitoring of geophysical events (see Box 3.8) to an extensive federation of infectious disease networks with a dual operational mode: conducting research during interepidemic periods, so that they are ready to translate results into rapidly-implementable actions during epidemics (see Box 3.9).<sup>315</sup> Many other networks, such as INDEPTH<sup>316</sup> (a global network of health and demographic surveillance systems) contribute significantly to the sector, although they are not specifically set up with emergency preparedness in mind.

### Box 3.8: Examples of disaster preparedness and response research networks

- The **Geotechnical Extreme Events Reconnaissance (GEER) Association** grew out of grassroots efforts to investigate and document the geotechnical impacts of the 1989

<sup>312</sup> WHO (2018) *WHO thematic platform on Health Emergency & Disaster Risk Management Research Network*, available at: <https://www.who.int/hac/techguidance/preparedness/WHO-Thematic-Platform-Health-EDRM-Research-Network-2018.pdf?ua=1>.

<sup>313</sup> Kayano R, Chan EY, Murray V *et al.* (2019) WHO Thematic Platform for Health Emergency and Disaster Risk Management Research Network (TPRN): report of the Kobe expert meeting *International Journal of Environmental Research and Public Health* **16(7)**: 1232.

<sup>314</sup> Parallel session on health emergency disaster risk reduction, International Conference on Silk-road Disaster Risk Reduction and Sustainable Development, 11–12 May 2019, Beijing (see: <http://www.sidrr.com/>).

<sup>315</sup> Ippolito G, and Vairo F (2019) Ebola: basic and social science, public health, and policy at the crossroads *The Journal of Infectious Diseases*: Published online: 4 April 2019.

<sup>316</sup> INDEPTH Network (2012) *About us*, available at: <http://www.indepth-network.org/about-us>.

Loma Prieta Earthquake, 1994 Northridge Earthquake, and 1995 Kobe Earthquake. It now responds to geotechnical extreme events (including earthquakes, floods, hurricanes, landslides, and fires) to obtain valuable perishable information that can be used to advance research and improve engineering practice.<sup>317</sup>

- **FEWS NET**, the Famine Early Warning Systems Network, is a leading provider of early warning and analysis on acute food insecurity. Created in 1985 by the US Agency for International Development (USAID) after devastating famines in East and West Africa, FEWS NET provides objective, evidence-based analysis to help government decision-makers and relief agencies plan for and respond to humanitarian crises. Analysts and specialists in 19 field offices work with US Government science agencies, national government ministries, international agencies, and NGOs to produce forward-looking reports on 28 of the world's most food-insecure countries.<sup>318</sup>

### Box 3.9: Role of international and regional infectious disease networks in emergency preparedness and response

The **International Severe Acute Respiratory and Emerging Infection Consortium** (ISARIC) is a global federation of clinical research networks, aiming to provide a coordinated, agile research response to outbreak-prone infectious diseases.<sup>319</sup>

In the light of the experiences of recent Ebola and Zika outbreaks, a number of **major international research networks** have been established with the specific aim of strengthening epidemic preparedness and research capacity in regions affected by these outbreaks, drawing on international expertise.<sup>320</sup> These include:

- The **African coALition for Epidemic Response and Training (ALERTT)**, a multidisciplinary consortium building a patient-centred clinical research network to respond to epidemics across sub-Saharan Africa;<sup>321</sup>
- **PANDORA-ID-NET**, a multidisciplinary 'One Health' initiative addressing the response to emerging infections in Africa through capacity development and training;<sup>322</sup>
- The **Platform for European Preparedness for (Re-)Emerging Epidemics (PREPARE)**, an EU-funded network for harmonised large-scale clinical research studies on infectious diseases, prepared to rapidly respond to any severe infectious disease outbreak, providing real-time evidence for clinical management of patients and for informing public health responses; and
- The **REDe**<sup>323</sup> collaboration, which brings together three Zika consortia, the **ZIKAlliance**, **ZIKAction**, and **Zika Preparedness Latin America Network** (ZikaPLAN) with the longer-term aim of establishing lasting capacity to conduct research in the event of other vector-borne and emerging infectious disease outbreaks in Latin America and the Caribbean.

<sup>317</sup> GEER (2019) *About GEER*, available at: <http://www.geerassociation.org/about-geer>.

<sup>318</sup> FEWS NET (2019) *About us*, available at: <https://fewsn.net/about-us>.

<sup>319</sup> International Severe Acute Respiratory and Emerging Infection Consortium (2019) *Homepage* available at: <https://isaric.tghn.org/>.

<sup>320</sup> GloPID-R (2018) *Reaching out: a meeting to advance clinical research preparedness for infectious disease outbreaks*, available at: <http://www.glopid-r.org/wp-content/uploads/2018/11/reaching-out-clinical-research-preparedness-meeting-report.pdf>; and PREPARE (2018) *Reaching out: a meeting to advance clinical research preparedness for infectious disease outbreaks*, available at: [https://www.prepare-europe.eu/Portals/0/Documents/Publications/Report%20Infographic\\_2018%2011%2019.pdf](https://www.prepare-europe.eu/Portals/0/Documents/Publications/Report%20Infographic_2018%2011%2019.pdf).

<sup>321</sup> ALERTT (2018) *A joint ALERTT & WHO workshop on 'ethics preparedness: facilitating ethics review during outbreaks': Dakar, 20-21 March*, available at: <https://www.alertt.global/content/joint-alertt-who-workshop-ethics-preparedness-facilitating-ethics-review-during-outbreaks>.

<sup>322</sup> PANDORA-ID-NET (2019) *Homepage*, available at: <https://www.pandora-id.net/>.

<sup>323</sup> ZIKAction (2019) *REDe*, available at: <http://zikaction.org/partners/other-eu-consortia/rede/>.



National research networks with similar aims to the regional collaborations listed above include the **Australian Partnership for Preparedness Research on Infectious Disease Emergencies** (APPRISE) in Australia<sup>324</sup> and **Research and Action Targeting Infectious Diseases** (REACTing) in France.<sup>325</sup>

3.29 A common theme across many of these research networks is the emphasis on the fundamental importance of working with affected communities and wider stakeholders in preparedness planning and research, as highlighted in the WHO's HEDRM framework (see paragraph 3.2).<sup>326</sup> We return to this central concern in Chapter 5.

## Role of technology and surveillance in supporting preparedness

3.30 Technological developments play an important part in providing the information necessary to inform the actions and decisions of actors and institutions discussed in the earlier part of this chapter. Alongside the essential role in infectious disease outbreaks played by functioning health systems that can generate the data required for effective epidemiological analysis,<sup>327</sup> preparedness for both infectious disease outbreaks and many forms of natural and human-made disaster relies on accurate systems for measuring, monitoring, and predicting risk. Effective management and control of disease also relies on tools that facilitate timely and accurate diagnosis. As illustrated in Box 3.10, research in diverse disciplines has underpinned significant improvements in surveillance and modelling techniques to inform emergency preparedness for both natural disasters and infectious disease outbreaks. These improvements include more effective monitoring and early warning, mitigation of hazards, and support for effective response and reconstruction. The speed of diagnosis for some conditions has been transformed through the development of mobile laboratories and bedside tests. In order to maximise the effect of such developments on immediate response, it has been suggested that a new interdisciplinary field of 'outbreak science' would help improve connections between modellers and public health practitioners.<sup>328</sup> We return in Chapter 9 to the issue of the widespread sharing and use of data on which many of these techniques depend.

### Box 3.10: Developments in emergency prediction, modelling, and diagnosis

- Using high-resolution mapping techniques and drones to improve understanding of past earthquake activity, and hence improve prediction;<sup>329</sup>
- Developing early warning tools that track water supplies worldwide and combining them with social, economic, and demographic data to flag up potential water crises;<sup>330</sup>

<sup>324</sup> APPRISE (2019) *Homepage*, available at: <https://www.apprise.org.au/>.

<sup>325</sup> REACTing (2019) *What we do*, available at: <https://reacting.inserm.fr/what-we-do/>.

<sup>326</sup> See, for example, GloPID-R (2018) *Reaching out: a meeting to advance clinical research preparedness for infectious disease outbreaks*, available at: <http://www.glopid-r.org/wp-content/uploads/2018/11/reaching-out-clinical-research-preparedness-meeting-report.pdf>, at page 7.

<sup>327</sup> See: Harman S, and Wenham C (2018) Governing Ebola: between global health and medical humanitarianism *Globalizations* **15**(3): 362-76, pp366-7 who trace the early failings to recognise the scale of the Ebola outbreak in Guinea in 2014 to relying on data from weak health systems, poor data collection, and logistical challenges in sharing timely information.

<sup>328</sup> Rivers C, Chretien J-P, Riley S *et al.* (2019) Using "outbreak science" to strengthen the use of models during epidemics *Nature Communications* **10**(1): 3102.

<sup>329</sup> Gao M, Xu X, Klinger Y *et al.* (2017) High-resolution mapping based on an Unmanned Aerial Vehicle (UAV) to capture paleoseismic offsets along the Altyn-Tagh fault, China *Scientific Reports* **7**(1): 8281.

<sup>330</sup> Reuters (14 June 2019) *Tech tool aims to predict global water conflicts before they happen*, available at: <https://af.reuters.com/article/worldNews/idAFKCN1TF1DC>. See also: IHE Delft (2018) *The Water, Peace and Security Partnership*, available at: <https://www.un-ihe.org/water-peace-and-security-partnership>.



- Drawing on large genomic and ecological datasets to develop predictive models aimed at speeding up identification of animal reservoirs for viruses such as SARS (severe acute respiratory syndrome), Ebola, and Zika;<sup>331</sup>
- Using whole genome sequencing to increase understanding of how antimicrobial-resistant pathogens evolve, particularly during the critical period before they emerge in clinical or public health surveillance;<sup>332</sup>
- Using phylogenetic approaches (comparing the genomes of pathogens to establish how closely related viruses from two individuals or populations are) to improve understanding of transmission patterns in epidemics;<sup>333</sup>
- Developing real-time mathematical models to help plan for how many hospital or community care beds might be required to limit the spread of an epidemic;<sup>334</sup>
- Developing and improving ‘near-patient’ diagnostic tests, enabling real-time diagnosis and more effective response;<sup>335</sup>
- Increasing use of digital health models,<sup>336</sup> for example using anonymous mobile phone mapping that tracks population movement to help predict where the next malaria outbreak is likely to emerge,<sup>337</sup> or the development by Facebook of detailed AI-powered maps to support work by the humanitarian sector.<sup>338</sup>

3.31 Critically, while these technologies provide valuable tools in emergency preparedness, they complement – but can never be a substitute for – the role played by those on the ground closest to the emergency. This latter role may be in the form of well-rehearsed community protocols for evacuation in an earthquake zone;<sup>339</sup> volunteers mapping ‘infection points’ that attract rats or mosquitoes in crowded urban spaces;<sup>340</sup> or in the training and support for health workers and communities to enable them to recognise

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- <sup>331</sup> Babayan SA, Orton RJ, and Streicker DG (2018) Predicting reservoir hosts and arthropod vectors from evolutionary signatures in RNA virus genomes *Science* **362(6414)**: 577-80. See also: News-Medical.net (15 October 2019) *New UCL-developed mathematical model could help predict next Ebola outbreak*, available at: <https://www.news-medical.net/news/20191015/New-UCL-developed-mathematical-model-could-help-predict-next-Ebola-outbreak.aspx>, citing Redding DW, Atkinson PM, Cunningham AA *et al.* (2019) Impacts of environmental and socio-economic factors on emergence and epidemic potential of Ebola in Africa *Nature Communications* **10(1)**: 4531.
- <sup>332</sup> Brown TS, Challagundla L, Baugh EH *et al.* (2019) Pre-detection history of extensively drug-resistant tuberculosis in KwaZulu-Natal, South Africa *Proceedings of the National Academy of Sciences* **116(46)**: 23284; and Scienmag (28 October 2019) *Using whole-genome sequencing for early identification and containment of AMR pathogens*, available at: <https://scienmag.com/using-whole-genome-sequencing-for-early-identification-and-containment-of-amr-pathogens/>.
- <sup>333</sup> Coltart CEM, Hoppe A, Parker M *et al.* (2018) Ethical considerations in global HIV phylogenetic research *The Lancet HIV* **5(11)**: e656-e66.
- <sup>334</sup> Elrha (2015) *Modelling Ebola in West Africa*, available at: <https://www.elrha.org/project/lshtm-modelling-ebola-west-africa/>.
- <sup>335</sup> Elrha (2015) *EbolaCheck*, available at: <https://www.elrha.org/project/ebolacheck/>; and Elrha (2015) *Point-of-care EVD diagnostic testing for Ebola treatment centres*, available at: <https://www.elrha.org/project/institute-pasteur-evd-diagnostic-testing-ebola/>. See also: Kelly-Cirino CD, Nkengasong J, Kettler H *et al.* (2019) Importance of diagnostics in epidemic and pandemic preparedness *BMJ Global Health* **4 (supplement 2)**: e001179, which highlights how much more needs to be done in this area, including in making new tests commercially viable to produce.
- <sup>336</sup> CSIS (2019) *Can digital health help stop the next epidemic?*, available at: <https://www.csis.org/analysis/can-digital-health-help-stop-next-epidemic>. See also: Thomson Reuters Foundation News (14 November 2019) *High-tech mapping, apps fight deadly dengue outbreak in Honduras - medical charity*, available at: <http://news.trust.org/item/20191114205041-km88n/>.
- <sup>337</sup> BBC News (10 June 2019) *Big data ‘can stop malaria outbreaks before they start’*, available at: <https://www.bbc.co.uk/news/health-48581317>.
- <sup>338</sup> Facebook (20 May 2019) *Helping organizations respond to health emergencies*, available at: <https://newsroom.fb.com/news/2019/05/disease-prevention-maps/>. See also: The Centre for Internet and Society (2016) *Ebola: a big data disaster - privacy, property, and the law of disaster experimentation*, available at: [https://github.com/cis-india/papers/raw/master/CIS\\_Papers\\_2016.01\\_Seal-McDonald.pdf](https://github.com/cis-india/papers/raw/master/CIS_Papers_2016.01_Seal-McDonald.pdf) for a more sceptical view of these uses of big data.
- <sup>339</sup> See, for example, Nuffield Department of Medicine (2019) *Preparing for disaster*, available at: <https://www.ndm.ox.ac.uk/ccouc-helps-communities-prepare-for-disaster>; and Chan EYY (2017) *Building bottom-up health and disaster risk reduction programmes* (Oxford: Oxford University Press).
- <sup>340</sup> The Guardian (2 September 2019) *Sewage, Zika virus - and the team in Brazil mapping disease hotspots*, available at: <https://www.theguardian.com/global-development/2019/sep/02/zika-virus-team-brazil-mapping-disease-hotspots>.

and respond to the first signs of epidemic.<sup>341</sup> This synergy between technical and social levels of preparedness emerged clearly in a review of the 2017 Ebola outbreak in a remote region of the DRC, which was limited to just eight cases.<sup>342</sup> It is thought to be the first such outbreak in which cases were identified in real time at the site of the outbreak, rather than months later; and the author describes the valuable role of the diagnostic assays and viral sequencing conducted at the site, alongside the speedy deployment of both Congolese and international experts.<sup>343</sup> However, he also points to two key factors that enabled the outbreak to be brought so rapidly under control: that a local nurse (1,700 km from the capital Kinshasa) had participated in an Ebola training programme the year before, and recognised the symptoms; and that relatives of the first person to die had implemented *ad hoc* protective burial practices.

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<sup>341</sup> WHO (8 November 2018) *New measures and strong partnership having positive impact on Ebola response in the Democratic Republic of the Congo*, available at: <https://www.who.int/news-room/detail/08-11-2018-new-measures-and-strong-partnership-having-positive-impact-on-ebola-response-in-the-democratic-republic-of-the-congo>.

<sup>342</sup> Nsio J, Kapetshi J, Makiala S *et al.* (2019) 2017 outbreak of Ebola Virus Disease in Northern Democratic Republic of Congo *The Journal of Infectious Diseases*: Published online: 3 April.

<sup>343</sup> *ibid.*

# Chapter 4

Developing an ethical  
compass

## Chapter 4 – Developing an ethical compass

### Chapter 4: overview

Research in global health emergencies unavoidably takes place in non-ideal circumstances, characterised by disruption, uncertainty, and great health need. This can be compounded by competing claims for legitimacy, time pressures, confusion, and distress. These factors present significant practical challenges to ethical decision-making as practitioners struggle to align their ethical obligations to challenging and often chaotic circumstances.

Effective research in emergencies also involves cooperation between numerous organisations, which may have conflicting priorities, and which are guided by their own, sometimes distinct, professional and ethical codes of practice. The question of what is (or is not) morally distinct about research in emergencies is thus complicated by the existence of multiple 'standard' approaches, including for different kinds of research, in different legal, social, and cultural contexts, and by different organisations and professions with diverse traditions. Crucially, the decisions taken at policy level, by funders, regulators, research institutions, journals, and others also shape and constrain the possibilities for ethical research conducted on the ground.

Drawing on the evidence and experience presented to the working group, this report proposes an 'ethical compass' to inform higher level policy approaches, and to help provide a common language and a common way of thinking through ethical dilemmas arising in emergencies. The ethical compass is made up of three very widely shared values:

- **Equal respect:** treating others as moral equals, including respecting their dignity, humanity and human rights;
- **Helping reduce suffering:** acting in accordance with fundamental duties, founded on solidarity, and humanity, to help those in need or suffering from disease; and
- **Fairness:** including both duties of non-discrimination in the treatment of others, and of the equitable distribution of benefits and burdens.

In many cases these values will pull in the same direction, suggesting a clear course of action. In cases where this is not possible, determining whether or not to conduct research will require careful, appropriately inclusive and transparent deliberation, independent review, and explanation. While the value of helping reduce suffering will always be important, considerations of what is fair, and what shows equal respect, must also influence the way research is conducted.

The three values provide a tool for thinking through whether ethical principles routinely applied to certain kinds of research, such as standards for informed consent, requirements for ethical review, and the importance of meaningful community engagement, might legitimately be adapted. Possible approaches include:

- interpreting standard principles in the light of the features of the emergency;
- recognising additional principles from partners' ethical traditions or in response to local needs; and
- taking action to strengthen other parts of the 'ethics ecosystem' where it is recognised that standard principles (such as informed consent), while still important, cannot provide the degree of protection required.

Such decisions may need to be taken on a case-by-case basis with respect to the features of the emergency, guided by consideration of the values.

At a policy level, the three values of fairness, equal respect, and helping reduce suffering underpin the approach that ‘duty-bearers’ such as governments, funders, employers and others need to take to enable and support ethical research during emergencies. This also includes duties to plan for the future, to minimise or even prevent the impact of future emergencies through strengthening health and health research systems.

## Introduction

- 4.1 The contexts in which global health emergency research takes place are diverse, complex, dynamic, and time-pressured. Despite these complexities, research is urgently needed for many aspects of emergency response in order to establish a robust evidence base for effective interventions in future emergencies. Indeed, in the absence of such evidence, there are strong ethical arguments in favour of research to obtain it: *not* doing research is not necessarily the ‘safer’ option given the benefits of providing better and safer care both now and in the future.
- 4.2 All health-related research has an ethical dimension, but the design and conduct of research in emergency settings presents a range of difficult ethical problems and questions not otherwise encountered in combination or with such intensity. This chapter seeks to identify and analyse what is required for the successful, politically-informed, culturally-appropriate, and sustainable conduct of such research against a background of well-founded public trust and confidence. For the results of this analysis to inform carefully justified research practice, we present an ‘ethical compass’ to guide considerations, both at practical and policy level.
- 4.3 There are several reasons why the working group concluded that the development of such a compass would be helpful and timely. Given the radically non-ideal circumstances, and the combination of urgency and uncertainty, ethical confusion in these circumstances is endemic. Paradoxically, perhaps, this confusion can itself be intensified by the large number of ethics frameworks, guidelines, and statements with some bearing on these situations (see paragraphs 1.22–1.30 and Appendix 4). A key feature of research and response activities in global health emergencies is cooperation and collaboration between many different actors and organisations (see paragraph 1.8 and Chapter 3). Many of these organisations and institutions have their own ethics frameworks for their workers and activities. Those seeking to work cooperatively together in the field may therefore be accountable to a range of different and sometimes competing ethical guidelines and frameworks. There is no single, readily-available off-the-shelf professional or institutional ethical framework or toolkit for use in such settings that benefits from widespread recognition and acceptance, despite recent valuable initiatives.<sup>344</sup> **An approach to ethics capable of offering the basis for a shared way forward in these deeply challenging contexts is required.**

<sup>344</sup> See, for example, the Global Code of Conduct for research in resource-poor settings which provides such a tool for research in non-emergency contexts: TRUST (2018) *Global code of conduct for research in resource-poor settings*, available at: <http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf>; WHO guidance on infectious disease outbreaks: WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available

4.4 A similar complexity characterises international, regional, and local ethics guidelines and frameworks even within the specific sphere of bioethics. The proliferation of guidance leads to overlaps, inconsistencies, and contradictions, while also leaving gaps (see paragraphs 1.22–1.27 and Appendix 4). Research in global health emergencies calls for collaboration between organisations with competing ethical commitments. It also involves the coordination of activities with ethical dimensions that have been conceptualised differently. These include:

- public health, with its focus on community needs and interests;
- clinical medicine, concerned with the health needs of individual patients and associated responsibilities of health professionals;
- medical research, with its focus on protecting the interests of participants while maximising scope for benefit of all patients in the future;
- social science research, concerned with understanding the diversity of people’s experiences and perspectives;
- health systems research, exploring how changes in the way services are provided can improve care;
- global health, concerned with questions of unfair and avoidable health inequalities, and the duties and responsibilities of national and international actors;
- humanitarian activities, governed by the humanitarian imperative to give and receive humanitarian assistance; and
- initiatives informed by a commitment to One Health, with its additional focus on environmental factors and animal health.<sup>345</sup>

4.5 It is important to recognise that the ways in which these ethical approaches have been conceptualised has traditionally been very much driven by researchers in the West. While a number of international guidelines do explicitly set out to provide universally applicable ethical principles,<sup>346</sup> this is contested by some. These objections may be on the basis that moral principles are simply not universally shared, or because the way in which the selected values or principles have been interpreted and codified has been too influenced by individualistic attitudes dominant in the West, particularly regarding understandings of autonomy.<sup>347</sup> Even the literature specifically focusing on global health ethics has to date been heavily dominated by researchers from high-income institutions.<sup>348</sup> As an international working group, we have sought to be alert to this bias, and to the relevance of other traditions, as we explore specific aspects of the ethical conduct of research, and in particular requirements for informed consent.

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at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>; and the ethics framework and toolkit developed by the research funder Elrha: Elrha (2017) *Research ethics tool*, available at: <https://www.elrha.org/researchdatabase/r2hc-research-ethics-tool/>.

<sup>345</sup> See, for example, WHO (2015) *Global health ethics: key issues*, available at: [https://apps.who.int/iris/bitstream/handle/10665/164576/9789240694033\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/164576/9789240694033_eng.pdf?sequence=1); Luyckx V, Biller-Andorno N, Saxena A *et al.* (2017) Health policy and systems research: towards a better understanding and review of ethical issues *BMJ Global Health* 2: e000314; Gopichandran V, Luyckx VA, Biller-Andorno N *et al.* (2016) Developing the ethics of implementation research in health *Implementation Science* 11(1): 161; and Johnson J, and Degeling C (2019) Does One Health require a novel ethical framework? *Journal of Medical Ethics* 45(4): 239-43.

<sup>346</sup> See, for example, the CIOMS guidance which make explicit reference to the universality of the ethical principles on which they are based: CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>.

<sup>347</sup> See, for example, Ryan MA (2004) Beyond a western bioethics? *Theological Studies* 65(1): 158-77; Durante C (2008) Bioethics in a pluralistic society: bioethical methodology in lieu of moral diversity *Medicine, Health Care and Philosophy* 12(1): 35-47; Chattopadhyay S, and De Vries R (2013) Respect for cultural diversity in bioethics is an ethical imperative *Medicine, Health Care, and Philosophy* 16(4): 639-45; and IOD PARC (2019) *Ethical standards rapid literature review*, available at: [https://assets.publishing.service.gov.uk/media/5d5e3df5ed915d08d612d835/DFID\\_Ethics\\_Literature\\_Review\\_FINAL\\_30\\_05\\_19.pdf](https://assets.publishing.service.gov.uk/media/5d5e3df5ed915d08d612d835/DFID_Ethics_Literature_Review_FINAL_30_05_19.pdf).

<sup>348</sup> Robson G, Gibson N, Thompson A *et al.* (2019) Global health ethics: critical reflections on the contours of an emerging field, 1977–2015 *BMC Medical Ethics* 20(1): 53.



- 4.6 In addition to these competing professional, institutional, regulatory, and conceptual ethical traditions, global health emergencies affect people and communities who will themselves be committed to cultural, religious, social, and other values of direct ethical and moral significance for the conduct of research. This would include, for example, the professional codes of traditional birth attendants or other traditional health workers,<sup>349</sup> alongside diverse understandings of community and family obligations and the role of the individual (see Box 4.1). Thus, in addition to the absence of a shared set of ethics guidelines for those working in humanitarian crises, there is no off-the-shelf conceptual framework to enable reflection on the ethical dimensions of such a multifaceted set of response and research activities.

#### Box 4.1: Examples of social and cultural values of ethical significance in research

Responses to our call for evidence and other forms of evidence-gathering highlighted a number of ways in which local cultural traditions and attitudes have ethical significance in health-related research. These include:

- traditions of care and ways of expressing love and respect, including rituals of touching and washing deceased family members to honour them;
- meanings, attachments, and stories associated with blood;
- differing approaches to what constitutes appropriate compensation and hospitality, for example when people give their time to contribute to research; and
- the role of the wider community with respect to individual choices.

- 4.7 We have drawn upon the experiences and evidence shared by those who contributed to our inquiry, and the different ethical traditions and conceptual approaches engaged, to identify some of the shared values that might provide an ‘ethical compass’ for those working in this field. Before presenting these values (see paragraphs 4.32–4.61), we explore two important considerations that have influenced how these values have emerged: first a consideration of the range and breadth of ethical challenges that arise during research in global health emergencies; and second an account of the conceptual approaches that could be taken to the question of ‘what is different in an emergency?’

## Identifying the questions

- 4.8 The broad question that this report addresses is: ‘what constitutes the ethical conduct of research in global health emergencies?’ Addressing this overarching question in a particular emergency requires us to answer a series of more concrete and focused questions, some of which have been noted in earlier chapters. These questions include:
- Who is affected by the emergency and by the possibility of research being conducted in connection with that emergency? Who are the core actors in addition to those directly affected – for example governments, humanitarian responders, research funders, and intergovernmental organisations? (See Chapter 3.)
  - How and by whom should decisions be made about what research should be conducted, where, and how?

<sup>349</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>, at page 26.

- What is the fair treatment of those whose lives, health and livelihoods are at risk as a result of the emergency? What voice should they have in decisions about the conduct of the research, and on what basis? What weight should be given to competing voices?
- What ethical criteria should inform the recruitment of potential research participants, and the way their consent to participate is sought? Is it right to exclude certain groups or individuals, such as pregnant women or children from the opportunity to participate?
- How should research participants be treated? For example, is it right to use randomised controlled trials in the context of a health emergency, particularly where standard care options are limited or non-existent? There are strongly held and conflicting views both as to whether such trial designs can be ethically implemented, and whether providing unproven treatments outside the research context can be justified.<sup>350</sup> What is owed to participants by virtue of their participation, whether at the time or in the future? Do those conducting research have an obligation to inform participants what their research has found? Is there an ongoing duty to provide access to interventions that prove effective? How about those who have been excluded from research participation?
- How should the front-line workers responsible for conducting the research be treated? This raises questions concerning the nature of fair pay, especially where local and international staff are working side-by-side. What duties of care are owed to workers both during the period of the research and afterwards, including for healthcare provision, protection, and support?
- What is the appropriate relationship between research and the provision of care, particularly in struggling healthcare systems? We noted in Chapter 2 the strong arguments in our community engagement workshop in Dakar: that research is ethically impermissible if very basic care needs are not being met (see paragraphs 2.29–2.31). At the same time, it was also recognised that there can be a tension between this claim and the possibility that good quality care related to the emergency may not be possible precisely because of the lack of research. This question becomes particularly acute where lack of funding for health systems is a key factor in the health emergency arising in the first place (see paragraph 3.1).<sup>351</sup>
- What is the proper division of resources between research in a global health emergency and other pressing needs, whether relating specifically to research or to action? There are other key moral challenges – such as eradicating global poverty, combatting climate change and biodiversity loss, and addressing future antimicrobial resistance – which do not fall under the heading of a global health emergency as used in this report. What criteria should determine how much scarce resource should be devoted to research in a global health emergency as opposed to these other important social goods? And whose perspectives are being considered in these funding decisions? Who is framing what research or what services are important to whom?
- How should different kinds of research be prioritised within the budget that funders allocate to research in emergencies, and on what basis? For example, what relative

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<sup>350</sup> See, for example, Adebamowo C, Bah-Sow O, Binka F *et al.* (2014) Randomised controlled trials for Ebola: practical and ethical issues *The Lancet* **384(9952)**: 1423-4, at page 1423. They argue that where the likelihood of survival is very low and there is no other alternative solution, then it is immoral to give a drug to some and a placebo to others.

<sup>351</sup> See: Nunes J (2016) Ebola and the production of neglect in global health *Third World Quarterly* **37(3)**: 542-56.

priority should be given, where appropriate, to supporting low-tech local innovation, or for improving supportive care within local infrastructure, versus the priority given to high-tech innovations developed in high-income countries (HICs) which may work very effectively but rely on sophisticated infrastructure to deliver?

- Can it ever be morally acceptable to respond *without* research / data collection where there is genuine uncertainty about the effectiveness of interventions?
- How should the many different forms of data and samples collected during research be treated? Who is the owner or custodian of the data and samples, and who should manage, store, and have access to them? How widely available should they be made?
- More generally, what are the fair terms of social cooperation for the production and dissemination of research, including fair cooperation between institutions in high- and low-income settings, and fair opportunities for all the researchers involved?

4.9 We come back to many of these more detailed questions throughout our report, as signposted in the discussion below. However, we also recognise that there are some fundamentally ethical questions that we simply cannot address in this report, but which should be acknowledged: not least because many triggers for global health emergencies are themselves fundamentally unethical, particularly in the case of conflict.

4.10 Two further considerations need to be borne in mind when identifying the values necessary to approach these questions. The first is that thinking about research in global health emergencies requires us to think about the ethical treatment of a variety of groups, whose needs and interests may diverge. There are, at least, four groups of people who need to be considered:

- affected populations (those whose lives, health, and livelihoods are threatened by the emergency);
- people within those populations who take part in research;
- front-line research workers; and
- potential beneficiaries of the research.<sup>352</sup>

4.11 The second consideration is that, when we look at *who* may potentially have *what* responsibilities, there will be a variety of different bodies and individuals who could be conceptualised as 'duty-bearers'. As we indicated in Chapter 3, relevant duty-bearers might include:

- national governments, including local health systems and local health practitioners;
- local, national, and international NGOs;
- community leaders;
- major funders, including the private sector;
- research ethics committees (RECs);
- international organisations such as the World Health Organization (WHO) and its regional offices, and other United Nations (UN) agencies;
- research institutions; and

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<sup>352</sup> Potential beneficiaries will include current generations and future people, and both those local to the research site, and those living elsewhere in the world. The number of people who fall into this category will, thus, be very large.

- academics, and academic professional bodies. [This list is non-exhaustive.]

All the above can have an impact on the conduct of research in global health emergencies and so all have a role to play. We say more about the nature and scope of these responsibilities at the end of this chapter (see paragraphs 4.64–4.71).

## What difference does an emergency make? – conceptual approaches

- 4.12 A pressing question that this report was asked to address is “whether there are circumstances in which the standard ethical requirements for the scrutiny and conduct of research should differ in emergencies; and if so, in what way, and with what justification?”<sup>353</sup> As we have illustrated above, however, this question is complicated by the impossibility of pinning down a single set of ‘standard ethical requirements’ that apply in *non-emergency* research (see paragraphs 4.3–4.6 and Appendix 4).
- 4.13 While perhaps the best-known and most widely applied guidelines for health-related research may be the Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) guidelines, these primarily cover biomedical research, just one of many research sectors relevant in a global health emergency. Moreover, even in this sphere, the way these guidelines are operationalised and understood will be dependent on the regulatory framework to which the relevant funding body is subject, such as the US Revised Common Rule,<sup>354</sup> in addition to the locally applicable legal, professional, and cultural requirements. Health researchers from different academic disciplines, those conducting interdisciplinary, operational or implementation research, and those engaging in any form of evidence generation within the humanitarian sector, will look to many other sources setting out ethical requirements or providing ethical advice, again subject to national law and the requirements of funding bodies (see paragraphs 1.22–1.25 and 1.28–1.29)
- 4.14 Those seeking to work cooperatively in an emergency are thus likely to have significantly different expectations of ‘standard’ ethical conduct (for example regarding the role of independent scrutiny, the proper approach to informed consent, and the question of when and how data obtained from research participants may legitimately be shared). This diversity of approach is complicated further by potentially conflicting jurisdictions, and possible cultural insensitivities embedded in imported ethical traditions or regulatory approaches. Those working in this field are also subject to diverse governance and accountability arrangements, funding regimes, and terms of employment, all of which have implications for the ethical conduct of any resulting research.
- 4.15 If those working in these different professional and organisational silos are to operate effectively together to provide meaningful evidence to improve future emergency response, then the ‘standard’ ethical approaches of some will have to be amended to avoid incompatibility with those of key partners. Yet the dangers of moving away from well-established ethical principles and practices in any field are substantial. Indeed, a common feature in emergencies is that there can be increased pressure to cut corners, based on the argument that extremity justifies treating generally-applicable standards

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<sup>353</sup> Terms of reference, at page ix.

<sup>354</sup> US Department of Health and Human Services (2019) *Office for Human Research Protections: regulations*, available at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html>.

and rights as dispensable.<sup>355</sup> Thus it is essential that the basis for, and the manner of, any such divergence is carefully justified, underpinned by shared values, and widely supported.

- 4.16 In order to identify such an approach, we first outline three possible responses to the question of whether an emergency calls for different ethical principles, simplifying considerations by initially considering these responses in the light of examples of single, rather than competing, ethical frameworks (paragraphs 4.17–4.27).<sup>356</sup> We then put forward our arguments for a combined approach, drawing on aspects of all three of these responses (paragraphs 4.28–4.30). Supporting and underpinning this approach, we then put forward our proposed ‘ethical compass’ (paragraphs 4.32–4.61).

### First response: the ‘identical principles’ response

- 4.17 One response says that the principles that would normally guide health-related research should also apply in the same way during a global health emergency. For example, it might be argued that the requirement that biomedical research proposals are always subject to independent ethical scrutiny before going ahead should apply during emergencies, just as they do during normal medical research. In employment, ethical duties to consider the welfare of front-line researchers and ensure they are not exploited should apply during emergencies just as they do in non-emergency settings: there is no reason to deviate from or dilute the principle just because it is an emergency. With publishing, it might be argued that the duty to publish findings where a novel intervention does *not* work applies in the context of global health emergencies in the same way.<sup>357</sup> It is important to emphasise that such an ‘identical principles’ approach does not necessarily imply identical *processes*: the way in which high level principles are operationalised into practical processes, as, for example, with the operationalisation of the principle of informed consent into culturally-sensitive and meaningful consent processes, should always be appropriate to context (for further discussion of this question in the context of consent, see Chapter 7).
- 4.18 The first response says, then, that the fact that we are facing an emergency does not give us reason to abandon or revise the ethical principles that would normally inform the conduct of health-related research. To explore this further, it may be helpful to ask what

<sup>355</sup> In addition to this, there are, of course, many examples from contemporary politics and history where leaders have invoked an emergency in order to bypass standard democratic procedures and constitutional requirements. For discussion, see: Honig B (2009) *Emergency politics: paradox, law, democracy* (Princeton, New Jersey: Princeton University Press); and Scarry E (2011) *Thinking in an emergency* (New York and London: WW Norton and Co.). See also: Sumathipala A, Jafarey A, Castro L *et al.* (2010) Ethical issues in post-disaster clinical interventions and research: a developing world perspective. Key findings from a drafting and consensus generation meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007 *Asian Bioethics Review* **2**(2): 124-42.

<sup>356</sup> There is an extensive body of work on emergencies and their implications for ethics and political principles. For example, the question of what to do in an emergency is discussed in just war theory. See: Walzer M (1977) *Just and unjust wars: a moral argument with historical illustrations* (Middlesex: Penguin) on his argument that in a “supreme emergency” conventional rules of how to wage war (such as non-combatant immunity) are suspended. The concept of “emergency powers” is also discussed in Lazar N (2009) *States of emergency in liberal democracies* (New York: Cambridge University Press). For discussions of ‘emergency ethics’, see: Sorell T (2013) *Emergencies and politics: a sober Hobbesian approach* (Cambridge: Cambridge University Press); and Zack N (2009) *Ethics for disaster* (Lanham, Maryland: Rowman & Littlefield Publishers). For reflections on the ethical and political dimensions of invocations of an emergency, see: Rubenstein JC (2015) Emergency claims and democratic action *Social Philosophy and Policy* **32**(1): 101-26; Honig B (2009) *Emergency politics: paradox, law, democracy* (Princeton, New Jersey: Princeton University Press); and Scarry E (2011) *Thinking in an emergency* (New York and London: WW Norton and Co.). In much research on emergencies, the work of Carl Schmitt plays a critical role: see, for example, Schmitt C (2005 [1922]) *Political theology: four chapters on the concept of sovereignty* (Chicago: University of Chicago Press), translated and with an introduction by George Schwab, with a foreword by Tracy B. Strong.

<sup>357</sup> WHO (2017) *Joint statement on public disclosure of results from clinical trials*, available at: <https://www.who.int/ictpr/results/jointstatement/en/>.



reason could be given to depart from standard practice. Two good reasons might be given:

- First, one good reason for departing from standard practice would be that it is not *possible* to adhere to the standard principles in a particular emergency. As discussed above, this would arise where professionals or organisations working together were guided by principles that were incompatible in one or more significant ways.
- A second good reason would be that it would be *harmful* to adhere to the standard principles in an emergency.

However, where it is possible to adhere to the standard principles and where adhering to them in an emergency does not have harmful implications *then* it would follow, according to this first response, that we should stick to these standard ethical principles.

- 4.19 The first reason for deviating from standard ethical principles refers to what it is 'possible' to do during a global health emergency. Two further points are worth noting about the concept of possibility. First, global health emergencies may differ considerably, and it would be wrong to assume that what is not possible in one context is also *necessarily* not possible in others. As emphasised above, it is important to pay heed here, as elsewhere, to the very different contexts in which research is taking place (see also paragraph 4.17).
- 4.20 Second, it is important to bear in mind that what is 'possible' or not 'possible' at one time is not necessarily set in stone, and, in some circumstances, is likely to depend on what measures were taken beforehand. For example, it might not be possible, in one sense, for a national ethics committee to deal effectively with the volume of requests made during a global health emergency. However, it might have been 'possible' if earlier preparatory action had been undertaken. So, what is 'possible' during a global health emergency will depend in part on what kinds of anticipatory action have been taken, and underscores the importance of forward-thinking. We return to the need for forward-looking policies below (see paragraphs 4.62–4.63). Similarly, what is impossible at one point in an emergency might become possible at later stages, for example as a result of supportive measures.

## **A second response: the 'interpretive' response**

- 4.21 A second response to the challenges posed by global health emergencies to the use of standard ethical frameworks distinguishes between *fundamental or standard principles* on the one hand, and *interpretations of those principles* on the other. The fact that there is an emergency does not in itself call for rejecting or abandoning these standard principles. However, the interpretive response then adds that the ways in which these principles are *interpreted* might need to vary in emergencies. That is to say, that whilst we might think that a particular interpretation of a principle would be best in normal circumstances, in an emergency the same interpretation may simply not be possible. The interpretive approach then says that what we should consider is: 'what is the best interpretation of that fundamental principle that is possible to implement in these difficult circumstances?' It is important to emphasise that this is different in kind from the way principles need to be 'operationalised' into practical processes, which should always be sensitive to the particular context (see paragraph 4.17). For example, expediting the process of ethical review during an emergency – by prioritising particular protocols that are more urgent, arranging additional meetings, or facilitating online discussions by committee members – does not involve any interpretation of the principle that research must be thoroughly and independently reviewed before it can go ahead. The process



might be faster and more flexible than standard operating procedures, but the aim is to achieve the same degree of scrutiny.

- 4.22 One way of illustrating the point in the context of global health emergencies would be to consider the role of community engagement. The role of community engagement in the development of study design is increasingly recognised as an essential feature in the ethical conduct of many forms of health research, to ensure that the way in which research will be conducted is both locally acceptable and culturally sensitive.<sup>358</sup> In some emergency contexts, however, it may be simply impossible to develop the trust-based relationships required for in-depth and extensive engagement from the very beginning. In such cases (and assuming that there is a strong enough justification for the research to take place), the interpretive response might allow the principle of community engagement to be interpreted by developing engagement processes as early as possible during the research process, and keeping design questions as open as possible to enable adjustments along the way in response to learning.<sup>359</sup> Of course, we often engage in the interpretation of principles in non-emergency cases. The suggestion here, however, is that in addition to these cases, interpretation may play a valuable role in emergencies when the ideal may be out of reach. When the maximal interpretation of a principle (such as community engagement) may not be feasible, the interpretive response calls for us to articulate the best interpretation of the principle that can be realised in the context of a global health emergency.
- 4.23 As this example implies, one important caveat is that there will be limits to just how much one can *interpret* a fundamental principle. There will be a minimum that must be satisfied for it to count as a legitimate interpretation of the basic idea. Some proposals for interpreting ‘community engagement’ or ‘consent’, for example, may run the risk of emptying the ideas of any content and making them empty gestures.

### A third response: the ‘different principles, or different weighting of the same principles’ response

- 4.24 A third kind of response to the question ‘what is different in emergencies?’ takes the following form: it says, ‘Normally we should adhere to certain principles, but it is not possible to do so in certain contexts. In these circumstances, we need either to be guided by additional ethical principles (the ‘different principle’ option) or to put extra emphasis on other (existing) principles (the ‘different weighting’ option) or both’.
- 4.25 One example of this approach in biomedical research permits alternatives to consent for adults who are temporarily unable to provide consent to research for themselves, for example because they are unconscious after an accident.<sup>360</sup> In such cases, it is recognised that there is no prospect of the potential research participant being able to provide consent, and so in this exceptional case someone close to them, who can

<sup>358</sup> WHO (2016) *Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP): outcome document of the consultative process*, available at: <https://www.who.int/blueprint/what/norms-standards/GPP-EPP-December2016.pdf>.

<sup>359</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>360</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guideline 16. See also: Millum J, Beecroft B, Hardcastle TC *et al.* (2019) Emergency care research ethics in low-income and middle-income countries *BMJ Global Health* 4 (supplement 6): e001260 for an overview of regulatory provisions of such ‘emergency care’ research in LMICs.

reasonably be assumed to have their interests at heart, may be asked to provide permission on their behalf. In normal circumstances, this would not be regarded as acceptable for competent adults: permitting participation in this way thus reflects acceptance of an additional principle in the emergency context (what we call above the 'different principle' option).

- 4.26 This example also illustrates the role of what we are terming 'the different weighting' option, and the potential interplay between the two parts of this third response. Permission by a relative is not regarded as sufficient on its own as a direct replacement for informed consent by the participant: ethical guidelines often impose additional requirements. These might specify, for example, that the research must be addressing an important question for the care of people in the same or similar situation to the unconscious participant, and cannot be conducted with conscious participants. They might also require that active support for the aims and methods of the research has been demonstrated through stakeholder engagement. In other words, it is recognised that a relative's permission is unlikely to do the same degree of 'moral work' as informed consent given personally by participants. When this is the case, more weight than normal will need to be placed on other parts of the ethics 'ecosystem', with the aim of achieving the same overall protections for research participants as those provided in non-emergency contexts.
- 4.27 Such strengthening of the ethics ecosystem may also be required even where additional principles or protections are not being introduced. The features of a global health emergency – in particular the likelihood that those most directly affected may have limited or no other options open to them – may mean that standard ethical requirements, however carefully followed, cannot achieve the same degree of protection of participants' interests as they would in non-emergency circumstances. More 'moral work' thus then needs to be achieved by other parts of the system, for example through more careful and rigorous scrutiny of the responsibilities of those in positions of power and authority. To use an employment example, a person might agree to work for an extremely low fee as a front-line researcher. They may do so because they are in extreme poverty and have no other reasonable options. It would be unacceptable to conclude from this that they consented to the low salary in any meaningful way, and so are not entitled to anything better. Those employing front-line researchers have ethical duties to those that they employ – including duties of 'fair pay' and 'due care' – that go beyond this purely contractual approach.<sup>361</sup>

## Combining the responses

- 4.28 We began this chapter by highlighting that research endeavours in global health emergencies call for the establishment of partnerships between different types of actors (including researchers, institutions, and health professionals). Each of these actors brings with them ethical guidelines, frameworks, and principles with a bearing on the conduct of the research and the context in which the collaborative effort takes place. We also noted that such initiatives involve a range of different, complementary activities that have often been the focus of ethical analysis and the development of normative frameworks, which may differ in important respects. In order to find a way forward for ethically robust research in these circumstances, elements of all three of the responses outlined above will be required.

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<sup>361</sup> See, for example, the discussion of the idea of a 'fair offer' in Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/project/children-research>, paragraphs 5.28-9.

4.29 Where it is possible, and not harmful, for researchers to follow in full the guidelines that would usually govern their work, this should be standard practice in emergency contexts. Where this is *not* possible (for example because of conflicting principles or governance arrangements between partners), or where there is reasonable cause for concern that this approach could be harmful, then there are a number of ways in which the second and third responses could be used, whether separately or in combination. For example:

- Principles may be common to all relevant frameworks, but need interpretation for the context, for example in order to avoid harm to participants, research workers, or the research itself.
- Other principles may differ between frameworks, but consensus may be achieved by particular interpretations.
- Still other principles will compete, and hence any agreed way forward will represent acceptance of what is a 'new' principle for some: for example, adding in a local requirement that would not be usual practice for partners from another culture or country. The use of community-level consent in addition to individual participant consent provides one example of an additional principle that has become widely accepted outside the emergency context in research in many settings, although it would not be recognised (or indeed necessarily thought acceptable) in many countries in the West.<sup>362</sup> Acceptance of principles that are new to some partners in the research may also involve a degree of interpretation on the part of the other partners.
- Finally, there may be circumstances where particular principles, however widely shared and endorsed, simply cannot do the necessary 'moral work' in a global health emergency, and so relevant duty-bearers need to rely more heavily on other parts of the ethics ecosystem to protect the interests of participants and others. As we discuss in Chapter 7, this may particularly apply in order to ensure participant interests are protected in circumstances where people might feel they have few choices but to consent to research participation.

## How to proceed

4.30 Such a 'combined approach' to the range of possible responses to any existing set of frameworks or principles critically requires two further elements:

- the identification of underpinning, and widely shared, values to guide decisions on whether and how to interpret principles, import additional principles, or put additional weight on existing principles; and
- a respectful and inclusive approach to deliberation regarding appropriate and context-sensitive solutions in cases where it is harmful or impossible to adhere to standard principles.

4.31 We now turn to our proposals for an 'ethical compass' to help achieve these aims, and to analyse the important questions (set out in paragraph 4.8) which need to be addressed in any useful approach to ethical research in global health emergencies.

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<sup>362</sup> See, for example, Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries*, available at: <http://nuffieldbioethics.org/project/research-developing-countries>.

## An ethical compass: introducing the core values

- 4.32 Three 'core' or 'guiding' values emerged in our deliberations.<sup>363</sup> We begin by briefly introducing these guiding values, and then provide a more fully-developed overview as we explore their implications for research in global health emergencies.
- 4.33 We conclude by highlighting the moral importance and urgency of advance planning for global health emergencies (see paragraphs 4.62–4.63) and by outlining in broad terms which kinds of responsibilities fall to which duty-bearers (see paragraphs 4.64–4.71).

## Equal respect for persons

- 4.34 We begin with the widely-recognised duty to treat people with respect, as moral equals (see paragraphs 2.4–2.22). This includes respecting and protecting their dignity, agency, humanity, and human rights. It also includes duties to justify policies to those affected, to listen to people's concerns and take them into account (public justification). Equal respect for persons is incompatible with ignoring or riding roughshod over people's point of view, and simply imposing one's own. Respect here requires an openness and willingness to engage in dialogue and deliberation, on terms of equality and equal recognition. This focus on equality of respect can also be expressed as mutual respect, emphasising the two-way nature of these relationships.
- 4.35 Another closely related feature of treating people with respect is being sensitive to cultural plurality and diversity. This has added importance in contexts where researchers may be unfamiliar with cultural norms, or the resonance of the locality or region's history. This may arise where researchers from HICs are engaging in research in low- and middle-income countries (LMICs) that have been subject to colonialism and imperialism, in research with populations that are currently vulnerable and lack political power, or in situations where there have been mass movements of people, whether for reasons of violence, political disruption, or economic need. It may also arise for researchers working in their home countries, given the scope for cultural plurality and diversity within nations and regions.

## Helping reduce suffering

- 4.36 There are fundamental duties, founded on solidarity and humanity, to aid those in need and to assist those suffering from disease (and other sources of suffering such as poverty or malnutrition). In the context of health research, an important element of this duty lies in the contribution research can make to improving the effectiveness of emergency response, both at the time and for the future.

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<sup>363</sup> Although they were not derived directly from any particular source, these three values resonate with a number of established accounts of ethics, including Beauchamp T, and Childress J (1994) *Principles of biomedical ethics*, Fourth Edition (New York: Oxford University Press); Kant I (1997[1785]) *Groundwork of the metaphysics of morals* (Cambridge: Cambridge University Press); and the emphasis on the 'primacy of the human being' in Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, available at: <https://rm.coe.int/168007cf98>. For a discussion of how these relate to traditional Chinese bioethical principles, see: Tsai DF (1999) Ancient Chinese medical ethics and the four principles of biomedical ethics *Journal of Medical Ethics* **25(4)**: 315-21. For discussion of how they relate to African bioethical principles, see the 2018 special issue on African perspectives in global bioethics, in *Developing World Bioethics* **18(3)**, available at: <https://onlinelibrary.wiley.com/toc/14718847/2018/18/3>. See also: Sachedina A (2009) *Islamic biomedical ethics principles and application* (Oxford: Oxford University Press).

## Fairness

4.37 Closely related to, and to some extent arising out of the duty to treat people with respect as moral equals, is a requirement for fairness throughout the research process. One important aspect of this is non-discrimination both in the making of practical and policy decisions and in ensuring proper inclusivity in communication and dialogue (see paragraphs 4.34–4.35). Another important element of fairness is ‘distributive justice’ which is concerned with the equitable distribution of burdens and benefits.<sup>364</sup> This is highly relevant in this context because what is at stake includes:

- fairness in the prioritisation of research and consideration of whose interests are being served by that research;
- fairness in the design of research, including inclusion criteria;
- fairness in the recruitment and treatment of research participants;
- fair treatment of front-line researchers and of other local collaborators; and
- a fair distribution of the benefits of research conducted.

## Taking context seriously

4.38 An ethically robust account of research in global health emergencies must recognise the importance of context when applying these three values. This is, in part, a corollary of the principle of equal respect. Respecting persons requires taking people’s practices, traditions, and values seriously and being aware of, and sensitive to, prevailing assumptions and norms. It requires listening to people and not issuing top-down edicts. It requires what Miranda Fricker terms ‘epistemic justice’.<sup>365</sup> Fricker distinguishes between two kinds of epistemic injustice, one she terms “testimonial injustice”: this refers to situations in which some disregard and dismiss the testimony of others because of their social identity.<sup>366</sup> It is important that research programmes (and those involved in them) exhibit the virtues of testimonial justice. This includes being alert to the power imbalances within communities, and finding ways to hear from those routinely marginalised or excluded within communities (see paragraphs 5.31–5.32).

4.39 In addition, it is vitally important to be aware of, and sensitive to, the historical record (for example, histories of colonisation, and narratives of paternalistic imperialism as well as histories of oppression, marginalisation, and conflict within affected communities) and to take active steps to address distrust and concerns arising in that context. Doing so is part of treating people fairly and with equal respect; moreover, it is also often crucial for the trust and support needed for research to be carried out in ways which promote scientific understanding and the alleviation of suffering.

4.40 Difficult decisions about the application, reinterpretation, or revision of standard ethical principles will need to be taken at many points and by many actors in the research

<sup>364</sup> For a canonical treatment of distributive justice, see: Rawls J (1971) *A theory of justice* (Oxford: Oxford University Press). Principles of distributive justice are routinely applied to many specific policy areas (such as health, migration, trade, natural resources, education, energy, climate change, the family, and so on). For the application of principles of distributive justice in the context of health, see: Daniels N (1985) *Just health care* (Cambridge: Cambridge University Press); Segall S (2010) *Health, luck, and justice* (Princeton and Oxford: Princeton University Press); and Venkatapuram S (2013) *Health justice: an argument from the capabilities approach* (Cambridge: Polity).

<sup>365</sup> See: Fricker M (2007) *Epistemic injustice: power and the ethics of knowing* (Oxford: Oxford University Press). The second kind of epistemic injustice identified by Fricker is what she calls “hermeneutic injustice”: this occurs when an oppressed group lacks a concept that captures their oppression/ill-treatment adequately. See also: De Sousa Santos B (2016) *Epistemologies of the South: justice against epistemicide* (London and New York: Routledge).

<sup>366</sup> Fricker M (2007) *Epistemic injustice: power and the ethics of knowing* (Oxford: Oxford University Press), especially chapters 2-6.



process. The particular emphasis we have placed on the importance of context in our deliberations, however, brings to the fore the particular importance of not overlooking the professional dispositions and character traits (virtues) of those conducting research 'on the ground'.<sup>367</sup> All moral principles and ethics frameworks require interpretation in practice. For those undertaking the difficult day-to-day work of research in emergency settings, virtues provide guidance and an orientation to action, but also involve interpretation and judgment and a sensitivity to context, rather than the rigid application of a set of rules or algorithms. Especially in the context of global health emergencies where, as we have noted (see paragraphs 4.3–4.6), there is a multitude of competing ethical traditions and frameworks, the virtue of practical wisdom (the ability to discern how to achieve the good that is aimed at) becomes a necessity. Virtues cannot simply be assumed to be present as part of good professional conduct: the structures to support them need to be in place in the cultures of the organisations and institutions involved in global health emergencies and humanitarian crises. We discuss these structures further in Chapters 7 and 10.

- 4.41 Having introduced these three core values (equal respect, helping reduce suffering, and fairness) and having noted different ways in which standard ethical principles might be applied, reinterpreted, or revised in the context of global health emergencies, we turn now to consider what the three core values mean in practice. The aim is to develop the three values more fully (moving from abstract formulations to more concrete norms) and to do so in ways that respond to the challenges that can arise in the context of global health emergencies.

## Using the core values in emergency contexts

### Equal respect

#### ***Equal respect, community engagement, and consultation***

- 4.42 First, equal respect for persons requires that those planning research should engage respectfully with those whose lives are affected.<sup>368</sup> This could be put in terms of procedural justice: the decision-making process needs to enact respect for the rights of those affected through inclusion and involvement. People have a right to inclusion.
- 4.43 There are various levels of communication, engagement, and active involvement. Some possibilities follow, starting with the most minimal and basic, and moving up to the more demanding and ambitious.
- **Information, communication and transparency:** those affected should be informed (in accessible ways) about what is being done, and what the risks are.
  - **Public justification:** those making decisions about research in health emergencies should set out not only what they are doing but why. Those who are affected are owed an explanation or justification for what is going on and why.

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<sup>367</sup> Influential discussions of the virtues include Confucius (*The analects*), Mencius Mengzi, Plato (*The republic*), Aristotle (*Nicomachean ethics*), and Hume (*The treatise of human nature*). More recently, see: Foot P (1978) *Virtues and vices* (Oxford: Blackwell); McDowell J (1979) Virtue and reason *The Monist* **62(3)**: 331-50; and Hursthouse R (1999) *On virtue ethics* (Oxford: Oxford University Press).

<sup>368</sup> See also: the discussion in Adhikari B, Pell C, and Cheah PY (2020) Community engagement and ethical global health research *Global Bioethics* **31(1)**: 1-12.



- **Consultation:** ideally, decision-makers should consult with affected communities. Consultation goes beyond simply informing people and justifying the policies adopted: it is more inclusive and enables affected parties to put forward concerns and make suggestions.
- **Inclusive decision-making:** the most inclusive level of engagement is one in which local stakeholders are not just consulted but take part in decision-making processes with respect to design, implementation, and evaluation. This goes beyond the other kinds of engagement: it involves genuinely inclusive and accountable decision-making. It requires that all reasonable steps are taken to ensure that all those concerned – including those who are the most vulnerable and marginalised – are genuinely included and represented, and the political process is not limited to liaising with elites.<sup>369</sup>

The engagement must be meaningful (and not simply reducible to box-ticking) – a point that we return to in Chapter 5.<sup>370</sup>

- 4.44 One important question concerns who should be included in public engagement. People often refer to ‘stakeholders’: the question then is ‘who has a stake in the process?’ One answer in the political context appeals to a version of what is often called the ‘all affected principle’. Stated roughly, it holds that those whose core interests are fundamentally affected by a political process have a right to some kind of political inclusion.<sup>371</sup> So the criterion then is – are X’s basic interests greatly affected by this? If so, the decision-makers have a duty to reach out and include X in the process (in one or more of the ways outlined above). Various stakeholders will be affected in different ways, depending on factors such as their social position and status within their community, their health, and their experience of research, and will need to be engaged in correspondingly different ways (see paragraphs 5.32 and 5.39).
- 4.45 We make two further comments. First, as was argued above, there is a reason, based on equal respect, for widespread information, consultation, and engagement. However, as respondents to our call for evidence pointed out, and as we noted above, there are also weighty practical and instrumental reasons for doing so.<sup>372</sup> Without such information and consultation, distrust, fear, and resentment can develop and grow.<sup>373</sup>

<sup>369</sup> See also: Sherry Arnstein and others (summarised in: Pratt B (2019) Constructing citizen engagement in health research priority-setting to attend to dynamics of power and difference *Developing World Bioethics* 19(1): 45-60) who similarly distinguish between lay control, partnership, and consultation.

<sup>370</sup> See, for example, “This epidemic [in DRC] will not be brought under control without a really significant shift in the response... Community trust and safety, as well as community engagement and ownership of the response is critical”: Reuters (3 May 2019) *Congo Ebola deaths surpass 1,000 as attacks on treatment centers go on*, available at: <https://www.reuters.com/article/us-health-ebola-who/congo-ebola-deaths-surpass-1000-as-attacks-on-treatment-centers-go-on-idUSKCN1S9161>.

<sup>371</sup> See: Whelan F (1983) Prologue: democratic theory and the boundary problem, in *Nomos XXV: liberal democracy*, Roland Pennock J, and Chapman JW (Editors) (New York and London: New York University Press), pp13-47, especially pp16-9. See also the work of Carol Gould regarding the rights of those affected by the decisions of institutions to democratic input into institutional policies and decisions: Gould CC (2014) *Interactive democracy: the social roots of global justice* (Cambridge: Cambridge University Press).

<sup>372</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>. See also: ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>373</sup> See, for example, Kummervold PE, Schulz WS, Smout E *et al.* (2017) Controversial Ebola vaccine trials in Ghana: a thematic analysis of critiques and rebuttals in digital news *BMC Public Health* 17(1): 642.

4.46 Second, taking equal respect seriously requires taking all reasonable steps to create an environment in which those affected (patients, families, health professionals, and others engaged in the emergency response) have a clear understanding of what to expect from each other and, as a result, have trust in the research process.<sup>374</sup> Such transparency can be achieved through, for example, developing good relationships; not making inflated promises that cannot be kept; keeping people informed throughout the research process; actively seeking to understand and overcome sources of distrust (which may have resulted from histories of colonialism, oppression, and exclusion); and hearing and responding to concerns. It requires building relationships, conducted on equal terms, and creating a context in which those affected have reasonable grounds for trusting those conducting the research. Finally, it involves recognising the limitations of what can be achieved in challenging contexts: while there may be good moral reasons for such limitations, they may still be a legitimate cause of distress that should be acknowledged.<sup>375</sup>

### ***Equal respect and relationships with research participants***

4.47 'Equal respect' also has implications for the treatment of research participants. In particular it grounds the importance of informed consent as a central part of the ethical conduct of research in various fields.<sup>376</sup> Seeking consent in a culturally-appropriate manner is one way of recognising that people are entitled to be treated with a certain dignity and status (this is one of the many reasons why consent matters). They are entitled to decide (for themselves and, where they wish, in consultation with others<sup>377</sup>) whether and how they wish to engage in research; and not have things done 'to' them in ways that are disrespectful to them as moral agents.

4.48 Being alert to the significance of equal respect for consent provides a basis for thinking through the particular challenges of consent in global health emergencies alluded to earlier (see, for example, paragraphs 4.27 and 4.29). Just as a person might 'choose' to accept work in very poor and exploitative conditions when they have no other options, those directly affected by global health emergencies may realistically have few, if any, other options when invited to take part in research. In such circumstances, accessible information about the proposed research, and culturally appropriate ways of seeking and documenting consent are a necessary way of demonstrating equal and mutual respect between researcher and potential participant. However, the moral burden that such consent can bear may be substantially less than in circumstances where people have many alternative courses of action open to them. In these cases, the value of equal respect can act as a guide in thinking through how other aspects of the ethics ecosystem can, in this case, be strengthened to ensure such respect is fully shown. We return to this concept of 'consent and beyond' in Chapter 7. Similarly, the value of equal respect provides a basis for determining whether and how additional principles, such as family

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<sup>374</sup> See, for example, O'Neill O (2018) Linking trust to trustworthiness *International Journal of Philosophical Studies* **26(2)**: 293-300. For an ethnographic account of the role of trust in vaccine research, see: Fairhead J, Leach M, and Small M (2005) Public engagement with science? Local understandings of a vaccine trial in *The Gambia Journal of Biosocial Science* **38(1)**: 103-16.

<sup>375</sup> See, for example, Williams B, and Atkinson W (1965) Symposium: ethical consistency *Proceedings of the Aristotelian Society, Supplementary Volumes* **39**: 103-38; and Marcus RB (1980) Moral dilemmas and consistency *The Journal of Philosophy* **77(3)**: 121-36.

<sup>376</sup> See also: Dickert NW, Eyal N, Goldkind SF *et al.* (2017) Reframing consent for clinical research: a function-based approach *The American Journal of Bioethics* **17(12)**: 3-11 for an account of multiple functions of consent processes.

<sup>377</sup> See, for example, Nuffield Council on Bioethics (2009) *Dementia: ethical issues*, available at: <https://nuffieldbioethics.org/publications/dementia> for a discussion of relational autonomy – recognising the essentially social element of decision-making, even in overtly individualistic societies.

permission, might be justified in circumstances where direct consent from the participant is not possible.

- 4.49 Treating research participants with equal respect extends beyond questions of consent at the point of being recruited into a study. Equal respect also has an important part to play in guiding relationships between research workers and participants throughout the lifecycle of the research programme, including for the way that participants' concerns about the research are addressed; how participant data generated during the research are handled; and how information about the research outcomes is shared with participants. The way in which equal respect for participants may translate to rights about the way data should be handled (for example entitlements to privacy, confidentiality and anonymity, and the limited interference with these rights permitted by reference to the rights and interests of others) has also been the subject of considerable analysis in human rights law (see paragraphs 1.33–1.36).

### ***Equal respect in research collaborations***

- 4.50 One further implication of equal respect is that any research collaboration in global health emergencies, whether within country or involving external partners, should be conducted on terms of equal respect. It must be genuinely collaborative.<sup>378</sup> This has several implications. First it calls for mutual cooperation between countries and institutions, reflecting their different capacities. In addition, it calls for respect between researchers and institutions. Finally, it requires the appropriate recognition of the contribution made by all involved in the research and that there should not be inequity within research groups (for example, regarding influence and control over the research agenda, and whose names appear on subsequent publications). These implications are developed more fully in Chapter 8.
- 4.51 One final point should be made about the nature of equal respect.<sup>379</sup> This is that the ideal of treating people with equal respect requires taking people as they are, and thus being sensitive to the role of human emotions. To give one example: any adequate normative framework needs to take into account the emotional reactions that front-line researchers will often have when faced with very difficult circumstances. A normative framework should not prescribe rules that impose unreasonable emotional demands on those on the front-line, or make unreasonable demands of them, for example by expecting them to stay aloof from desperate needs unrelated to their role as researchers. What is needed are ethical principles for human beings – not for automatons. Related to this, an ethical framework must be accessible and meaningful to those who will have to work with it. It should be expressed in a way that is comprehensible and makes sense to them.
- 4.52 To sum up: equal respect requires engaging meaningfully with communities whose lives, health, and livelihoods are affected by global health emergencies; the creation of respectful relationships between research participants and researchers, sustained throughout the full trajectory of the research from recruitment of participants to

<sup>378</sup> Ezekiel J Emanuel *et al.* refer to “collaborative partnership” in: Emanuel EJ, Wendler D, Killen J *et al.* (2004) What makes clinical research in developing countries ethical? The benchmarks of ethical research *The Journal of Infectious Diseases* **189**(5): 930-7, at page 931. See also: Rid A, and Emanuel EJ (2014) Ethical considerations of experimental interventions in the Ebola outbreak *The Lancet* **384**(9957): 1896-9.

<sup>379</sup> This point applies to all applications of this ideal, whether in relation to affected communities, or research participants; or to the process of collaboration between different institutions or countries.

publication of the findings; and similarly mutually respectful relationships between the different researchers and institutions involved in the research.

## Helping reduce suffering

4.53 A second core value is the basic ethical goal of contributing towards the reduction of suffering. This has several potential implications for research in global health emergencies, including research conducted in real time during emergencies, and research conducted in order to improve emergency preparedness.

- This goal – often referred to as a ‘social value’ requirement<sup>380</sup> – grounds the whole point of engaging in research. It is the reason why research is so important.
- It also generates an ethical responsibility to maximise research effectiveness by adhering to the standards of best research practice, including in the conduct of activities designed to generate evidence (such as needs assessment and evaluation) that are not formally recognised as ‘research’. This requires for example (i) maintaining good records; (ii) reviewing, evaluating, and critiquing practice; and (iii) learning from experience. It also has a further implication – namely (iv) that those who produce the research should also publish what does not work as well as what does (so that others do not waste resources on treatments which have been found to be ineffective).<sup>381</sup>
- The duty to help reduce suffering has an implication for the question ‘Who should have access to any research findings and any associated interventions or other benefits?’ Given the importance of alleviating suffering, it is crucial to make the benefits of research as generally available as possible – as illustrated, for example, by the controversy that arose in 2008 around affordable access to flu vaccines for Indonesia ultimately leading to the development of benefit-sharing agreements through the WHO’s Pandemic Influenza Preparedness (PIP) Framework (see Box 9.2 in Chapter 9).<sup>382</sup>
- Finally, it is important to recognise that a commitment to reducing suffering might also constrain how much is spent on research concerning a specific global health emergency. There are other competing demands. These include:
  - a. other important social goals (including addressing other pressing moral goals (such as combating poverty, malnutrition, gender injustice, biodiversity loss, antimicrobial resistance, other threats to health, and climate change) that are not included under the heading of a global health emergency);
  - b. responding directly to the suffering during a global health emergency, including through the provision of ancillary care alongside research, and potentially;
  - c. conducting research and providing care for *other* global health emergencies.

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<sup>380</sup> See, for example, London AJ (2018) Social value, clinical equipoise, and research in a public health emergency *Bioethics* **33(3)**: 326-34. See also: Emanuel EJ, Wendler D, Killen J *et al.* (2004) What makes clinical research in developing countries ethical? The benchmarks of ethical research *The Journal of Infectious Diseases* **189(5)**: 930-7; and Lairumbi GM, Parker M, Fitzpatrick R *et al.* (2011) Stakeholders understanding of the concept of benefit sharing in health research in Kenya: a qualitative study *BMC Medical Ethics* **12(1)**: 20.

<sup>381</sup> See, for example, McGoey L, and Jackson E (2009) Serostat and the suppression of clinical trial data: regulatory failure and the uses of legal ambiguity *Journal of Medical Ethics* **35(2)**: 107-12; and McGoey L (2009) Compounding risks to patients: selective disclosure is not an option *The American Journal of Bioethics* **9(8)**: 35-6.

<sup>382</sup> Suleman M, Ali R, and Kerr DJ (2014) Health diplomacy: a new approach to the Muslim world? *Globalization and Health* **10(1)**: 50. See also: Fischer WA, Crozier I, Bausch DG *et al.* (2019) Shifting the paradigm - applying universal standards of care to Ebola virus disease *New England Journal of Medicine* **380(15)**: 1389-91.

- 4.54 While the remit of many organisations may clearly establish the focus of their work (for example specifically research, or specifically development), some institutions will face a choice as to how best to use their resources. Where there is a tension, then there needs to be some principle guiding how any trade-off should be negotiated. One major consideration would obviously be – ‘what best reduces suffering?’ (see also paragraph 4.73 for consideration of where there is tension between the three values of the ethical compass). As noted earlier, the number of beneficiaries of such research is potentially very large as it includes both current and future generations, and the beneficiaries may include people throughout the world. This said, the number of potential beneficiaries for other social goals (such as combating climate change or biodiversity loss, or antimicrobial resistance) also includes current and future generations too. Given these points, a full account would need to consider what duties – embedded in justice – members of one generation have to future generations.<sup>383</sup>
- 4.55 One further point is that in practice it may be hard to engage successfully in research in global health emergencies without attending to other pressing social needs. As we described earlier (paragraphs 2.30–2.31), the health threats generated by the particular emergency may not be the only, or even the main, concern of affected populations. If response efforts are not meeting people’s basic needs – for example for food, shelter, physical security, and basic healthcare – they are unlikely to see the value in participating in research associated with those response efforts.<sup>384</sup> In these circumstances, it may be very difficult to conduct research in ways that are either respectful or fair.
- 4.56 To sum up this second value: the importance of helping reduce suffering grounds the importance of research; it calls for norms of best practice and efficiency so as to ensure the greatest social contribution is realised; it informs the dissemination of results and data, and access to the benefits of research; and can inform priority-setting and guide trade-offs between research in global health emergencies and other activities.

## Fairness

- 4.57 The third core value of fairness has several implications. First, there should be fairness in the choice of the research agenda. Resources are scarce, and there are many pressing problems – including ones that are *not* ‘global health emergencies’ (in the sense used in this report) but which nonetheless involve widespread suffering. In light of this, one question is whether and when it is just to devote resources to research in a global health emergency. This is fundamentally a question of distributive justice, about the fair allocation of resources. It is important to emphasise – especially bearing in mind discussions about the definition of a ‘global health emergency’ – that there are other pressing medical and other problems which may not fall under the heading of our inquiry. To say that they are not a ‘global health emergency’ is not (of course) to say that they do not matter. Having once allocated money specifically for research in an emergency, there is also the second-tier question of fairness in prioritising *between* competing research proposals – why study X rather than study Y?

<sup>383</sup> For discussion, see: Caney S (2018) Justice and future generations *Annual Review of Political Science* 21: 475-93; and Caney S (2018) Justice and posterity, in *Climate justice: integrating economics and philosophy*, Kanbur R, and Shue H (Editors) (Oxford: Oxford University Press), pp157-74.

<sup>384</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.



- 4.58 Concerns for fairness also call for an impartial approach when it comes to recruiting participants for any trial (no favouritism and no unjustified exclusions). Obviously there are scientific factors that should guide who is eligible to be a participant; but there is also an ethical principle of impartiality that should apply.<sup>385</sup> There is the question raised above about whether historically excluded groups such as pregnant women or children should be included, and whether exclusion is unfair. As noted in the discussion on equal respect, requirements for fair treatment apply not only at the point of recruitment and when seeking consent, but throughout the full research process (see paragraph 4.49).
- 4.59 Fairness also entails a duty not to exploit or ill-treat front-line researchers (so, for example, ensuring that there is proper pay and transparency about pay structures, healthcare, compensation, protection, and support in the case of any adverse post-trial repercussions). Some front-line researchers may be in positions of considerable vulnerability and it is imperative to avoid exploitation and to avoid exacerbating existing inequalities of gender, class, disability, and nationality.
- 4.60 Finally, there might be a broader implication for the funding of research in health emergencies and access to the resulting findings and associated benefits. On funding: from the point of view of justice, it is unreasonable to expect the poorest countries to contribute the same amount as the wealthiest. Contribution to funding should then be guided by an 'ability to pay' principle. On access, again, if we look at it from the point of view of justice, it is unreasonable and unfair to restrict access to the outcomes of research when sharing them could help enable people to enjoy the human right to the highest attainable standards of health (see paragraphs 1.33–1.36). There is then a duty here to cooperate in enabling research and in making the benefits as widely available as possible.
- 4.61 To sum up: fairness has implications for priority-setting; it calls for impartial recruitment and reinforces the requirement for respectful and non-exploitative treatment of research participants; it requires the equitable treatment of front-line researchers (non-exploitative terms, fair pay, and due care); finally, it also requires fair terms of social cooperation for the funding of research and the equitable dissemination of results.

## Planning for the future

- 4.62 Taking the three moral values identified earlier as our 'ethical compass' has one further important implication: namely it underscores the importance of forward-planning and preparedness. There can be a tendency for policy to be short-term and reactive, rather than proactive. Political actors often respond to unfolding catastrophes where there are "identifiable victims" and when vivid images of suffering are captured through television, photojournalism, and social media.<sup>386</sup> However, they are often less likely to make

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<sup>385</sup> Examples of challenges to such impartiality include pressure to prioritise particular communities in determining the order of access to a health intervention within a cluster RCT: *Global Forum on Bioethics in Research*, 30 November-1 December 2017, Bangkok.

<sup>386</sup> For relevant psychological literature, see: Kahneman D (2011) *Thinking, fast and slow* (London: Allen Lane); and Bloom P (2016) *Against empathy: the case for rational compassion* (London: The Bodley Head), and the literature in behavioural economics on discounting. On "identifiable victims", see: Jenni K, and Loewenstein G (1997) Explaining the 'identifiable victim effect' *Journal of Risk and Uncertainty* **14**(3): 235-57; and Thomas Schelling's discussion of "individual deaths" and "statistical deaths" in chapter 5 (*The life you save may be your own*) of Schelling T (1984) *Choice and consequence: perspectives of an errant economist* (Cambridge, Massachusetts, and London, England: Harvard University Press), pp113-46, at page 115.



preparations when a global health emergency is a mere possibility rather than a reality, and other demands loom large.<sup>387</sup>

- 4.63 This leaves societies less well-equipped to deal with global health emergencies than they need to be. In addition, making decisions in time-pressured circumstances can lead to less considered policies. For these reasons, there is a strong case for establishing clear procedures in advance – for example through designing pre-prepared expedited review processes – rather than being caught off-guard. In addition, there is a case for making contingency plans for increased staffing and support for bodies like national ethics committees which may be put under considerable pressure. As noted above, preparatory measures can increase what is ‘possible’ during an emergency and thereby contribute to the realisation of fairness and the alleviation of suffering. A failure to do so, by contrast, increases the prospects and severity of hard choices and difficult trade-offs.<sup>388</sup> Achieving this kind of preparedness requires funding and political commitment.<sup>389</sup>

## Duty-bearers and responsibilities

- 4.64 A complete discussion of how best to engage in research in the context of global health emergencies needs to identify not only what the relevant values and principles are, but also who has what responsibilities. A detailed account of these responsibilities will be discussed in the following chapters. This section sets out several general considerations that can inform how responsibilities ought to be distributed (and, as such, among whom). Earlier a (non-exhaustive) list of potential duty-bearers was identified, including national governments and local community leaders, intergovernmental organisations, NGOs, research funders and institutions, and RECs (see paragraph 4.11). On what basis might responsibilities to uphold the values and principles identified above be distributed among such actors? A number of different principles have been suggested for distributing responsibilities. Three approaches seem particularly relevant here.<sup>390</sup>
- 4.65 First, there is what David Miller terms “**remedial responsibility**”.<sup>391</sup> The central thought here is that those who bring a problem about bear a responsibility to make amends. In the context of global health emergencies, it might be argued that if an organisation culpably causes a global health emergency (for example by not adhering to proper safety protocols) then it bears some responsibility to help remedy the situation. This might involve supporting research into how best to treat the harmful health effects.

<sup>387</sup> See: Meyer R, and Kunreuther H (2017) *The ostrich paradox: why we underprepare for disasters* (Philadelphia: Wharton School Press). Dr Eve Lackritz, who leads WHO’s Zika Task Force, said one of her main tasks is to keep up the sense of urgency. “My biggest fear is complacency and lack of interest by the global community,” she said: The New York Times (2 July 2019) *The Zika virus is still a threat: here’s what the experts know*, available at: <https://www.nytimes.com/2019/07/02/health/zika-virus.html>.

<sup>388</sup> And is very much more expensive: Wellcome (19 December 2018) *Why we need a globally coordinated approach to preparing for epidemics*, available at: <https://wellcome.ac.uk/news/why-we-need-globally-coordinated-approach-preparing-epidemics>.

<sup>389</sup> For discussion of ways that political institutions can be designed to encourage less ‘presentism’ and more forward-thinking, see: Ascher W (2009) *Bringing in the future: strategies for farsightedness and sustainability in developing countries* (Chicago and London: University of Chicago Press); Caney S (2016) Political institutions for the future: a five-fold package, in *Institutions for future generations*, González-Ricoy I, and Gosseries A (Editors) (Oxford: Oxford University Press), pp135-55; and Caney S (2019) *Democratic reform, intergenerational justice and the challenges of the long-term (CUSP essay series on the morality of sustainable prosperity (No. 11))*, available at: <https://www.cusp.ac.uk/themes/m/m1-11/>.

<sup>390</sup> For instructive discussions of responsibility, see: Hart H (1968) *Punishment and responsibility: essays in the philosophy of law* (Oxford: Clarendon Press); Honoré A (1999) *Responsibility and fault* (Oxford: Hart); and Miller D (2001) Distributing responsibilities *Journal of Political Philosophy* 9(4): 453-71.

<sup>391</sup> Miller D (2001) Distributing responsibilities *Journal of Political Philosophy* 9(4): 453-71, pp455-64.

- 4.66 Any reliance on this principle will need to take on board many complications. In some cases, for example, a global health emergency may result from the interaction of many different actors and factors. No one may be at fault. In other cases, it might be unfair to require an organisation to address a global health emergency. For example, an organisation might have caused a problem but not be at fault because it adhered to all reasonable standards of due care. Or an organisation might lack the necessary resources and it might be unreasonable to require it to bear burdens.<sup>392</sup> Despite these caveats, a qualified version of this principle may have a role to play in some specific circumstances, particularly in relation to lack of attention to emergency preparedness, or unfairness with respect to the use of available resources for preparedness. Where some culpably contribute to causing a global health emergency and have the resources to make amends, it would seem reasonable to suggest that they have some remedial responsibility.
- 4.67 The next two principles might have greater applicability. The second principle takes a more forward-looking approach. It **ascribes responsibilities, in part, by identifying who has the greatest ability to help realise the values and principles outlined earlier.**<sup>393</sup> This principle can be applied in different ways.
- First, it might be applied to the question of sharing of financial costs. This principle would suggest that, when considering who should fund research in a global health emergency, there is a case for allocating the financial costs to those with the greatest ability to pay. At the very least, responsibilities to contribute financially should be sensitive to who has the ability to pay (see the related discussion of fairness at paragraph 4.60).
  - Second, it might be applied to the question of who performs which tasks. This principle would suggest that those who can most effectively discharge a duty might have a (defeasible) duty to do so. It would also suggest that those who can induce others to perform their responsibilities may have a duty to do so. For example, journal editors, funders, and professional associations can have responsibilities because they exercise some power over researchers.
- 4.68 Again there will be limits to this principle. In the first place, it might put unreasonable burdens on some and be unfair. Someone might, for example, be able to discharge the responsibility well (better than others), but following this principle might result in unreasonably demanding burdens being placed on them.<sup>394</sup> Second, an organisation that has the ability to bear considerable financial burdens or that can discharge the responsibility well might be able to make significant contributions to other pressing social goals (for example, suffering which is not covered by global health emergencies). An argument would, then, be needed to explain why they should use their ability to assist for this specific kind of case and not another. It might be that they are uniquely well-placed to assist and that others are less well-placed to do so; or they may have good working relationships with others working on global health emergencies. The point is that some argument is needed to show why they should discharge their duty in this way. A third qualification might also need to be added: that an organisation may have the capability to contribute but might lack the legitimacy to do so. For example, a body that has acquired its resources in an illegitimate way, or which has a tarnished reputation and

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<sup>392</sup> Miller discusses these and other complexities that such a principle needs to take into account: *ibid.*

<sup>393</sup> For versions of this approach, see: Goodin R (1985) *Protecting the vulnerable: a re-analysis of our social responsibilities* (Chicago and London: Chicago University Press); and Sen A (2010) *The idea of justice* (London: Penguin), pp205-7, and 270-1.

<sup>394</sup> For a useful discussion of some of these limitations, see: Miller D (2001) Distributing responsibilities *Journal of Political Philosophy* 9(4): 453-71, pp460-2.

is seeking to win over public support, may have the capacity to bear considerable financial burdens but might lack the necessary moral standing.

- 4.69 This said, these three points do not suggest that the principle should be abandoned. Rather, they show that the principle needs to be stated carefully and qualified to take on board various complications. Furthermore, there are powerful considerations in support of some versions of this principle and it would be implausible to claim that no weight should be attributed to agents' ability to make a positive contribution. When there are important tasks and great potential harms and benefits there is a strong (defeasible) case for ensuring that the responsibility is allocated to those with the ability to discharge the tasks well.
- 4.70 The third principle **ascribes responsibilities on the basis of people's relationships and their occupancy of various roles**. It is widely accepted that people have special responsibilities to people with whom they are in a social relationship. For example, someone who employs front-line research workers will, in virtue of this, have responsibilities to those they employ and a duty of care to them. Closely related to this, persons can have responsibilities by virtue of their occupation of a certain role. For example, someone overseeing a research programme in a global health emergency may – by virtue of their position – have a special responsibility to the research participants. Or to give another example: REC members will also have various responsibilities as part of their job.
- 4.71 In sum: there is a plurality of different principles in identifying duty-bearers and their respective responsibilities – each of which may (in some form) have a role to play.

## Conclusion

- 4.72 We began this chapter by highlighting the fact that research in global health emergencies unavoidably takes place in highly non-ideal circumstances, characterised by disruption, uncertainty, distress, and great health need. This presents significant practical challenges to ethical decision-making, as practitioners struggle to align their ethical obligations to challenging and often chaotic circumstances. It also brings together actors with diverse ethical commitments – sometimes taking the form of explicit, institutional guidelines or frameworks – in multinational collaborations. This takes place against the backdrop of complex and competing sources of control and influence from governments, funders, journals, and many others; and in a context of a multitude of international, regional, and local ethics guidance characterised by overlaps, inconsistencies, contradictions, and lacunae. We argued that this means there will often be no readily available off-the-shelf framework to guide best practice. What is required is an approach to ethics capable of offering the basis for a shared way forward. **Our response to this requirement has been the development of an 'ethical compass' comprising three widely shared values: equal respect, helping reduce suffering, and fairness. Our hope is that in the careful deliberations preceding and accompanying the establishment and implementation of collaborative partnerships between key actors – including governments, funders, researchers, and community representatives – the proposed compass and the important substantive moral values it reflects will act as both a guide and a reasonable constraint.**
- 4.73 In many cases these values will pull in the same direction: it will be possible to respect participants equally, conduct research with a reasonable expectation of helping reduce suffering, and to do so in a way that is fair. In cases where this is not possible, proceeding

with research (or choosing not to proceed) would require careful, appropriately inclusive and transparent deliberation, independent review, and explanation. As noted in the earlier discussion of human rights (see paragraphs 1.33–1.36), no one value can be ignored altogether, however compelling the others may be in the circumstances. To this extent each of the values could be seen as acting as a constraint on the way the others might guide action.

- 4.74 The features of the ethical compass introduced here are reflected in subsequent chapters in three important ways. First, the selection of the chapter topics is itself to some degree a reflection of the importance placed on these values by those who contributed evidence and experience to the inquiry, including working group members. Second, the discussion within each chapter explores: (i) how the values of equal respect, helping reduce suffering, and fairness relate to the aspect of global health research addressed in the chapter; (ii) the relevant duty-bearers and the nature and scope of their responsibilities, and (iii) the appropriate response to and the possible limitations of existing ethical standards and frameworks. We turn first to the need to develop a more inclusive approach to influence throughout the research endeavour (Chapter 5); followed by considerations of study design and review (Chapter 6), consent (Chapter 7), fair collaborations (Chapter 8), use of data and samples (Chapter 9) and better support for front-line workers (Chapter 10).

# Chapter 5

Influence throughout the  
research endeavour: an  
inclusive approach

## Chapter 5 – Influence throughout the research endeavour: an inclusive approach

### Chapter 5: overview

Equal respect for persons requires that those planning research should engage seriously and respectfully with relevant stakeholders. The ‘all affected principle’ (the idea those whose interests are fundamentally affected by a process have a right to inclusion) provides a guide to thinking about who has a stake in any particular emergency. This includes governments and research institutions; local health services, voluntary organisations, and research institutions in the affected area; and members of affected communities. Communities are complex and diverse, and it is essential to identify those with informal influence within the different subgroups that make up a community, as well as those with more formal leadership roles.

#### *Influencing decisions about prioritisation and funding*

The way funding decisions are taken needs to change to create a more collaborative approach between funders, and to ensure that a wider range of voices is heard in determining the kind of research that should get funded. A longer-term goal is to shift the power balance in funding decisions towards lower-income countries, and find ways of ensuring publics within those countries have input into research priorities. **We recommend:**

- collaboration between funders and relevant governments / national research institutions / UN bodies at the start of an emergency, to agree research priorities;
- a dedicated pooled funding resource for research in emergencies, with inclusive and diverse representation from research institutions around the world among its leadership and embedded in decision-making processes; and
- innovative approaches among funders to find ways to support and incentivise researchers to include affected communities directly in plans for grant applications.

#### *Influencing how research is conducted on the ground*

Meaningful engagement with affected communities involves the creation of trusting / trustworthy relationships between researchers and diverse parts of those communities. At best, such engagement should involve affected populations from the beginning and throughout the research endeavour in ongoing dialogue contributing to the design, conduct, and outcomes of research. Developing community engagement networks in advance to facilitate relationships is a key part of emergency preparedness, for example in association with regional research initiatives or community health structures. In the absence of preparedness, a pragmatic approach may be required during an emergency, including scope for learning / adapting in response to feedback as the research progresses. The values of equal respect and fairness, alongside the importance of helping reduce suffering through research, should help guide consideration of how much ‘adaptation’ of ideal processes is acceptable. **We recommend:**

- National governments should embed engagement practices in local health systems, to ensure sustainability.
- Research funders should require coherent, achievable, and inclusive plans for community engagement in funding proposals, while avoiding being over-prescriptive on how this might be achieved.



- 5.1 Global health emergencies disproportionately affect those who are already disadvantaged. They are more likely to be exposed to risk, partly because of where they live. In some cases, this will be a consequence of living in places with inadequate or poorly maintained infrastructure; or on poor quality, marginal land more likely to be subject to disastrous events or close to sources of disease. In the vast majority of cases, this exposure to risk will take place against a background of socioeconomic inequality and political marginalisation. These risks and vulnerabilities are further compounded by the fact that, partly for the reasons set out above, such populations are less likely to have access to well-resourced health services with the potential to mitigate the effects of disaster (see also paragraphs 3.1–3.3).<sup>395</sup> In addition to lack of funding and relevant infrastructure, these health systems are also likely to suffer as a consequence of enduring and stark international imbalances in the distribution of health research funding, which mean that appropriate interventions may either not be available at all, or that their use may be inadequately informed by a robust, relevant evidence base.<sup>396</sup>
- 5.2 As we noted in our introduction to this report, the question of *how* decisions about research are made, and whose interests are taken into account in those decisions, is a fundamental element of research ethics. In Chapter 4, we argued that the ideal of equal respect for persons requires that those planning to engage in research should engage seriously and respectfully with relevant stakeholders, and supported the ‘**all affected principle**’ (the idea that all those whose interests are fundamentally affected by a process have a right to some kind of inclusion) as a guide to thinking about who should be considered to have a stake.
- 5.3 This claim has implications at two distinct levels when important decisions about research are made. The first of these is when decisions are being made (often by organisations very remote from the location of the emergency) about how funding should be prioritised, and what kinds of studies should be supported, including as part of emergency planning in advance of any specific emergency. One example of a formal prioritisation mechanism in an infectious disease context is the World Health Organization (WHO) Blueprint which sets out a global strategy for prioritising diseases and pathogens for research (see Box 3.5). Key prioritisation decisions are made by an international expert group, convened by the WHO to develop and review the strategy.<sup>397</sup> This approach, while involving a relatively small number of people, represents a significant step forward in drawing in experts from across the world, in contrast to earlier more informal and *ad hoc* prioritisation exercises initiated by academic institutions or individual research funders.<sup>398</sup> The second level where the ‘all affected’ principle arises relates to decisions about the details of how any study, once initially selected, is implemented in a particular location and community, including with respect to key features such as framing research questions, study design and inclusion criteria. In both

<sup>395</sup> On-the-ground roundtable, 25 June 2018. See also: Global Preparedness Monitoring Board (2019) *A world at risk: annual report on global preparedness for health emergencies*, available at: [https://apps.who.int/gpmb/assets/annual\\_report/GPMB\\_annualreport\\_2019.pdf](https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf).

<sup>396</sup> The WHO Global Observatory on Health R&D aims to provide an accurate picture of how and where global health research funds are spent: WHO (2019) *About the Global Observatory on Health R&D*, available at: [https://www.who.int/research-observatory/why\\_what\\_how/en/index4.html](https://www.who.int/research-observatory/why_what_how/en/index4.html).

<sup>397</sup> Current membership of the Scientific Advisory Group is available at: <https://www.who.int/blueprint/about/sag-members/en/>.

<sup>398</sup> See, for example, the account of the more *ad hoc* arrangements in prioritising ZMapp as a candidate treatment for Ebola in the early days of the West African outbreak: Davey RT, Jr, Dodd L, Proschan M *et al.* (2018) The past need not be prologue: recommendations for testing and positioning the most-promising medical countermeasures for the next outbreak of Ebola virus infection *The Journal of Infectious Diseases* **218** (supplement 5): S690-S7.

cases, the question of who should be ‘at the table’ when decisions are being made, and whose voices should be influential in the final decision, is crucial.<sup>399</sup>

- 5.4 In practice, most research funders concerned with health and development research are currently based in high-income countries (HICs);<sup>400</sup> and governmental funders, in particular, are expected to prioritise the health security of their own citizens in determining their funding objectives. While the philanthropic sector is much freer to set its own priorities and ways of working, its decision-making mechanisms may still lack accountability and diversity, and are likely to be subject to conscious or unconscious bias, especially where workers are mainly from HICs. Private sector priorities are inevitably strongly directed by commercial drivers, although these can be influenced by regulatory requirements or by corporate social responsibility policies, or through involvement in public-private sector partnerships (see paragraph 3.22).<sup>401</sup> Governments of low- and middle-income countries (LMICs) facing global health emergencies may thus, at present, have little direct influence over the funding decisions of these external funding bodies, even though the leading role of governments in setting health research priorities in their own countries is well-established, including in the emergency context.<sup>402</sup> The often disadvantaged populations directly facing the consequences of emergencies are even less likely to be in a position to influence the decisions made elsewhere, and those who are marginalised within their own communities, least of all.
- 5.5 Yet, as we noted in Chapter 4, respondents to our call for evidence argued that there are both intrinsic and instrumental reasons for putting a strong emphasis on stakeholder engagement at both these levels (see paragraph 4.45 and Box 5.1).<sup>403</sup> Indeed, while the evidence base for these instrumental claims is still developing, and there is as yet little clarity on what constitutes best practice in particular settings, there is growing evidence that *failure* to engage with those most likely to be affected by proposed research leads to poor outcomes.<sup>404</sup>

### Box 5.1: Hearing local voices: responses to the call for evidence

“... local voices should be heard to make the response effective, beneficial, resource friendly, as well as to reduce the possibility of stigmatization and social exclusion of the population in question. Mechanisms vary as to how such voices should be solicited / heard as it is sometimes impossible or difficult for people to communicate with

<sup>399</sup> Pratt B, Merritt M, and Hyder AA (2016) Towards deep inclusion for equity-oriented health research priority-setting: a working model *Social Science & Medicine* **151**: 215-24.

<sup>400</sup> See, for example, Healthresearchfunders.org (2019) *Homepage*, available at: Healthresearchfunders.org. See also: McGregor S, Henderson KJ, and Kaldor JM (2014) How are health research priorities set in low and middle income countries? A systematic review of published reports *PloS One* **9(9)**: e108787; and also Nuyens Y (2007) Setting priorities for health research: lessons from low- and middle-income countries *Bulletin of the World Health Organization* **85(4)**: 319-21 on the implicit values used. (Both cited in: Pratt B, Sheehan M, Barsdorf N *et al.* (2018) Exploring the ethics of global health research priority-setting *BMC Medical Ethics* **19(1)**: 94.)

<sup>401</sup> See, for example, the role of regulation in requiring the pharmaceutical sector to conduct research in children as well as adults in certain circumstances, even though this may not be a commercial priority: Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/project/children-research>. See also: the discussion of the duties of funders, including pharma, in Pierson L, and Millum J (2018) Health research priority setting: the duties of individual funders *The American Journal of Bioethics* **18(11)**: 6-17.

<sup>402</sup> Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries*, available at: <http://nuffieldbioethics.org/project/research-developing-countries>. See also the discussion on the role of the WHO and the IHR at paragraphs 3.5 and 3.16 above.

<sup>403</sup> See also the earlier accounts and discussion of community involvement and leadership in Chapter 2 (paragraphs 2.1–2.22); and IARAN (2018) *From voices to choices: expanding crisis-affected people’s influence over aid decisions: an outlook to 2040*, available at: [https://static1.squarespace.com/static/593eb9e7b8a79bc4102fd8aa/t/5be216ff562fa77a941b14eb/1541543685634/Voices2 Choices\\_FINAL-compressed.pdf](https://static1.squarespace.com/static/593eb9e7b8a79bc4102fd8aa/t/5be216ff562fa77a941b14eb/1541543685634/Voices2 Choices_FINAL-compressed.pdf) which makes this case in general terms for development aid in crises.

<sup>404</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

emergency workers remotely or through channels they choose, such as social media or even physically attending meetings for example.” *Jihad Makhoul, American University of Beirut*

““Hearing local voices” will be much more feasible in situations where the event occurs in a locale where the event is predictable (e.g. recurrent hurricanes) and where prior consultation with communities is therefore feasible. Where possible, such consultations should be undertaken in a structured and deliberate manner. In other cases (e.g. an earthquake), this will not be possible. In those cases, engagement with local authorities and other community leaders is necessary but will be constrained and limited in scope.” *Humanitarian Health Ethics Research Group*

“our general sense is that in most cases local actors are not ‘at the table’ in any consistent or principled way. For the most, decisions are made far from the location, and there is a descending order of appearance at the table (Ministries or government officials, mostly at the national level if IHR involved, and on a sliding scale down from there.)” *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“... regardless of the circumstances, research institutions should actively engage with affected communities while planning research to determine the trial design and understand cultural requirements and challenges which need to be taken into consideration.” *Bartholomew Wilson, PREVAIL*

“Importantly, the platform built during a GHE should be maintained after it is over, because local voices should also be listened to in the post research phase, when it comes to important decisions about secondary research on stored samples and data; benefit sharing measures; deployment of/access to the findings of the research etc.” *Raffaella Ravinetto, Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Marianne van der Sande, Head of the Public Health Department, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Anne Buvé, Vice-Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium*

- 5.6 In the remainder of this chapter, we explore first the question of strategic decision-making and prioritisation at the funding level, and how this might include a wider range of stakeholders. We then look more locally at the question of community engagement in the conduct of specific studies in particular locations.

## Influencing decisions about prioritisation and funding

- 5.7 Decisions about research policy are currently taken in circumstances of significant inequity. There is therefore a two-part challenge in considering ethical approaches to the way research is prioritised. First we need to consider how, starting from the status quo, funding decisions that determine what research is likely to be conducted in global health emergencies could start to take better account of the perspectives, needs, and interests of populations directly affected by those emergencies, through the inclusion of the voices of a much wider range of stakeholders. We suggest that this approach is ethically indicated, for reasons connected with the three core values in our ethical compass:
- in response to the requirement to show equal respect to ‘all affected’ (see paragraph 5.2);

- in order to help promote much greater fairness with respect to research choices (see paragraph 4.54); and
- because such an approach is likely to lead to research of more relevance to local needs, and hence more likely to be effective in reducing suffering (see paragraphs 4.53–4.56).<sup>405</sup>

Second, we need to consider how these funding mechanisms might contribute over time to a shift in these power imbalances. These two parts of the challenge are, of course, connected.

## Working towards a more inclusive approach to decision-making

- 5.8 Given that, for most emergencies,<sup>406</sup> and for the immediate future, control over research funds is currently exercised a long way from those directly affected by an emergency, how realistically can the voices of ‘all those affected’ influence the research agenda? To find more inclusive ways for major research funders to take crucial prioritisation decisions – particularly in the emergency planning stage where specific research populations may not necessarily be identifiable – it is important to take a wide view of who is a ‘stakeholder’ or part of the ‘community of affected persons’. In particular, it is essential to broaden out our focus from the populations who directly and immediately suffer as a result of the emergency, to include national governments (and in particular ministries of health) and leading research institutions in affected countries among those stakeholders. It is also important to take account of non-geographic communities such as patient organisations and survivor groups, who have personal and collective experience of the particular health challenges with which research in emergencies may be concerned, and hence much of value to contribute.
- 5.9 The WHO and other UN agencies emphasise the primary and central role of national governments in leading emergency preparedness and response, with appropriate international and foreign assistance as necessary, and coordination provided through UN institutions.<sup>407</sup> In contrast, for example, with the chaotic ‘landgrab’ for patients and research participants described in the West Africa Ebola outbreak, clinical trials conducted in the subsequent outbreaks in the Democratic Republic of the Congo (DRC) from 2018 onwards have been coordinated through WHO, with principal investigators (PIs) working closely with the national government (see paragraph 2.32 and Box 6.1). While it is important to recognise that national governments may not act in the interests of all their citizens – not least where territory is disputed and/or no government is generally recognised – the (rebuttable) starting point needs to be that national governments take the lead in setting health and research priorities for their country (see also paragraph 5.13). If this is to be meaningful, major external funding bodies will need to find ways of accounting for such priorities in their own approaches to funding decisions.
- 5.10 Similarly, national research institutions and the scientists working within them are essential stakeholders. However, we heard repeated accounts of researchers from

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<sup>405</sup> See also: Røttingen J-A, Regmi S, Eide M *et al.* (2013) Mapping of available health research and development data: what’s there, what’s missing, and what role is there for a global observatory? *The Lancet* **382(9900)**: 1286-307; and Pratt B, and Vries J (2018) Community engagement in global health research that advances health equity *Bioethics* **32**: 454-63 who make the case for ‘shared health governance’ as an underpinning ethical justification for such inclusive approaches in priority-setting.

<sup>406</sup> Recognising that while some global health emergencies may happen in the Global North, the vast majority affect those living in the Global South.

<sup>407</sup> WHO (2016) *International Health Regulations: third edition*, available at: <http://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf>; and UNISDR (2015) *Sendai framework for disaster risk reduction 2015-2030*, available at: [http://www.unisdr.org/files/43291\\_sendaiframeworkfordrren.pdf](http://www.unisdr.org/files/43291_sendaiframeworkfordrren.pdf).

countries affected by emergencies only being offered the opportunity to be involved in research initiated and led by others, despite their own local knowledge of what research priorities might better serve the needs of the affected communities.<sup>408</sup> (See Chapter 8 for a more detailed consideration of fair collaborations.)

- 5.11 Neither governments, nor educated elites, can, in any country, be said to be 'representative' of the whole country's population. Gaps may be particularly acute when the affected communities are themselves marginalised through poverty and/or very remote from capital cities.<sup>409</sup> Local community engagement in the way research studies are carried out in that locality are particularly important as a result of these disjunctions (see paragraphs 5.26–5.40). Nevertheless, national governments and research institutions have an important role to play when considering how the 'all affected principle' might be applied when research funding bodies remote from the scene of an emergency have to make decisions quickly about how their funds can best be used.
- 5.12 There is scope, in turn, for national institutions to draw in wider input through their own stakeholders, particularly in the context of setting priorities for research in advance of possible emergencies, as part of emergency planning and/or general health systems strengthening (see Box 5.2). Such approaches, involving geographic communities, and communities of common interest or expertise (such as in the second example in Box 5.2), enable decision-makers within national institutions to draw on a broader set of perspectives and needs than would otherwise have been the case. The second example, describing a regional initiative, also offers a model for influencing the thinking of major research funders directly.

### Box 5.2: Ethical priority-setting: work in progress

**Example 1:** as there is little current research on the ethics of global health research priority-setting, an international workshop of bioethicists was held in 2015 to sketch out a research agenda, and draw together preliminary suggested approaches.<sup>410</sup> Workshop participants identified 'health need', rather than 'burden of disease' as a key criterion to guide priority-setting, and noted the value of input from a diverse range of community members in providing robust evidence of that need. It was suggested that such evidence could be sought 'bottom up' through research institutions engaging with their surrounding communities, with this process then feeding into considerations at national level. Such a general approach to health research priority-setting (put forward in the non-emergency context) could also inform a country's emergency planning.

**Example 2:** research priorities during infectious disease emergencies in West Africa were explored in the region in the aftermath of the West African Ebola outbreak, using the Delphi method to reach consensus among the bioethicists, social scientists, ethics committee members, and community members involved.<sup>411</sup> Participants prioritised studies that focused on mitigating the suffering in the present and those that seek to identify means of prevention for future epidemics, over studies that might save future

<sup>408</sup> RECAP meeting, American University of Beirut, 15-16 January 2019; and Sibai AM, Rizk A, Coutts AP *et al.* (2019) North-South inequities in research collaboration in humanitarian and conflict contexts *The Lancet* **394**(10209): 1597-600.

<sup>409</sup> The scope for domestic institutions to exercise power in unjust ways was emphasised at the Oxford workshop (see Appendix 1). The role of community health workers in exercising power (justly or unjustly) as well as providing a genuine link to local communities is illustrated in: Nunes J (2019) The everyday political economy of health: community health workers and the response to the 2015 Zika outbreak in Brazil *Review of International Political Economy*: 1-21.

<sup>410</sup> Pratt B, Sheehan M, Barsdorf N *et al.* (2018) Exploring the ethics of global health research priority-setting *BMC Medical Ethics* **19**(1): 94.

<sup>411</sup> Folayan MO, Haire B, Allman D *et al.* (2018) Research priorities during infectious disease emergencies in West Africa *BMC Research Notes* **11**(1): 159.



putative lives. On this basis, it was argued that phase II and III drug trials should be prioritised over phase I studies. Participants also made recommendations relating to future research design, including access by groups such as pregnant women and children (see Chapter 6).

- 5.13 There are clear challenges to this emphasis on the role of governments in cases where a national government does not have moral and/or legal authority in an area affected by the emergency, for example in areas that are the subject of territorial dispute between two or more nations, or in areas of civil unrest. In the absence of any clear source of moral authority in the affected territory, it may be justifiable for external actors to take on a more dominant role with respect to research, on a time-limited basis, on the basis of the needs of those directly affected by the emergency.<sup>412</sup> The legitimacy of external actors clearly remains a critical question. One possible approach for addressing legitimacy includes WHO regional offices taking a leading role in coordinating research, and working wherever possible with locally-respected NGOs that are best placed to bring knowledge of health needs. Such information should guide decisions about what research should be prioritised. Quandaries where the legitimacy of national governments' actions towards their citizens is contested are not limited to questions of research leadership: they constitute a constant operational challenge for the humanitarian sector, where the humanitarian principles of humanity and neutrality conflict (see paragraphs 1.31–1.32 and Box 1.9).<sup>413</sup>
- 5.14 While many important prioritisation decisions are taken at a strategic level (for example, how much a funder is prepared to allocate to a particular emergency, or the broad parameters of a major funding call), this is not the full picture. Further important decision points include decisions by researchers / research collaborations as to how they put together their research proposals in response to funding calls, and the process (in particular the role of peer reviewers) by which funders then decide which applications to fund. While in emergencies these timescales may be very tight, there are examples of how communities directly affected by emergencies have had a central role in influencing a research topic, particularly where existing research relationships have developed over time (see Box 5.3). Particular features of funding arrangements – such as the availability of funding for scoping and development work to support initial preparatory work on research priorities, and rapid turnaround times in funding processes – can support researchers in moving to a more inclusive approach at the very start of their project planning.

**Box 5.3: Developing an ethics toolbox for research with and for participants with limited literacy in Ebola-affected countries: building on existing relationships**

Research funded by Elrha exploring the perceptions of research by survivors, researchers, and ethics committee members in Sierra Leone, Guinea, and Liberia was undertaken in partnership with survivors' organisations in all three countries.<sup>414</sup> As part of the process of writing up the study, researchers presented their findings to

<sup>412</sup> See, for example, Pratt B, Sheehan M, Barsdorf N *et al.* (2018) Exploring the ethics of global health research priority-setting *BMC Medical Ethics* **19**(1): 94, where some workshop participants suggested more of a role for external actors in priority-setting in such situations.

<sup>413</sup> See, for example, MSF (2011) *Humanitarian negotiations revealed: the MSF experience*, available at: [https://lakareutangranser.se/sites/default/files/humanitarian\\_negotiations\\_revealed.pdf](https://lakareutangranser.se/sites/default/files/humanitarian_negotiations_revealed.pdf); and the role of organisations such as Physicians for Human Rights: AAAS (2019) *Assessing the status of medical facilities in Syria*, available at: <https://www.aaas.org/resources/assessing-status-medical-facilities-syria>.

<sup>414</sup> Humanitarian Health Ethics (2018) *Participants' perceptions of Ebola research: report to participants*, available at: [https://humethnet.files.wordpress.com/2018/06/hhERG\\_perceptions\\_ebola\\_research\\_participants\\_report\\_draft.pdf](https://humethnet.files.wordpress.com/2018/06/hhERG_perceptions_ebola_research_participants_report_draft.pdf).



participants, and sought their feedback. One of the needs emerging from these discussions was that of accessible materials for adults with limited literacy to understand research concepts.

In June 2018, the Canadian International Development Research Centre put out a call for Ebola-related research during a hard-to-control outbreak in DRC. With only three weeks between the call and the submission deadline, it was the relationships created during the West African study that made it possible for survivors' groups and researchers in Canada, Guinea, and the DRC to put together a research proposal: to "develop, pilot, and disseminate, in partnership with African research staff and lay participants, the first ever open access primer on research and research participation developed with and geared to limited literacy adults in sub-Saharan Africa".<sup>415</sup> Stakeholders affected by Ebola have been involved from the outset in defining research questions, methods, and objectives. The toolbox is currently in its development phase, with piloting scheduled to take place in Guinea and the DRC in 2020. It includes a series of short films, produced by the School of Fine Arts of Dabreka (Guinea), cartoons, posters, and a facilitator guide.

- 5.15 As this example suggests, a key factor in affected communities having a direct influence on the nature of research being funded is likely to be the development of pre-existing relationships. Such relationships may most feasibly be developed in circumstances where research is built into emergency planning processes, and hence time constraints are not so acute.<sup>416</sup> While the practice of involving local stakeholders from the beginning of the scoping and planning process is still very much in its infancy, even outside the emergency context, a draft toolkit for supporting communities and researchers in such collaborative approaches has been developed in the context of global health research more generally (see Box 5.4).

#### Box 5.4: Sharing power with communities in priority-setting for health research projects: a toolkit

This (draft) toolkit<sup>417</sup> is the result of a project drawing on citizen engagement literature from a number of disciplinary fields (including development studies and community-based participatory research),<sup>418</sup> and on qualitative research with researchers, ethicists, community engagement practitioners, and workers in community-based organisations.<sup>419</sup> It consists of three worksheets and a companion document to support researchers and

<sup>415</sup> Humanitarian Health Ethics (2019) *Strengthening the ethics of clinical research with and for limited literacy participants in Ebola affected countries: a toolbox*, available at: <https://humanitarianhealthethics.net/home/research/hhe-research-studies/strengthening-the-ethics-of-clinical-research-with-and-for-limited-literacy-participants-in-ebola-affected-countries-a-toolbox/>; and personal communication, Elysée Nouvet (27 November 2019).

<sup>416</sup> See, for example, Chan EYY (2017) *Building bottom-up health and disaster risk reduction programmes* (Oxford: Oxford University Press). See also: TRUST (2017) *San Council launches San code of research ethics*, available at: <http://trust-project.eu/san-council-launches-san-code-of-ethics/>. The San Code states that the process will "set out specific requirements through every step of the research process. This process starts with a research idea that is collectively designed": South African San Institute (2017) *San code of research ethics*, available at: <http://trust-project.eu/wp-content/uploads/2017/03/San-Code-of-RESEARCH-Ethics-Booklet-final.pdf>.

<sup>417</sup> Personal communication, Bridget Pratt (27 August 2019). See also: NIHR and Institute of Development Studies (2019) *A resource guide for community engagement and involvement in global health research*, available at: <https://www.nihr.ac.uk/documents/researchers/manage-your-funding/NIHR%20Community%20Engagement%20Involvement%20Resource%20Guide%202019.pdf>, at page 6.

<sup>418</sup> Pratt B (2019) Constructing citizen engagement in health research priority-setting to attend to dynamics of power and difference *Developing World Bioethics* **19(1)**: 45-60.

<sup>419</sup> Pratt B (2019) Towards inclusive priority-setting for global health research projects: recommendations for sharing power with communities *Health Policy and Planning* **34(5)**: 346-57; and Pratt B (2019) Inclusion of marginalized groups and communities in global health research priority-setting *Journal of Empirical Research on Human Research Ethics* **14(2)**: 169-81.

community organisations in working together to design priority-setting processes in ways that share power with communities potentially affected by the research, including with subgroups of the community who are marginalised or disadvantaged.

The toolkit is a reflective project-planning aid to be completed as a research team. The ethical issues raised in the worksheets are not designed to have right or wrong answers, but to encourage consideration of what would be valuable and feasible in the circumstances, and whether (in cases where meaningful consultation or sharing of power is impossible) there might nevertheless be justification for going ahead. Issues raised include:

- Which local organisations to work with, and the capacity both of researchers and these partner organisations to engage more broadly with community members;
- Who is leading the process; what community roles are engaged; and how disadvantaged or lower status stakeholders are included;
- Whether community partners and members are involved from the very beginning, and whether their role is one of consultation or of shared power;
- How individual and organisational interests are represented and in what numbers (e.g., should there be greater numbers of those who are usually less powerful?);
- The use of appropriate spaces to meet, means of deliberation (separate meetings with different groups or all in together), and respectful ground rules. All these are important in avoiding ‘presence without voice’ where those supposedly engaged are unable to speak up.
- Consideration of who facilitates, synthesises, and documents discussions and decisions;
- Alertness to the possible unintended harms that might arise, and how these might be mitigated; and
- How costs incurred by community organisations and members will be reimbursed; and how researchers will be accountable to communities for their actions.

5.16 When considering ways of creating more inclusive processes for setting research policy and research prioritisation in emergencies, it is also important to take account of existing broader challenges in research funding that can have an adverse impact on the effective and equitable funding of emergency research. Issues raised with us at a roundtable of research funders included:<sup>420</sup>

- The current lack of practical mechanisms (despite significant strategic work in the infectious disease field by the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) group of funders – see paragraph 3.24) to enable funders, as a group, to stand back and ask: ‘what research is really important here for those most affected?’, rather than each applying their own criteria as to what studies to fund.<sup>421</sup> There have, for example, been reports of the problems experienced by ethics committees in countries affected by major outbreaks when asked to review numerous studies, often from the same institutions, that aim to be conducted in the same populations at the same time, with no sense of prioritisation between them.<sup>422</sup> Similar concerns, particularly around ‘over-researching’ populations accompanied by very limited subsequent benefit, have been raised with respect to research among refugees

<sup>420</sup> Roundtable with funders, 8 March 2019.

<sup>421</sup> Ibid.

<sup>422</sup> Personal communication, Patricia Kingori (11 June 2018). See also: Schopper D, Ravinetto R, Schwartz L *et al.* (2017) Research ethics governance in times of Ebola *Public Health Ethics* **10**(1): 49-61; and Gailits N, Nouvet E, Pringle J *et al.* (2019) *Blurring lines: complexities of ethical challenges in the conduct of West African Ebola research*, available at: <https://www.elrha.org/wp-content/uploads/2019/10/Gailits-et-al.-Blurring-Lines-Ethical-Challenges-in-West-African-Ebola-Research.pdf>.

and host populations during the conflict in Syria.<sup>423</sup> This lack of effective collaboration is also problematic in scientific terms, as there is a higher risk that studies will be in competition with each other, unable to recruit enough participants, and unable to provide useful results. Relatedly, recent analysis of the published grant review processes of the largest funders of global research highlighted how rarely reviewers of grant applications were asked to consider the magnitude of the health problem, or the disadvantage of the potential beneficiaries. The analysis also noted that such grant review processes also typically only included scientists.<sup>424</sup>

- The way in which emergency research may not fare well in general funding calls, as it may be assessed as relatively risky, suggesting that there is a need for specialist funding calls dedicated to research in emergencies. Moreover, certain kinds of research – such as implementation research that may be very valuable in bridging the gap between clinical trials and health systems research – may not fit standard criteria, and hence are less likely to be successfully funded, regardless of the quality and importance of the proposal.
- The way in which non-communicable diseases tend to be particularly overlooked, and yet may be the most important immediate health need in some kinds of emergency, with important associated research questions associated with innovative ways of reaching displaced patients.<sup>425</sup>

5.17 In Chapter 4, we emphasised that it was necessary to consider not only the relevant values that should inform research conducted in global health emergencies, but, critically, also to identify who had responsibilities to take action and to initiate needed change (see paragraph 4.64). In particular, we suggested that such responsibilities should lie with those institutions with the greatest ability to act – whether by reference to their resources, or their position of influence (see paragraph 4.67–4.69). Respondents to our call for evidence made a strong case for funders to recognise and act on their role as ‘duty-bearers’, and this concept was regarded positively by funders contributing to our roundtable meeting. A further issue that emerged at that discussion was that of access to beneficial interventions after research, and the positive role that funders can potentially take in guaranteeing such access. The example was cited of the role of public sector or philanthropic funders ensuring that they exercise their negotiating power with any private sector partners involved in researching novel interventions. This might ensure that new interventions are affordable for local health systems and/or UN agencies to purchase so that affected populations can actually benefit – while also ensuring that such negotiations are appropriately timed to avoid delays to research at critical junctures.<sup>426</sup>

## Shifting the balance of power

5.18 The discussion in the section above is based on the status quo: that is, where a very high proportion of research funding, and the associated powerful influence on the research agenda, derives from institutions in a relatively small number of HICs. We

<sup>423</sup> Sibai AM, Rizk A, Coutts AP *et al.* (2019) North-South inequities in research collaboration in humanitarian and conflict contexts *The Lancet* **394**(10209): 1597-600.

<sup>424</sup> Pierson L and Millum J (in draft) Grant reviews and health research priority setting: do research funders uphold widely endorsed ethical principles? Presented at Global Health Bioethics conference, Oxford 1-2 July 2019.

<sup>425</sup> For example, the need to find innovative ways to provide care for people with chronic NCDs such as diabetes and high blood pressure where people are displaced and unable to access their usual routes for chronic care: Elrha (2019) *Updates from our research: NCDs among Syrian refugees in Jordan*, available at: <https://www.elrha.org/project-blog/updates-from-our-research-ncds-among-syrian-refugees-in-jordan/>.

<sup>426</sup> Roundtable with funders, 8 March 2019.

present below recommendations as to how those institutions might develop their policies and approaches in ways that enable a much wider range of voices to be heard in decisions about the prioritisation of research conducted in preparation for, and during, emergencies. In Chapter 8, we take up the related question of what needs to be done over the long-term to support capacity development in countries which have limited institutional capacity for research, and whose researchers are thus strongly disadvantaged in their ability to obtain funds for locally-identified research needs (see paragraphs 8.25–8.33).

- 5.19 However, it is also important to recognise, even if only in the form of a very long-term aspiration, that in order for influence and power genuinely to be shared by those most affected by the decisions made, the physical location of funders also needs to become much more dispersed (see paragraph 3.26).<sup>427</sup> Examples of progress in this area include the Alliance for Accelerating Excellence in Africa (AESA), an agenda-setting and funding platform for health and development research, which explicitly describes its mission as “shifting the centre of gravity for African science to Africa”.<sup>428</sup> AESA is an initiative of the African Academy of Sciences (AAS), which itself leverages funding both from African governments and a wide range of HIC partners, providing a possible model of the way forward.<sup>429</sup>

## Conclusions and recommendations on influence over priority-setting

- 5.20 We have identified two distinct, if interrelated, areas where change is needed to help promote more coordinated, responsive, and inclusive approaches to research prioritisation in global health emergencies. The first is the need for much better coordination by major research funders – with each other and with other key players – at the strategic level when making decisions that shape what research takes place in emergencies. The second is the importance of finding ways to make those decision-making processes much more inclusive of those living in countries that are directly affected by the emergency, thus increasing the likelihood that the health and research needs of those directly affected are better taken into account. We recognise that these issues are also highly relevant across the health research field in general and are not unique to research in emergencies. They are also very important in the context of research related to emergency preparedness, as well as research related to immediate response.

- 5.21 Possible ways forward suggested to us included:

- **The creation of a register** for major funders to record current and future areas of planned funding relevant to emergency preparedness and emergency response. This might include, where applicable, information about partners / collaborators, and products.<sup>430</sup> Such a register would provide the basis for avoiding duplication, identifying areas of shared interest and, where appropriate, facilitating collaborative approaches.

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<sup>427</sup> This has also become an important issue for the humanitarian sector. See: Civil Society News (28 June 2017) *Oxfam International reaches agreement to move headquarters to Nairobi*, available at: <https://www.civilsociety.co.uk/news/oxfam-reaches-agreement-to-move-headquarters-to-nairobi.html>.

<sup>428</sup> The African Academy of Sciences (2019) *Homepage*, available at: <https://aasciences.ac.ke/aesa>.

<sup>429</sup> See also: Research Professional News (12 September 2019) *Fragile trust and pale male leadership: Wellcome chief speaks out*, available at: <https://researchprofessionalnews.com/rr-news-africa-pan-african-2019-9-fragile-trust-and-pale-male-leadership-wellcome-chief-speaks-out/>.

<sup>430</sup> Roundtable with funders, 8 March 2019.

- Some form of **‘triage’ system** where, at the start of an emergency, funders come together to agree shared priorities for research in collaboration with those responsible for emergency response. Such a system would require, as a minimum, working arrangements agreed in advance between emergencies, with input from key research funders, diverse national governments, relevant UN agencies (whether WHO, the United Nations Office for the Coordination of Humanitarian Affairs (OCHA), or the United Nations Refugee Agency (UNHCR)), and national / regional research institutions. In each particular emergency, national governments and national research institutions from the affected country or countries, and the relevant WHO regional office, would automatically join.

5.22 On the first suggestion, we recognise that there are a number of existing ways in which funding organisations share information about the research they fund, including the coordination and mapping mechanisms within the WHO’s R&D Blueprint (necessarily focusing on the priority pathogens that are the concern of the Blueprint); the Global Observatory on Health R&D (which brings together a wide range of publicly available information on funding flows and product development);<sup>431</sup> and WorldReport, an open-access, interactive mapping database highlighting biomedical research investments and partnerships from major funding organisations.<sup>432</sup> The scope of the data shared in WorldReport varies from funder, but typically is retrospective.

#### **Recommendation 1 (directed to the funders of WorldReport)**

**We recommend that the valuable WorldReport initiative, mapping research investments and partnerships, be expanded to include a much wider range of prospective research plans of relevance to global health emergencies. This would facilitate increasingly coordinated planning of research relating to emergency preparedness and response.**

5.23 On the second suggestion, we understand that there is currently work underway, coordinated by WHO and partners and stakeholders, to strengthen mechanisms for supporting the integration of research into outbreak response, with a primary emphasis on ownership by relevant national authorities, and coordination and technical assistance from relevant stakeholders and partners. This would include agreeing relevant research priorities during infectious disease outbreaks. **We warmly welcome this initiative.**

#### **Recommendation 2 (directed to WHO and other stakeholders)**

**We recommend that WHO work with all stakeholders to expedite the development of mechanisms for supporting the integration of research into outbreak response, including standing operating procedures for agreeing research priorities in infectious disease outbreaks; and that this valuable model is also extended to research in other forms of emergency.**

5.24 There are well-recognised practical challenges of coordinating funding in tight timeframes between organisations with very different governance structures. A further

<sup>431</sup> WHO (2019) *About the Global Observatory on Health R&D*, available at: [https://www.who.int/research-observatory/why\\_what\\_how/en/index4.html](https://www.who.int/research-observatory/why_what_how/en/index4.html).

<sup>432</sup> National Institutes of Health (2019) *World report*, available at: <https://worldreport.nih.gov/app/#/>.



step towards achieving a responsive and collaborative approach to funding in emergencies would therefore be through the creation of a dedicated source of funding, held under its own governance arrangements, and with its own prioritisation and allocation processes.<sup>433</sup> This would involve funders, once satisfied with the robustness of the governance arrangements, genuinely relinquishing a degree of their power as to how the funding they have contributed will be spent.

### **Recommendation 3 (directed to Heads of International Research Organizations)**

**We recommend that the Heads of International Research Organizations take the lead in exploring the scope and appetite for the creation of a dedicated pool of resources, established with its own governance arrangements, for funding research for emergency preparedness and response. A necessary requirement of any such funding mechanism would be the diversity of representation from research institutions around the world, particularly among affected countries, among its leadership and decision-making processes, and a strong emphasis on coordination.**

5.25 While a coordinated approach is essential at the strategic level to avoid duplication and waste, there is also much that can be done by individual funders to facilitate more inclusive approaches to the prioritisation and planning of research at the level of individual grant applications.

### **Recommendation 4 (directed to funders)**

**We recommend that individual funding bodies should put in place innovative ways in which they can facilitate researchers in involving affected communities directly at the grant application stage – for example through the availability of small seed grants to enable initial scoping work, and sufficient flexibility to enable shifts in focus after grants have been awarded in response to community input.**

## **Engagement with affected communities in the conduct of research**

*“When you don’t see the problem the same way, you can’t craft solutions together.”<sup>434</sup>*

5.26 When we introduced the values of our ethical compass in Chapter 4, we argued that the exercise of respect for the equal moral agency of all persons requires certain kinds of attitudes and dispositions on the part of those conducting research. In particular, it requires taking people’s practices, traditions, and values seriously, and being aware of, and sensitive to, prevailing assumptions and norms, including the implications of the historical record (see paragraphs 4.38–4.39). Such respect also brings with it important procedural requirements, including public justification for any decisions taken that affect

<sup>433</sup> See, for example, Wellcome Trust and CIDRAP (2015) *Recommendations for accelerating the development of Ebola vaccines: report and analysis*, available at:

[http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola\\_virus\\_team\\_b\\_report-final-021615.pdf](http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_virus_team_b_report-final-021615.pdf), at page 60.

<sup>434</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>, at page 6.



a particular population, and a willingness to engage in dialogue and deliberation on terms of equality and equal recognition (see paragraph 4.43).<sup>435</sup>

- 5.27 This understanding of what ‘equal respect’ might demand in the context of research in global health emergencies underpins the moral importance of sustained and sincere engagement with the communities with whom researchers hope to conduct their research. The building of mutually respectful relationships that is inherent in such engagement is also a necessary part of creating a context in which individuals affected by the emergency have reasonable grounds for trusting both individual researchers and the wider research endeavour (see paragraph 4.46).
- 5.28 These ethical justifications for engaging with the communities where research takes place were strongly supported by contributors to the workshop on community engagement in emergencies that we co-hosted in Dakar with the African coalition for Epidemic Research, Response and Training (ALERRT) network of research centres;<sup>436</sup> and also in the approach taken in the WHO’s Good participatory practice guidelines for emerging and re-emerging pathogens.<sup>437</sup> Key themes from the debates at the Dakar workshop included:
- The central role of community engagement in supporting a **mutually respectful partnership** between researchers and communities, conceived as being the opposite of using people as a tool for others’ aims and ambitions;
  - the need for such a partnership to **start from a recognition of the experiences of people affected by the emergency**, and the history associated with those experiences which may have powerful implications for what is and is not acceptable in the research context (see paragraph 2.27);
  - the understanding of community engagement both as an **art or disposition** – what it is to engage empathetically with the expectation of mutual learning – and as a **set of processes**,<sup>438</sup> and
  - the recognition of the **diversity of communities**, and the ethical imperative to find ways of engaging with those who are marginalised, as well as those who occupy more influential positions within the population or have formal leadership roles.
- 5.29 The ethical goals of engagement discussed at the workshop included aspiring to achieve **joint ownership of the research** taking place; helping promote **transparency** and removing causes of doubt and suspicion; and resulting in the creation of **well-founded**

<sup>435</sup> Parker M (2006) Deliberative bioethics, in *Principles of health care ethics*, Ashcroft R, Dawson A, Draper H, and McMillan J (Editors) (Chichester, West Sussex: John Wiley & Sons).

<sup>436</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>437</sup> WHO (2016) *Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP): outcome document of the consultative process*, available at: <https://www.who.int/blueprint/what/norms-standards/GPP-EPP-December2016.pdf>.

<sup>438</sup> Many similar points were made at a health systems research conference in Liverpool in 2018, captured in a blog: E-Mops (20 January 2019) *Blog: Engaging with communities’ worlds, or asking them to engage in ours? Ideas on participation and power from the Health Systems Global 2018 Symposium*, available at: <http://e-mops.ning.com/profiles/blogs/engaging-with-the-communities-worlds-or-asking-them-to-engage-in>. The same issues arise in HICs, for example with reference to concerns in some parts of the public around vaccines. See, for example, Slate (15 April 2019) *Forget about ‘because science’*, available at: <https://slate.com/technology/2019/04/vaccination-values-science-based-policy.html>; and Wellcome (2019) *Wellcome global monitor 2018*, available at: <https://wellcome.ac.uk/reports/wellcome-global-monitor/2018>.

**trust** in the research endeavour.<sup>439</sup> The aspiration of joint ownership of research is likely to be a long-term goal and cannot be a minimum requirement of research in emergencies (see paragraphs 5.37–5.38). However, the fundamental importance of transparency and well-founded trust for emergency response and research (and the consequences where these are not present), have been well illustrated in many settings: for example, in recent infectious disease outbreaks such as the ninth and tenth Ebola outbreaks in the DRC,<sup>440</sup> and in angry responses to new research findings relating to the safety of the dengue vaccine in the Philippines.<sup>441</sup>

5.30 The support at the workshop for these ethical claims underpinning community engagement was accompanied by a keen awareness of the challenges (both conceptual and practical) and the real risks of community engagement being deployed unthinkingly as the single solution to all research problems. Below, we consider first the conceptual and definitional questions (paragraphs 5.33–5.37), and then some of the practical issues that arise in seeking to engage meaningfully under the time- and resource- pressed constraints of an emergency (paragraphs 5.39–5.40).

## Scope and challenges of community engagement

5.31 When talking about ‘community engagement’, two definitional questions immediately arise: what is meant by a ‘community’; and the nature and scope of the proposed ‘engagement’. Throughout this report, we have used the broader term ‘stakeholder’ to refer to *all* those with an interest or concern with respect to research being conducted in emergencies, from national governments and international organisations of many different kinds, to individual members of research teams and local populations. We use ‘community’ here to refer to that group of stakeholders, local to the site of the emergency, who are not directly part of the professional research effort, although for some their role (for example as healthcare workers) may bring them into contact with it. In the context of infectious disease outbreaks, the WHO Good participatory practice guidelines use the following definition which accords broadly with the approach taken by the Dakar workshop contributors:

*“the population to be recruited, trial participants, families of trial participants, people living in the immediate area where the research is conducted, local survivor groups or networks, people resident within or surrounding the area affected by the emerging pathogen epidemic, religious leaders, opinion leaders, media, local health-care authorities, healthcare providers, traditional healers, local non-governmental organizations (NGOs), community-based organizations (CBOs), and community-based women’s groups and youth groups.”<sup>442</sup>*

<sup>439</sup> See also: The Academy of Medical Sciences, the Medical Research Council (part of UK Research and Innovation (UKRI)), and the Interacademy Partnership (forthcoming) *Interdisciplinary research in epidemic preparedness and response*.

<sup>440</sup> National Geographic (23 May 2019) *Life amid an Ebola outbreak: combating mistrust - and saving lives*, available at: <https://www.nationalgeographic.com/culture/2019/05/ebola-democratic-republic-congo/>. See also: UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo’s 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf); and Stat News (7 March 2019) *Doctors Without Borders fiercely criticizes Ebola outbreak control effort*, available at: <https://www.statnews.com/2019/03/07/doctors-without-borders-criticizes-ebola-control-effort/>.

<sup>441</sup> Larson HJ, Hartigan-Go K, and de Figueiredo A (2018) Vaccine confidence plummets in the Philippines following dengue vaccine scare: why it matters to pandemic preparedness *Human Vaccines & Immunotherapeutics*: Published online: 12 October.

<sup>442</sup> WHO (2016) *Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP): outcome of the consultative process*, available at: <https://www.who.int/blueprint/what/norms-standards/GPP-EPP-December2016.pdf?ua=1>, at page 10.

- 5.32 As this very wide-ranging definition implies, the term ‘community’ masks a deeply diverse group of groups and subgroups. Within the group of “people resident within or surrounding the area affected” by an emergency, there may be many divisions and subdivisions, with often significant differences in status, influence, and economic situation.<sup>443</sup> While respectful contact with those in formal leadership roles will be essential for researchers, this will not be sufficient to ensure that teams are alert to the full range of perspectives of those living in the local area; and indeed some voices may be deliberately ignored or silenced by local leaders.<sup>444</sup> Local populations may also, in practice, subvert the authority of formal leaders, for example by ignoring or working around official guidance and healthcare advice.<sup>445</sup> Workshop contributors emphasised the difference between ‘gatekeepers’ (those with formal roles which gave them particular status, for example in local administrative or political systems, or through their religious role); and ‘influencers’ (people who in less formal ways represented, or were aware of, the perspectives of particular groups such as leaders of women’s or youth associations). The role of military actors may also be complex: it was suggested that in conflict zones local militias may sometimes be respected, because they are perceived as keeping local communities safe;<sup>446</sup> while government forces may be feared and distrusted.<sup>447</sup>
- 5.33 The concept of ‘engagement’ is similarly diversely understood. In some countries, clear distinctions are made between, for example, ‘public engagement’ that aims to increase awareness of science among the general public, ‘participation’ (being recruited to a study as a research participant), and ‘involvement’, where members of the public directly influence research priorities, act as co-applicants on a research project or are members of advisory or steering groups.<sup>448</sup> In the PREVAIL research partnership in Liberia, the general term ‘social mobilisation’ was used to describe a number of distinct strands of work, including ‘communication’ (public awareness), ‘engagement’ (activities that brought with them at least a degree of influence on the research process), and ‘advocacy’ (where social mobilisers used information gained by community engagement processes in order to advocate for wider change outside the immediate research setting).<sup>449</sup>
- 5.34 When we first discussed the implications of the core value of equal respect for ‘engaging’ with those whose lives are affected by research (see paragraph 4.43), we used the term inclusively to cover a range of activities starting from communication at one end of the spectrum, to inclusive decision-making in which local stakeholders are fully engaged and influential in all key aspects of decision-making across the research endeavour at the

<sup>443</sup> See, for example, the issues of ethnicity and caste discussed in UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo’s 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf), at page 15.

<sup>444</sup> *ibid.*, pp14-9.

<sup>445</sup> See, for example, Parker M, Hanson TM, Vandi A *et al.* (2019) Ebola, community engagement, and saving loved ones *The Lancet* **393**(10191): 2585, who explore the ambiguous role of paramount chiefs in Sierra Leone and the way people circumvented official advice and services in order to care themselves for family members with Ebola in the forest: “People everywhere live in complicated social spaces. Engaging with communities necessitates a politically nuanced understanding of specific circumstances and awareness that local intermediaries are unlikely to represent the views of everyone.”

<sup>446</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>447</sup> See, for example, CNN (23 June 2019) *Fighting Ebola is hard but in the Congo mistrust and fear is making it harder*, available at: <https://edition.cnn.com/2019/06/22/health/ebola-outbreak-congo-intl/index.html>.

<sup>448</sup> NIHR Involve (2019) *What is public involvement in research?*, available at: <https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/>.

<sup>449</sup> Kennedy SB, Neaton JD, Lane HC *et al.* (2016) Implementation of an Ebola virus disease vaccine clinical trial during the Ebola epidemic in Liberia: design, procedures, and challenges *Clinical Trials* **13**(1): 49-56; and ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

other. In what follows, we use ‘communication’ to refer to activities that are essentially one-directional, and ‘community engagement’ to cover any activities that involve two-way interactions. In practice, these activities will often come under the same umbrella, for example of ‘risk communication and community engagement’ teams.

- 5.35 At best, and as implied above in the concept of ‘joint ownership of research’, community engagement activities should actively involve affected populations from the very beginning and throughout the course of the research endeavour. This should take the form of a two-way process that contributes to the aims, design, conduct, and outcomes of research. If fully realised, such an approach might be better described as ‘co-production of research’, as, for example, in the research underpinning the development of a ‘toolbox’ of materials to support explanations of research for adults with limited literacy, described in Box 5.3 above. Such collaborative approaches are increasingly welcomed and discussed in the literature, particularly in the context of research associated with service developments and evaluations.<sup>450</sup> For highly technical biomedical research, such as that associated with the development of new vaccines and therapies, the role of communities (even outside the emergency context) is likely to be somewhat different. However, there is still a strong moral case for the voices of those affected to be heard from the beginning, including in questions of study design, to the extent that this can be made possible. This is *not* a challenge to the need for scientific rigour, but rather a recognition that research always needs to be contextually sensitive, and that affected populations are positioned to provide important expertise on how that can be achieved, as well having a moral claim to such involvement (for further discussion of involvement specifically in study design issues, see paragraphs 6.16–6.19). Engagement should also enable those affected by the emergency to influence ongoing and future research agendas by offering them the opportunity to highlight what is of primary concern to them, as described in Box 5.5 below.
- 5.36 **Looking to the future, we suggest that there are strong ethical reasons for both funders and governments to prioritise investment in community engagement mechanisms to maximise the possibility of meaningful relationships being created from the very beginning in future emergencies.** Such mechanisms should be at the heart of the national and regional research networks being developed as part of emergency preparedness (see Box 3.9), and in local and national health emergency and disaster risk management plans (see paragraph 3.2). The importance of ongoing investment in mechanisms that have developed during emergencies, thus ensuring that experience and capacity gained during the emergency is not lost, was strongly reinforced by participants in the Dakar workshop.<sup>451</sup> These mechanisms will be most sustainable when they are embedded in local health structures, such as the teams of (often volunteer) community health workers who play a key role in providing basic services in

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<sup>450</sup> For further discussion of co-production, see, for example, Filipe A, Renedo A, and Marston C (2017) The co-production of what? Knowledge, values, and social relations in health care *PLOS Biology* **15(5)**: e2001403; and Oliver K, Kothari A, and Mays N (2019) The dark side of coproduction: do the costs outweigh the benefits for health research? *Health Research Policy and Systems* **17(1)**: 33.

<sup>451</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.



many countries;<sup>452</sup> or in citizen networks taking the lead in local preparedness and education for natural or human-made disasters.<sup>453</sup>

- 5.37 It is also essential to address the question of how respectful approaches to community engagement can be addressed when emergencies arise in the absence of such clear preparation and mechanisms. To say that no research can take place at all without full engagement of all parts of a community from the very beginning would be to set a very high bar indeed: it could lead to significant lost opportunities to help reduce the suffering of those directly affected by the emergency. Drawing on our discussions of the 'interpretive' response to standard ethical principles, we have already suggested that the principle of community engagement could justifiably be interpreted by developing engagement processes as early as possible during the research process, and keeping design questions as open as possible to enable adjustments along the way in response to learning (see paragraphs 4.21–4.22). Workshop contributors described this as a 'learn / adapt, learn / adapt' model, under which perspectives, suggestions, and concerns of various parts of an affected community can be taken into account and can influence the conduct of research as it develops (see Box 5.5 on how this approach developed in Liberia during its Ebola outbreak).
- 5.38 However, there are important limits to 'interpreting' a principle, and in particular the risk that the interpretation of a principle loses sight of what is most important (see paragraph 4.23). In this context, we suggest that other elements of our ethical compass – equal respect and fairness – act as a critical balancing factor and constraint on considerations of how best to help reduce suffering. **In the absence of pre-existing relationships and effective systems, it is highly unlikely that everything can be in place in the early stage of an emergency to facilitate full engagement from the very start of the research endeavour. However, equal respect demands clear communication from research teams from the very beginning, accompanied by real commitment to start developing the relationships necessary to build two-way processes as quickly as possible. Fairness demands that those efforts include consideration of the experiences and views of marginalised parts of those communities, alongside those of more influential and powerful members.** We now turn to these practical challenges, and how they have been addressed in recent emergencies.

#### Box 5.5: The role of communities in influencing research: an example from the PREVAIL studies

*Joseph Boye Cooper, Soka Moses, and Bartholomew Wilson provided the working group with an account of how communities in Liberia influence the research that PREVAIL undertakes.*

PREVAIL was established in response to the outbreak of Ebola in Liberia in August 2014. On the emergence of the outbreak, the country's leaders – concerned that Liberia had no capacity to respond to the virus – contacted the US administration to request assistance. As a result of the request, PREVAIL was launched as a research

<sup>452</sup> See, for example, UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo's 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf); and Boyce MR, and Katz R (2019) Community health workers and pandemic preparedness: current and prospective roles *Frontiers in Public Health* 7: 62.

<sup>453</sup> See, for example, the role of 'radiation risk communicators' established in the light of the Fukushima disaster: Kimura AH (2018) Fukushima ETHOS: post-disaster risk communication, affect, and shifting risks *Science as Culture* 27(1): 98-117; and the role of schools: Earthquake Education & Disaster Preparedness Program (2007) *Earthquake Education & Disaster Preparedness Program wants to help increase preparedness*, available at: [https://www.preventionweb.net/files/3426\\_Earthquakefull.pdf](https://www.preventionweb.net/files/3426_Earthquakefull.pdf).

collaboration between the Liberian Government and the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID).

Social mobilisation and engagement were vital to ending the Ebola outbreak in Liberia. The country's health systems broke down, so communities took the initiative to help the sick – for example by creating awareness, promoting hand washing, and allowing safe burials. They also helped in the reporting of Ebola cases and transporting people to holding centres, so that they could then be moved to emergency treatment units (ETUs) when spaces were available, and helping quarantined families with food and water and other basic commodities. This community action provided PREVAIL's partners with a positive signal about communities' role. PREVAIL invited some of these community mobilisers to form the PREVAIL Social Mobilisation and Communication (SMC) committee to undertake work directly with communities. The SMC now acts as a bridge that links PREVAIL's research endeavours with the community members that they aim to engage, and potentially enrol.

During the early stages of protocol development for PREVAIL's research work, the organisation's SMC committee begin conversations with future potential research participants living in communities and their leaders, and with government agencies. PREVAIL works with communities in the knowledge that in order to conduct research, community buy-in is needed at all levels in order for community 'ownership' of research to be achieved. Community buy-in is supported through a range of actions by SMC, including talking to community leaders, women, and young people. PREVAIL also organises formal meetings and informal discussions around the research, in addition to encouraging communities to set up their own fora to talk about the studies. The SMC committee members make themselves available to answer questions that arise from these discussions and meetings. They also collaborate with the principal investigators (PIs) to communicate the results of the research studies to the participants and their communities. The research participants are also given their data (for example clinical laboratory test results) which they may share with their primary care providers, if they wish, to inform treatment.

These endeavours are not 'one-off' events: the SMC committee goes back and forth between communities and PREVAIL's research teams, ensuring that any clarifications or questions that the community members require are available – for example, regarding the meaning of technical terms and addressing rumours. The SMC committee also works with members of the media, providing information directly about ongoing PREVAIL research studies and offering training on understanding and reporting of scientific research. Every few months, the team participates on the Ministry of Information periodic press briefings to provide updates and results from the ongoing PREVAIL research and planned research protocols. The SMC committee also discusses major points regarding the research with communities, including who can participate, how long the study will last, and how participants can enrol. Communities' questions that arise out of these discussion points are brought back to the study team, and subsequently contribute to the development of FAQs and the protocol.

One example of PREVAIL's work with potential research participants in communities is exemplified in its approach to PREVAIL 8 (a research project on HIV).<sup>454</sup> The SMC committee met with leaders and members of HIV support groups in-country and talked to them about the research and its enrolment processes. The support groups expressed strong views on what social mobilisation and community engagement strategies should be used and what the protocol should be named in order to mitigate stigma: they did not

<sup>454</sup> ClinicalTrials.gov (2019) *PREVAIL VIII: A CoHOrt Clinical, Viral, and ImmunoNOlogic Monitoring Study of People Living With Retroviral Infection in Liberia (HONOR)*, available at: <https://clinicaltrials.gov/ct2/show/NCT03733093>.



want it to be called ‘the HIV study’, but rather by another name. The study was subsequently named ‘A coHOrt clinical, viral, and immuNOlogic monitoring study of people living with retroviral infection in Liberia (HONOR)’. The participants also expressed their opinion about the questions the research should help answer, in order to improve the quality of care for people living with HIV in country.

## Approaches to community engagement

5.39 While we recognise the challenges of rapidly setting up effective mechanisms to create two-way communication with communities already disrupted by the emergency, there is a growing body of evidence of this being successfully achieved, alongside increasing access to resources to support practitioners.<sup>455</sup> Drawing on the experience shared at the Dakar workshop,<sup>456</sup> and in reports collating ‘lessons learned’, particularly in the context of recent Ebola outbreaks,<sup>457</sup> we highlight below components of good practice cited to us. However, given the diversity of situations in which the need for such engagement could arise, it is important to avoid being too prescriptive.

- Focusing on the importance of developing **mutual understanding** – and recognising that this is not necessarily the same as agreement. Consensus may not always be achievable, but understanding different perspectives is a necessary part of a respectful approach. **Being clear about what is *not* possible** and avoiding promising what cannot be delivered is an essential part of developing mutual trust and respect.
- Recognising that **everyone engaged in research will influence local perceptions of the research** – while community engagement activities will be conducted by those with particular expertise, everyone in the research team has a part to play in creating respectful relationships through the way that they conduct themselves.<sup>458</sup> This highlights the importance of research teams investing in communications training for all workers involved in a study, hence increasing cultural sensitivity and awareness, and reducing the risk of team members inadvertently contributing to disengagement.
- **Working with social scientists**, using methods such as ‘power-mapping’, to understand power dynamics within a society and the breadth and complexity of the

<sup>455</sup> See in particular the development of the MESH Community Engagement Network for sharing / accessing useful resources, and the development of an online training course on the practice and ethics of participatory visual methods for community engagement in public health and health science: Mesh (2019) *Homepage*, available at: <https://mesh.tghn.org/>; and Mesh (2019) *The practice and ethics of participatory visual methods for community engagement in public health and health science*, available at: <https://globalhealthtrainingcentre.tghn.org/practice-and-ethics-participatory-visual-methods-community-engagement-public-health-and-health-science/>.

<sup>456</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>457</sup> National Academies of Sciences, Engineering, and Medicine (2017) *Integrating clinical research into epidemic response: the Ebola experience*, available at: <http://nationalacademies.org/hmd/reports/2017/integrating-clinical-research-into-epidemic-response-the-ebola-experience.aspx>; and UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo’s 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf).

<sup>458</sup> It was argued in the Dakar workshop, for example, that “if you’re not an engager through your behaviour, by default you’re a disengager”. See: ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>, at page 9.

populations affected.<sup>459</sup> This approach aims **to ensure that marginalised and often-overlooked parts of the community are included in community engagement processes**. This may be particularly important at the outset, so that contracts for community engagement are appropriately allocated, taking into account that some marginalised groups may be suspicious of mediators drawn from majority groups, or the likely importance of enabling engagement with women to be led by female workers.

- **Working with existing networks and structures**, both in terms of those with official roles of status (for example, administrative or cultural leaders and religious leaders), and those with less formal standing who in practice can speak for, or facilitate access to, parts of the community. Examples frequently cited include women's associations, youth groups, church communities, traditional healers, and associations of bicycle couriers / chauffeurs.
- **Planning upfront for practical aspects, for example around language and cost**. These issues are not unique to emergencies but, if not recognised and planned for, will delay and reduce the impact of community engagement in emergency settings.<sup>460</sup> Moreover, understanding community engagement in the context of building relationships helps explain the importance of meeting local norms of hospitality. Budgets for community engagement activities need to cover the costs of conducting engagement activities, and not simply the staff costs of engagement practitioners. This would include the costs of refreshments during activities, and the reimbursement of the costs incurred by community members in taking part. Budgets should be flexible to enable engagement practitioners to respond appropriately to the needs that they may encounter, and to other demands of hospitality (for example, taking a small gift when visiting people's homes).
- **Using a wide variety of methods**, appropriate to the setting, to reach different parts of the community and ensure diverse voices are heard (and importantly that people feel able to speak once present). A willingness to travel to remote villages as well as holding information sessions in more populated settings, offering one-on-one, focus group, and women-only discussions, producing targeted messaging and FAQs in a variety of forms, using broadcast media, jingles and songs, and text messages are all cited.<sup>461</sup> Appropriate use of local languages, even where languages such as English, French, or Spanish are widely used for administrative purposes, may be critical in reaching parts of communities who would otherwise be unable to contribute.<sup>462</sup>

<sup>459</sup> See, for example, Enria L, Lees S, Smout E *et al.* (2016) Power, fairness and trust: understanding and engaging with vaccine trial participants and communities in the setting up the EBOVAC-Salone vaccine trial in Sierra Leone *BMC Public Health* **16**(1): 1140; and ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>, at page 3.

<sup>460</sup> See, for example, E-Mops (13 April 2019) *Participatory action research in action*, available at: <http://e-mops.ning.com/profiles/blogs/participatory-action-research-in-action>.

<sup>461</sup> See, for example, Oxfam (2009) *In the wake of the tsunami: an evaluation of Oxfam International's response to the 2004 Indian Ocean tsunami*, available at: [https://www.oxfam.org/sites/www.oxfam.org/files/file\\_attachments/oxfam-international-tsunami-evaluation-summary\\_3.pdf](https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/oxfam-international-tsunami-evaluation-summary_3.pdf), at page 12, for an example of women's engagement in disaster management after the 2004 tsunami. See also: Kennedy SB, Neaton JD, Lane HC *et al.* (2016) Implementation of an Ebola virus disease vaccine clinical trial during the Ebola epidemic in Liberia: design, procedures, and challenges *Clinical Trials* **13**(1): 49-56; National Academies of Sciences, Engineering, and Medicine (2017) *Integrating clinical research into epidemic response: the Ebola experience*, available at: <http://nationalacademies.org/hmd/reports/2017/integrating-clinical-research-into-epidemic-response-the-ebola-experience.aspx>; UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo's 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf); and Hugelius K, Adams M, and Romo-Murphy E (2019) The power of radio to promote health and resilience in natural disasters: a review *International Journal of Environmental Research and Public Health* **16**(14): 2526.

<sup>462</sup> Nature (10 June 2019) *Indian initiatives aim to break science's language barrier*, available at: <https://www.nature.com/articles/d41586-019-01815-1>.

- Ensuring that iterative systems are in place to allow for what is learned in both community engagement activities, and through complementary social science research, can **feed back into the research process**. Genuine scope for feedback to influence research processes on the ground is essential, alongside honesty and transparency about what is not open to change. While the work of social scientists and community engagers are complementary, they can benefit from joint structures, for example through a shared community advisory board, so that lessons learned through either route can be fed back and inform future engagement.
- Recognising the **essential role of the media** – for example through research teams working with local and national media organisations, and with patient / survivor groups to increase journalists’ awareness of science and help avoid media communications contributing to panic during an emergency.<sup>463</sup>

5.40 As the examples above demonstrate, a large number of different organisations involved in emergency response and research have significant roles to play in facilitating community engagement activities. The defining line between community engagement in response and in research is unlikely to be clear. Indeed, as described by the PREVAIL research partnership (see Box 5.5), initial action by community members in support of effective response may provide a basis for effective community collaboration and engagement in subsequent research activity. We have argued above (see paragraph 5.36) that national governments have a key responsibility to prioritise investment in sustainable community engagement processes, embedded in local health services and in local emergency planning systems. Below, we highlight the specific role that research funders are well placed to play in supporting and promoting meaningful community engagements in the research they fund.

#### Recommendation 5 (directed to funders)

**Research funders should require coherent, achievable and inclusive plans for community engagement in funding proposals, while avoiding being over-prescriptive on how this might be achieved, thus allowing for activities to be guided by reality on the ground. They should include explicit reference to community engagement in budget templates, accompanied by the recognition that budgets need to allow for community activities and reimbursements, as well as staff costs.**

<sup>463</sup> Hugelius K, Adams M, and Romo-Murphy E (2019) The power of radio to promote health and resilience in natural disasters: a review *International Journal of Environmental Research and Public Health* **16(14)**: 2526. See also: Institute for Research & Development in Health & Social Care (2019) *Workshop report: the post disaster role of media representatives (exclusively for media representatives)*, available at: <https://www.ird.lk/wp-content/uploads/2019/07/Media-Representatives-Disaster-Management-Workshop-Report-21MAY2019.pdf>.



# Chapter 6

An inclusive approach to  
study design and review

## Chapter 6 – An inclusive approach to study design and review

### Chapter 6: overview

Global health emergencies pose significant challenges to the design and ethical review of research. An ethical approach to these challenges involves being alert to the heightened vulnerabilities involved and responding flexibly to the emergency context. Our ethical compass provides a guide to consider how standard procedures might need to be adapted and when this can be justified.

It is unethical to ask people to take part in research unlikely to produce meaningful results, which hence will not help reduce suffering. This highlights the importance of scientific rigour and validity. It also emphasises the importance of study designs that are locally acceptable: designs that cannot recruit enough participants, for example because of unaddressed local concerns, will not be feasible. Key questions to ask are:

- **Is this the right study** for this location and this population / subpopulation? Who has been involved in identifying and characterising the problem that the research seeks to answer? Will local populations benefit from any positive findings? And then:
- **Is this the right design** for this location and this population? How have local needs, concerns or preferences been taken into account?

We recommend that:

- **Study protocols should be developed with the input of local communities before being finalised, in order to ensure that proposed procedures are acceptable.** Even in multi-site trials, there will be elements that can and should be operationalised differently in different sites in response to engagement and feedback.
- **Any exclusion criteria from studies should be clearly justified** with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of ‘vulnerable groups’.

Independent ethical review (both in the country affected and, where relevant, in other countries) provides an important safeguard for research participants, and the *standard* of review should not be compromised in any way by the emergency context. All concerned (funders, governments, research institutions, and affected populations) need to have assurance that proper scrutiny has taken place. The *processes* used to achieve that scrutiny, on the other hand, can and should be adapted as necessary to the context, including scope for expediting urgent applications, with flexible means of communication and deliberation. Access to local expertise to understand both the possible risks of the research and the wider risks to which people are exposed through the emergency is essential. Planning for such processes, and supporting the development of ethical review structures in countries and sectors that are currently underserved, are important parts of emergency preparedness. It is also essential to recognise that independent ethical review is only one part of the ‘ethics ecosystem’ and does not absolve researchers from their own duties of ethical reflection (see Chapter 10). We recommend:

- **development of collaborative systems, at national and, where relevant, at international (e.g., WHO regional) level** to facilitate rapid and responsive review in emergencies, including access to ethical expertise where needed; and
- **an explicit step of ethical consideration**, for example with a manager or colleague, **as part of developing plans for needs assessment or evaluation** not covered by research governance arrangements.



- 6.1 The features of a global health emergency identified in Chapter 1 (see paragraph 1.8) pose a number of major challenges for the design, and then the review, of research proposals. Throughout the process of prioritising, designing, and reviewing a study, decisions are likely to have to be made within very tight timeframes in the knowledge that delay also carries risk. This would include, for example, decisions on what constitutes an acceptable balance of risk and potential benefit in a context of considerable scientific uncertainty. The wider contextual risks (both physical and non-physical) to which populations may be exposed may affect the consideration of the balance of risks and benefits of study participation; they may also not be well-understood, especially by non-local researchers and reviewers. Such risks include stigma associated with local attitudes to disease or research, or inadvertent loss of confidentiality through the very act of research participation. The risk of exclusion from research is also important, and may be overlooked, especially where studies offer access to potential benefits (financial or non-financial) that are otherwise unavailable to the population (see also Chapter 7).
- 6.2 Global health emergencies also pose unique challenges to the functioning of research ethics committees (RECs), particularly where these are already under-resourced and/or disrupted by the nature of the emergency. In addition to the pressure of responding flexibly and within tight timescales, RECs may also be faced with sudden increases in the number of protocols being presented for review, and study designs that are unfamiliar to committee members.

## Study design: an inclusive way forward

- 6.3 The question of what constitutes an ethical study design in an emergency, and whether unproven interventions should be offered outside clinical trial contexts, has been subject to intense debate in recent emergencies. The design of interventional trials during the West Africa Ebola outbreak, for example, was “controversial and divided opinions between researchers, physicians, ethicists and regulators,”<sup>464</sup> and the issue has since generated considerable debate in the bioethics literature.<sup>465</sup> Similarly conflicting views were expressed to us in response to our call for evidence, particularly on the permissibility of individual randomisation to novel interventions in the context of a currently untreatable disease.<sup>466</sup> However, the successful establishment in the Democratic Republic of the Congo (DRC) in 2019 of a collaborative clinical trial, in which all participants with Ebola were randomised to one of four novel interventions, suggests that significant progress has been made in designing clinical trials in ways that are sensitive to the concerns of populations facing potentially devastating outbreaks, while still meeting the regulatory requirements necessary to license successful candidate interventions in the future (see Box 6.1).

<sup>464</sup> Alirol E, Kuesel AC, Guraiib MM *et al.* (2017) Ethics review of studies during public health emergencies - the experience of the WHO ethics review committee during the Ebola virus disease epidemic *BMC Medical Ethics* **18**(1): 43.

<sup>465</sup> See, for example, Kombe F, Folayan MO, Ambe J *et al.* (2016) Taking the bull by the horns: ethical considerations in the design and implementation of an Ebola virus therapy trial *Social Science & Medicine* **148**: 163-70; Eyal N, and Lipsitch M (2017) Vaccine testing for emerging infections: the case for individual randomisation *Journal of Medical Ethics* **43**: 625-31; and Folayan MO, Haire B, Allman D *et al.* (2018) Research priorities during infectious disease emergencies in West Africa *BMC Research Notes* **11**(1): 159.

<sup>466</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.

### Box 6.1: Study design and use of experimental interventions outside clinical trial conditions – learning from Ebola

The 2014–16 West Africa Ebola outbreak brought to the fore the ethical challenges of designing studies of novel interventions for diseases where no effective vaccines or treatments currently exist. Advocates of individual randomised controlled trials (iRCTs) argued for the need for studies to include individual randomisation to a comparator arm to ensure scientific robustness and social value. Others argued it was unethical to withhold the hope offered by investigational interventions given the high fatality rate in West Africa under standard care.<sup>467</sup> Guidance issued by the World Health Organization's (WHO) Ethics Working Group emphasised that “all scientifically recognized methodologies and study designs should be considered as ethically acceptable”, whether or not they involved randomisation to control groups.<sup>468</sup> However, the group noted that some study designs might not be acceptable to the study population, or feasible for logistical reasons. Further guidance, issued by the World Health Organization (WHO) in 2016, reinforced the importance of methodological rigour in research, noting that “exposing research participants to risk is ethically unacceptable if the study is not designed in a manner capable of providing valid results.”<sup>469</sup> An expert panel convened by WHO in 2014 also approved ‘monitored emergency use of unregistered and investigational interventions’ (MEURI – see paragraph 1.17), enabling access to such interventions outside strict trial protocols during the outbreak.<sup>470</sup>

#### Progress with novel treatments

- While a number of therapeutic trials were approved and initiated during the West Africa Ebola outbreak, a subsequent review by the US National Academies of Science, Engineering and Medicine (NAS) expressed concern that, despite all the resources, time, and effort put in, none was able to reach a definitive conclusion about efficacy. The NAS also expressed concern about the use of unproven interventions outside a trial, because of the lost opportunity to generate information on safety and efficacy; the risks of public misconception as to the status of the treatment; and possible implications for loss of future trust in researchers and research.<sup>471</sup>
- The situation in the latest outbreak in the DRC has been very different. A single multi-drug randomised control trial, evaluating the safety and efficacy of four different drugs, was coordinated by the WHO in partnership with key health institutions in the DRC and humanitarian organisations. This enabled all patients entering the facilities where the trial was operating to be offered a novel intervention. Preliminary results for two of the drugs were sufficiently promising for the Data and Safety Monitoring Board (DSMB) to recommend in August 2019 that the study be stopped, and all future patients be

<sup>467</sup> Alirol E, Kuesel AC, Guraiib MM *et al.* (2017) Ethics review of studies during public health emergencies - the experience of the WHO ethics review committee during the Ebola virus disease epidemic *BMC Medical Ethics* **18**(1): 43; Eyal N, and Lipsitch M (2017) Vaccine testing for emerging infections: the case for individual randomisation *Journal of Medical Ethics* **43**: 625-31; and the account in chapter 2 of National Academies of Sciences, Engineering, and Medicine (2017) *Integrating clinical research into epidemic response: the Ebola experience*, available at: <http://nationalacademies.org/hmd/reports/2017/integrating-clinical-research-into-epidemic-response-the-ebola-experience.aspx>.

<sup>468</sup> WHO (2014) *Ethical issues related to study design for trials on therapeutics for Ebola Virus Disease: WHO Ethics Group discussion - summary of discussion*, available at: [http://apps.who.int/iris/bitstream/handle/10665/137509/WHO\\_HIS\\_KER\\_GHE\\_14.2\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/137509/WHO_HIS_KER_GHE_14.2_eng.pdf?sequence=1), at page 2.

<sup>469</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, at page 33.

<sup>470</sup> WHO (2014) *Ethical considerations for use of unregistered interventions for Ebola viral disease: report of an advisory panel to WHO*, available at: [http://apps.who.int/iris/bitstream/handle/10665/130997/WHO\\_HIS\\_KER\\_GHE\\_14.1\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/130997/WHO_HIS_KER_GHE_14.1_eng.pdf?sequence=1). Further guidance on MEURI was subsequently issued in WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>.

<sup>471</sup> National Academies of Sciences, Engineering, and Medicine (2017) *Integrating clinical research into epidemic response: the Ebola experience*, available at: <http://nationalacademies.org/hmd/reports/2017/integrating-clinical-research-into-epidemic-response-the-ebola-experience.aspx>, at page 43.

randomised to receive one of these two products in an extension study.<sup>472</sup> A report of the study commented how: “Reaching a successful conclusion to this challenging trial required careful planning as well as the cooperation, support, and coordination of national and international health agencies, government leaders, pharmaceutical companies, dedicated oversight boards, scientists, and nongovernmental organizations.”<sup>473</sup>

### Vaccines

Promising results from a phase III vaccine trial in West Africa (rVSV-ZEBOV, produced by Merck)<sup>474</sup> led to this vaccine being used on an unlicensed ‘expanded access’ basis in subsequent outbreaks in Guinea and the DRC.<sup>475</sup> It is used in the form of a ‘ring’ vaccination in which health workers, the contacts of people with confirmed Ebola, and the contacts of those contacts, are offered vaccination in order to prevent the infection spreading. A second experimental vaccine (involving two doses leveraging different vaccines, Ad26.ZEBOV and MVA-BN-Filo, manufactured by Johnson & Johnson<sup>476</sup>), is being introduced in the DRC, with the aim of being able to offer vaccination to everyone within targeted areas.<sup>477</sup> On 11 November 2019, the European Medicines Agency (EMA) approved the Merck vaccine for market, thus facilitating stockpiling, and potentially wider distribution.<sup>478</sup>

- 6.4 In the light of recent debates over the acceptability of individual randomisation, the issue of ‘alternative’ trial designs (many of which are not particularly new) have been the subject of renewed attention (see Box 6.2). Stepped wedge designs, for example, are seen by some as avoiding the ethical challenges of individual randomisation, as all participants eventually receive the study intervention (although the ethical differences between delaying and denying access to a potentially beneficial intervention have been disputed).<sup>479</sup> Adaptive studies use statistical techniques and real-time analysis to minimise the number of study participants receiving interventions that appear to be less effective.<sup>480</sup> While the recent focus of ethical debate has been on the role of these designs in novel therapeutic studies, designs such as stepped wedge and cluster randomised trials may be particularly relevant to a much wider range of emergency research, for example in implementation research exploring the effectiveness of

<sup>472</sup> National Institute of Allergy and Infectious Diseases (12 August 2019) *Independent Monitoring Board recommends early termination of Ebola therapeutics trial in DRC because of favorable results with two of four candidates*, available at: <https://www.niaid.nih.gov/news-events/independent-monitoring-board-recommends-early-termination-ebola-therapeutics-trial-drc>.

<sup>473</sup> Mulangu S, Dodd LE, Davey RT *et al.* (2019) A randomized, controlled trial of Ebola virus disease therapeutics *New England Journal of Medicine* **381(24)**: 2293-303, at page 2302.

<sup>474</sup> Henao-Restrepo AM, Longini IM, Egger M *et al.* (2015) Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial *The Lancet* **386(9996)**: 857-66; and Gsell P-S, Camacho A, Kucharski AJ *et al.* (2017) Ring vaccination with rVSV-ZEBOV under expanded access in response to an outbreak of Ebola virus disease in Guinea, 2016: an operational and vaccine safety report *The Lancet Infectious Diseases* **17(12)**: 1276-84.

<sup>475</sup> WHO (2018) *Ebola vaccine frequently asked questions*, available at: <https://www.who.int/emergencies/diseases/ebola/frequently-asked-questions/ebola-vaccine>.

<sup>476</sup> Johnson & Johnson (7 November 2019) *Johnson & Johnson announces submission of European marketing authorisation applications for Janssen’s investigational Ebola vaccine regimen*, available at: <https://www.jnj.com/johnson-johnson-announces-submission-of-european-marketing-authorisation-applications-for-janssens-investigational-ebola-vaccine-regimen>.

<sup>477</sup> WHO (23 September 2019) *Second Ebola vaccine to complement “ring vaccination” given green light in DRC*, available at: <https://www.who.int/news-room/detail/23-09-2019-second-ebola-vaccine-to-complement-ring-vaccination-given-green-light-in-drc>.

<sup>478</sup> Nature (12 November 2019) *‘Make Ebola a thing of the past’: first vaccine against deadly virus approved*, available at: <https://www.nature.com/articles/d41586-019-03490-8>.

<sup>479</sup> Binik A (2019) Delaying and withholding interventions: ethics and the stepped wedge trial *Journal of Medical Ethics* **45(10)**: 662.

<sup>480</sup> FDA (2019) *Adaptive designs for clinical trials of drugs and biologics: guidance for industry*, available at: <https://www.fda.gov/media/78495/download>.

delivering recognised interventions in the particular emergency context, or in evaluating the roll-out of services.

- 6.5 These and other approaches to trial design were the focus of the 2017 Global Forum on Bioethics in Research (GFBR), an annual event that seeks to bring the voices and perspectives of low- and middle-income countries (LMICs) to the fore in discussions on emerging ethical issues in research.<sup>481</sup> It was widely agreed that it was more helpful to consider, in any specific context, what was the best design for the goals of a study, rather than thinking in terms of ‘standard’ and ‘alternative’ designs. However, while approaches including adaptive, cluster randomised, and stepped wedge designs were agreed to offer potential – practical and ethical – advantages, it was noted that they raised novel ethical questions. It was also noted that there was limited ethical guidance currently available on these designs, and that RECs in some countries were hesitant to accept them because lack of familiarity contributed to concerns around their ethical acceptability.

### Box 6.2: Alternative trial designs and associated ethical challenges

In **cluster trials**, groups or clusters (such as health centres or villages), rather than individuals, are randomly assigned to an intervention:

- Ethical challenges include defining who is the participant (for example the individual or the health workers providing the service), and hence who should be invited to consent, particularly where the focus of the research is on different ways of delivering services between ‘clusters’ based on clinics or geographical communities.<sup>482</sup>

In **stepped wedge trials**, an intervention is allocated sequentially to study participants or to clusters (as in the 2015 Ebola ring vaccination trial where the clusters of contacts of infected persons were randomly assigned to immediate or delayed vaccination):

- Ethical issues include distinguishing between implementation (in the form of the staged roll-out of a new service or policy) and research; and dealing with local pressures to decide on the sequence of clusters receiving the intervention.

In **adaptive trials**, the allocation of participants to study arms (or indeed the study arms themselves) can change throughout the study in response to ongoing statistical analysis of emerging results.<sup>483</sup>

- Ethical challenges include the difficulties of achieving informed consent for particularly complex study designs.

- 6.6 A key concern underpinning the debate about individual randomisation derives from the scope for research in some cases to offer participants the prospect of direct health benefit – and hence associated concerns about fairness with respect to those excluded. In early stage research, such prospect may be highly uncertain (and indeed

<sup>481</sup> GFBR (2017) *Meeting report: ethics of alternative clinical trial designs and methods in LMIC research*, available at: <http://www.gfbr.global/wp-content/uploads/2018/12/GFBR-2017-meeting-report-FINAL.pdf>. See also the case studies included in this meeting report which were debated at the forum and provide an account of these different trial designs in a range of settings.

<sup>482</sup> Ethical issues identified by participants at the GFBR, see: GFBR (2017) *Ethics of alternative clinical trial designs and methods in low- and middle-income country research: 28-29 November, Bangkok*, available at: [https://www.wellcomevents.org/WELLCOME/media/uploaded/EVWELLCOME/event\\_535/GFBR\\_Bangkok\\_summary\\_slides.pdf](https://www.wellcomevents.org/WELLCOME/media/uploaded/EVWELLCOME/event_535/GFBR_Bangkok_summary_slides.pdf); and GFBR (2017) *Meeting report: ethics of alternative clinical trial designs and methods in LMIC research*, available at: <http://www.gfbr.global/wp-content/uploads/2018/12/GFBR-2017-meeting-report-FINAL.pdf>. See also: Horn AR, Weijer C, Hey SP *et al.* (2018) Thinking clearly about the FIRST trial: addressing ethical challenges in cluster randomised trials of policy interventions involving health providers *Journal of Medical Ethics* **44(9)**: 593-8.

<sup>483</sup> See, for example, FDA (5 February 2019) *Impact story: a flexible clinical trial design suitable for emerging disease outbreaks*, available at: <https://www.fda.gov/drugs/science-and-research-drugs/impact-story-flexible-clinical-trial-design-suitable-emerging-disease-outbreaks>.



accompanied by the prospect of significant risk), reinforcing the need for scientifically rigorous study design, and careful consent processes to avoid risks of therapeutic misconception (see also Chapter 7).<sup>484</sup> However, as illustrated by vigorous debates over access to novel therapeutics both in low-income countries (LICs) and high-income countries (HICs), once there are even very early indications that a particular intervention may indeed offer benefits that exceed existing standards of care, there will be very strong pressure for it to be made more widely available (see paragraph 1.17).<sup>485</sup> In the context of research in an emergency, such pressures may have an impact on policy-makers in at least two ways: when determining inclusion criteria for studies; and in the scope for making interventions available outside the trial itself, through ‘compassionate’ or ‘extended’ use arrangements.<sup>486</sup>

- 6.7 From a traditional research ethics perspective, concerns about fairness in inclusion criteria focus primarily on whether data will be generated with respect to groups who might benefit from the research in the longer term. Thus, if older people are predictably likely to be able to benefit from a particular intervention, sufficient older people should be included within the study to ensure the generation of sufficient data on the effect of the intervention in older populations.<sup>487</sup> However, the question of ‘fair access’ to the study intervention *during* the study is generally not a consideration because what is being offered is participation in research, not access to a service. A competing argument, drawing on public health ethics, might hold that where there is justification for believing a novel intervention will be of benefit (as in phase III studies of vaccines, for example), then fair access questions *should* be taken into account in setting the study inclusion criteria.<sup>488</sup> Such a tension arises wherever an intervention might be perceived as simultaneously constituting both research and treatment (see paragraphs 1.16–1.17).
- 6.8 Similar tensions, between scope for current and future benefit, arise in the context of ‘compassionate’ or ‘extended’ access to novel interventions outside a clinical trial context. The NAS, for example, has expressed reservations about such access because of the risks that this might undermine capacity to run proper trials, and hence delay, or even prevent altogether, the generation of good quality evidence on effectiveness to inform future practice (see Box 6.1). Respondents to our call for evidence, by contrast, expressed significant reservations about prioritising future benefit over scope for benefit at the time for those directly affected by the emergency (see Box 6.3).

<sup>484</sup> WHO (2014) *Ethical issues related to study design for trials on therapeutics for Ebola Virus Disease: WHO Ethics Group discussion - summary of discussion*, available at:

[http://apps.who.int/iris/bitstream/handle/10665/137509/WHO\\_HIS\\_KER\\_GHE\\_14.2\\_eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/137509/WHO_HIS_KER_GHE_14.2_eng.pdf?sequence=1). It is valuable to note, for example, that ZMapp, widely seen as such a focus of hope in West Africa, was dropped in August 2019 from trials in the DRC, as being less effective than two other candidate treatments for Ebola: Mulangu S, Dodd LE, Davey RT *et al.* (2019) A randomized, controlled trial of Ebola virus disease therapeutics *New England Journal of Medicine* **381**(24): 2293-303

<sup>485</sup> In the context of the West African Ebola outbreak, the fact that some medically evacuated international workers had access to experimental interventions that were not easily available in West Africa underlines the contentious nature of this issue: Davey RT, Jr, Dodd L, Proschan M *et al.* (2018) The past need not be prologue: recommendations for testing and positioning the most-promising medical countermeasures for the next outbreak of Ebola virus infection *The Journal of Infectious Diseases* **218** (supplement 5): S690-S7.

<sup>486</sup> See, for example, Folayan MO, Haire B, Allman D *et al.* (2018) Research priorities during infectious disease emergencies in West Africa *BMC Research Notes* **11**(1): 159.

<sup>487</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guideline 3.

<sup>488</sup> See discussion of different approaches to equity (and other ethical considerations) in Luyckx V, Biller-Andorno N, Saxena A *et al.* (2017) Health policy and systems research: towards a better understanding and review of ethical issues *BMJ Global Health* **2**: e000314.

**Box 6.3: Study design: prioritising people now or in the future? – responses to the call for evidence**

“The assumption here is that one contradicts the other? And I am not sure this is correct. If for example there is an immediate need for intervention requiring research, one can prioritize benefit to people as a first stage; then continue by working towards longer term goals.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“Are they really always independent of each other? Allowing the suffering and death of the living for the benefit of those that might be born does not seem a reasonable price.” *David B. Morton (Professor Emeritus, University of Birmingham, UK)*

“It depends on the severity of the health threat ... There is a humanitarian imperative to put the interests of the suffering first.” *Bridget Haire, Kirby Institute, UNSW Sydney, Australia*

“By definition, a GHE means that people are in serious risk, and therefore this needs to be the priority.” *Donal O’Mathuna, PhD*

“Prioritizing designs that will maximize knowledge over designs that maximize the possibility of benefit for people affected by the current emergency may be acceptable when the people affected by the current emergency express a preference for the latter. Such decisions would require careful consultations with local and national leadership, people in affected communities, directly-affected persons, and potential participants.” *Humanitarian Health Ethics Research Group*

6.9 The 2015 outbreak of the Zika virus disease in Latin America spurred further debate on broader inclusion criteria in research, given the implications of Zika infection for pregnant women and their babies.<sup>489</sup> Guidance published in 2019 by the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies (PREVENT) working group on the inclusion of pregnant women in vaccine trials in emerging epidemic threats makes the clear case for trials to be designed in ways that include pregnant women for reasons of contemporary and future fairness.<sup>490</sup> In contrast with earlier epidemics, in the latest Ebola outbreak of Ebola in the DRC, pregnant and lactating women have been able to access an experimental vaccine,<sup>491</sup> and children (also historically an excluded group) have been included in therapeutic trials.<sup>492</sup>

6.10 Médecins Sans Frontières (MSF) has, in the past, taken the clear stance that studies involving participants accessed via MSF treatment centres should have the potential to benefit those affected at the time, and should not exclude any groups who might potentially benefit. Logistical factors such as whether research interventions are

<sup>489</sup> See, for example, GFBR (2016) Proceedings from the Global Forum on Bioethics in Research (GFBR)’s ‘ethics of research in pregnancy’ meeting *BMC Reproductive Health* **14(supplement 3)**; and Ethics Working Group on ZIKV Research and Pregnancy (2017) *Pregnant women and the Zika virus vaccine: research agenda*, available at: <https://static1.squarespace.com/static/574503059f72665be88193e9/t/5954a4f6099c01adfc66f492/1498719491483/Full+Guidance%2C+Pregnant+Women+%26+the+Zika+Virus+Vaccine+Research+Agenda.pdf>.

<sup>490</sup> Krubiner CB, Faden RR, Karron RA *et al.* (2019) Pregnant women & vaccines against emerging epidemic threats: ethics guidance for preparedness, research, and response *Vaccine*: in press, corrected proof. See also: Faden RR, Krubiner CB, Lyerly AD *et al.* (2017) Ethics, pregnancy, and ZIKV vaccine research & development *Vaccine* **35(49, Part B)**: 6819-22.

<sup>491</sup> UN News (21 September 2019) *Pregnant, nursing women can now be given Ebola vaccine, UN health agency announces*, available at: <https://news.un.org/en/story/2019/02/1033281>. See also: Stat News (20 February 2019) *Ebola vaccine will be provided to women who are pregnant, marking reversal in policy*, available at: <https://www.statnews.com/2019/02/20/ebola-pregnancy-reversal/>; and Stat News (13 June 2019) *Ebola vaccine for pregnant women: one step closer but still more to go*, available at: <https://www.statnews.com/2019/06/13/ebola-vaccine-pregnant-lactating-women-2/>, criticising the limited scope of policy change.

<sup>492</sup> ClinicalTrials.gov (2019) *Investigational therapeutics for the treatment of people with Ebola virus disease*, available at: <https://clinicaltrials.gov/ct2/show/NCT03719586>.



available now in sufficient quantity, and can be sustainably administered in this particular setting, may thus affect consideration of what studies are judged to be ethically acceptable.<sup>493</sup> Similarly, negotiations with suppliers over the affordability of interventions may lead to significant delays in establishing clinical trials, thereby affecting both their viability, and the possibility of affected populations receiving direct benefit.<sup>494</sup> A further challenge to the inclusion of groups traditionally classified as vulnerable in studies that offer prospect of direct benefit, has been that of obtaining insurance in the case of adverse events. While the strong ethical consensus during the Ebola vaccine studies was to include pregnant women, they were excluded as a result of concerns on the part of pharmaceutical companies' insurers.<sup>495</sup> The WHO has since worked on developing an insurance mechanism to support countries who make unlicensed interventions available to their populations under the WHO's emergency use assessment and listing procedure (EUAL – see paragraph 1.27).<sup>496</sup>

## Working group approach

- 6.11 The starting point for the working group, with respect to the design and the review of studies, is that **an ethical approach to these issues in emergencies does not involve taking shortcuts or accepting a lack of rigour – but rather is concerned with what is appropriate for the context.** In one of our roundtable meetings, the need for a 'heightened' approach to ethics in global health emergencies was strongly put forward.<sup>497</sup> We agree with the sentiment, but are concerned that the language of 'heightened ethics' risks being interpreted in the sense of additional and burdensome layers of scrutiny. Instead, **we argue for a 'heightened alertness' to ethics, emphasising the importance of being alert to the challenges and vulnerabilities inherent in the situation, but without assuming that the answer is necessarily a more burdensome process.** Rather, the focus should be on *who* is involved in that process, and *how* that process can best fit both the context and the constraints. Below we discuss further what this might mean for study design, before turning in the second half of this chapter to the processes of review.
- 6.12 Our ethical compass points to the underpinning rationale for conducting research in these contexts in the first place: in order to help reduce suffering both at the time and in the future (see paragraph 4.53). This value underpins the requirement of scientific validity, the importance of which was reiterated in each roundtable meeting we held.<sup>498</sup> **We agree with the WHO that it is unethical to ask people to participate in research with little chance of producing meaningful results. It is similarly unethical to ask people to participate in other forms of 'evidence-gathering' such as needs assessment or programme evaluation, if there is not a reasonable expectation that the information gathered will contribute towards improved services, whether at the time or in the future.**

<sup>493</sup> Rid A, and Antierens A (2017) How did Médecins Sans Frontières negotiate clinical trials of unproven treatments during the 2014–2015 Ebola epidemic?, in *The politics of fear*, Hofman M, and Au S (Editors) (Oxford: Oxford University Press).

<sup>494</sup> Personal experience within the working group; see also: Lang T (2015) Ebola: embed research in outbreak response *Nature* **524(7563)**: 29–31.

<sup>495</sup> Gomes MF, de la Fuente-Núñez V, Saxena A *et al.* (2017) Protected to death: systematic exclusion of pregnant women from Ebola virus disease trials *Reproductive Health* **14(supplement 3)**: 172.

<sup>496</sup> WHO (2017) *Workshop on expanded access to experimental Ebola vaccines during outbreaks*, available at: <https://www.who.int/blueprint/expanded-access-ebola-vaccines.pdf?ua=1>, at 5.1.

<sup>497</sup> On-the-ground roundtable, 25 June 2018.

<sup>498</sup> For a list of roundtables held by the working group, see Appendix 1.

- 6.13 We further endorse the view put forward at the 2017 GFBR (see paragraph 6.5) that **instead of thinking about ‘gold standard’ versus ‘alternative’ designs, the approach should be to start from the problem, and then identify the best methodology and design for this particular study in this particular context.** Such an approach does not deviate from standard principles, but rather reiterates the overriding importance of context (paragraphs 4.17). Several respondents to our call for evidence put this point strongly to us, as illustrated in Box 6.4.

**Box 6.4: Choosing a study design: responses to the call for evidence**

“The best research is not methodologically driven, but question or problem driven. It is arguably lazy to fall back on most frequently used design approaches simply because they are most frequently used. A good protocol will consider the problem and choose a suitable methodological design, not simply try to fit a square peg into a round hole, a choice of design is wrong because it will not work in the setting”. *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“In general, researchers should be prepared to adapt methodologies and research designs to respond to changing context in emergency settings.” *Anonymous respondent*

“I question how ethical are study designs which are parachuted in from other countries, and where we know such designs have not been carefully scrutinized to check for relevance and acceptability, or even validity locally.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“decisions about study design and acceptable risk should not hamper the response to the GHE, nor vice versa. There may be a need to be more pragmatic than in “routine research”, and there may be a need to anticipate repeated (design) modifications along the study.” *Raffaella Ravinetto, Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Marianne van der Sande, Head of the Public Health Department, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Anne Buvé, Vice-Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium*

- 6.14 A second important point emerges from our recognition that the value of equal respect involves taking people as they are and being sensitive to the role of human emotions: that we need **“ethical principles for human beings, not automatons”** (see paragraph 4.51). This is important both from the perspective of researchers (especially those on the front-line, expected to recruit and sustain relationships with participants) and potential participants themselves. **In some contexts, certain study designs, however theoretically justifiable, may be perceived very negatively as a source of loss of hope for those excluded (whether from the study as a whole or from the active arm). However carefully the study is explained, the anger, distress, and sense of exploitation arising out of that loss of hope may make it impossible to conduct the study successfully. In such cases, it is not fruitful to debate whether that study design is ‘ethical’ in the abstract, but rather whether the study, in any form that is scientifically meaningful, is *feasible* in this location and situation.**
- 6.15 This importance of understanding what might be feasible in a particular context dovetails with both the ethical and instrumental reasons put forward in the previous chapter for ensuring that local stakeholders have a voice in how research is conducted in their community (see paragraphs 5.26–5.30). Such engagement, if conducted respectfully with a genuine desire to hear other perspectives, will help avoid one of the potential

harms of research described by one of the respondents to our call for evidence as “communities and individuals feeling like they’ve had ‘things done to them’ and that they were completely disempowered in the process.”<sup>499</sup>

6.16 Engagement with stakeholders should, to the extent possible in the circumstances, explore the questions:

- **Is this the right study for this location and this population?** Why should it be done here? Is it meeting an important need for this population, or for future populations in similar situations – and is the context such that it is reasonable to ask people to consider taking part? What access are participants, and the wider community, likely to have in the future to any benefits deriving from the research?

- **And then, if so: is this the right design for this location / population?**

6.17 In exploring these questions, it is essential to be alert to the challenges to meaningful engagement discussed in Chapter 5. Local communities are far from homogenous, and hence different subgroups within a local area may have different needs and experiences, and hence different responses to the research proposal. Some concerns raised may be based on misunderstandings rather than on genuine disagreement with the proposed study’s aims or methodology, clear communication strategies, and opportunities to respond to any misunderstandings or unfounded fears, will therefore be an essential starting point for engagement. However, engagement must also offer scope for airing and recognition of different viewpoints and priorities, in order to come to an agreement on a shared way forward as to what research is possible and appropriate (see paragraph 5.39). The scope of the questions to explore set out above also illustrates the necessary *breadth* of engagement discussed in Chapter 5. The contributions of national governments (to research priorities and to questions of future access and benefit), national and local research institutions, local health services, and directly affected populations are all complementary, and necessary, parts of the picture.

6.18 The question of whether the design proposed is right in this context, and the role of local stakeholders in coming to that decision, also encompasses the issue of what constitutes acceptable risk.<sup>500</sup> Local knowledge is essential to understand what risks might be generated by particular research methodologies (for example the dangers of inadvertent stigmatisation that international researchers may not be aware of), and the risks to which people affected by the emergency are already being exposed (see Box 6.5).

#### Box 6.5: Acceptable risk: responses to the call for evidence

“risk is not a one size fits all determination. So, it is not clear that there is a variation in the way risk assessment is done, just variation in the risk elements to be assessed. It would be wrong to imply that risks are being assessed differently in a GHE. Instead we should clarify that the risks are higher in the context, so the risk assessment outcome is different from a non-GHE context.” *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinotto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

<sup>499</sup> Jantina de Vries, responding to our call for evidence.

<sup>500</sup> Note the Council’s earlier report on the ethics of research with children, in which it was argued that input from families with lived experiences of particular conditions was key in determining acceptable risk: Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/project/children-research>.

“In adjudicating the degree of acceptable risk during emergencies it is important to emphasize the role of local ethics and regulatory bodies in deciding the basis of variation for their populations.” *Ann H. Kelly, Department of Global Health & Social Justice, King’s College London*

“There will be need to define and have a common understanding of what is acceptable risk in related to traditional values, cultural and societal norms in global health emergency interventions or humanitarian emergency response.” *Ernest Tambo*

“what would be acceptable risk in one place may not be in another. So one has to take it case by case, I do not think we can generalize, because situations and contexts are so different, although general guidelines can be drawn.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“Particular challenges arise for diseases with high rates of mortality, either where there isn’t genuine equipoise, or where there are no available alternatives other than the trial intervention. (NB: these are two different things, and should not be conflated).” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

“If the risk is high, this might influence some variation. For example, the very high risk of Ebola justified bringing some interventions into human trials sooner than normal because people were dying. What changed was the need to get research done, and so the risks needed to be presented to participants and moved along in research. However, the study design should still have been driven by the study question.” *Dónal O’Mathúna, PhD*

6.19 There are two important practical factors critical to the success of promoting community engagement in developing responsive and respectful study designs in emergencies:

- **Willingness to act in response to input:** this kind of engagement – aiming to achieve at least a degree of local ownership of research conducted during an emergency – is only possible if the study protocol and/or other elements of implementation have not been set in stone at earlier stages. We heard an anecdotal account of where social science research and community engagement discussions had elicited clear requests for revised procedures (not related to the science), but received a response to the effect that ‘that may be a good idea but here is the protocol and you have to follow it.’<sup>501</sup> Such experiences illustrate the importance of engaging with local stakeholders in good faith (not using the language of community engagement simply to achieve pre-decided aims); of being clear about what cannot realistically be changed; and having mechanisms in place to modify study plans in response to feedback. We return to this point later regarding the role of ethical review committees (see paragraph 6.36).
- **Recognition that community engagement processes themselves may need to develop over time.** Developing trustworthy relationships with key individuals and organisations at the different levels described above takes time – and the social value

<sup>501</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>, at page 6. See also: IFRC (2019) *From words to action: towards a community-centred approach to preparedness and response in health emergencies*, available at: [http://apps.who.int/gpmb/assets/thematic\\_papers/tr-5.pdf](http://apps.who.int/gpmb/assets/thematic_papers/tr-5.pdf), at page 42; and Oxfam (2 May 2019) *How to build community trust to fight Ebola in the Democratic Republic of Congo (DRC)*, available at: <https://views-voices.oxfam.org.uk/2019/05/community-trust-ebola-response/>.

of some research may depend on rapid implementation.<sup>502</sup> It will be a matter of judgment as to ‘how much’ engagement is sufficient to underpin the ethical and feasible development of any particular study. Where initial involvement by affected communities is limited, it will be important to ensure that there are mechanisms for learning and adapting as the research evolves, so that there is increasing engagement as the research progresses, even if it is relatively weak at the beginning.<sup>503</sup> Such an approach of developing community engagement over time is an example of the ‘interpretive’ response to standard ethical principles in emergencies explored in Chapter 4. There are limits on how far such compromises with the need for meaningful engagement can go; and if they go too far, it will be very difficult to conduct the research ethically, as discussed earlier (see paragraph 4.23).

**Recommendation 6 (directed to researchers, research institutions, research ethics committees, and funders)**

**Study protocols should be developed with the input of local communities and local researchers before being finalised, in order to ensure that proposed procedures are acceptable to communities, as well as meeting ethical requirements. Even in multi-site trials, there will be elements that can and should be operationalised differently in different sites, in response to engagement and feedback. Ethics committees should actively encourage such involvement, and as a minimum should expect local engagement in the development of appropriate tools for communication and consent procedures.**

***Inclusion criteria***

6.20 The perceived opportunity for hope in an otherwise hopeless situation may be a powerful factor in attitudes to novel interventions, whether within the research context or through extended access arrangements. Such hope raises concerns regarding therapeutic misconception, with associated challenges for the consent process (see paragraph 7.3). It also raises questions of fair access for often excluded groups (see paragraphs 6.6–6.10): both for those affected at the time (even recognising the uncertainties of any associated benefit); and for equivalent groups in the future (who will be less able to benefit if data relevant to them are not collected). The issue of fair access arises particularly powerfully where a respected body such as the WHO authorises expanded

<sup>502</sup> Note, however, that in outbreaks there is scope for advance planning in surrounding at-risk countries as advised in the context of Ebola in the DRC: WHO (18 October 2019) *Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 18 October 2019*, available at: [https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo](https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo); and also in more protracted emergencies such as the impact of conflict on displaced persons. See: UNHCR (2008) *A community-based approach in UNHCR operations*, available at: <https://www.unhcr.org/uk/publications/legal/47ed0e212/community-based-approach-unhcr-operations.html>, at chapter 3.

<sup>503</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.



use on the basis of possible benefit.<sup>504</sup> This issue arises equally *outside* emergencies and is a subject of ongoing debate.<sup>505</sup>

- 6.21 It is important to consider why certain groups have traditionally been categorised as ‘vulnerable’ and are less likely to be included in research. Reasons include challenges in being able to provide informed consent for themselves (for example adults with diminished or impaired capacity); or concerns that the risk of being harmed by the research is higher than for other potential participants (for example unknown risks of harm to the fetus if pregnant women are included in certain kinds of research). However, it is also important for these risks to be weighed carefully against the risks of exclusion.<sup>506</sup> Alzheimer’s Disease International and Alzheimer’s Pakistan, for example, have highlighted the lack of an evidence base on services for people with dementia in humanitarian crises, and have called for them to be actively included in research.<sup>507</sup> Children are often excluded from clinical research until significant progress has been made with adult participants, and yet may be the worst affected in many emergencies.<sup>508</sup> Such decisions may be made for financial, rather than ethical, reasons, but understood or presented as ethical constraints (see paragraph 6.10).
- 6.22 Our ethical compass highlights the importance of equal respect, helping reduce suffering, and fairness. In other issues discussed in this report, two or more of these elements may be in tension, leading to the need for difficult trade-offs. In this case, however, all three point to the importance of avoiding inclusion and exclusion criteria based on simple categorisation of a group as ‘vulnerable’. Rather, **the risks and benefits of including, or excluding, particular groups must be considered in the specific context where the research is taking place, and in the light of the risks to which these groups are exposed as a result of the emergency, regardless of research.** It is important to recognise and address where external factors, such as insurance, are the real constraints: we welcome the WHO’s work in helping developing solutions for this challenge in novel therapeutics.

### Recommendation 7 (directed to researchers, sponsors, and ethics committees)

**Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of ‘vulnerable groups’.**

<sup>504</sup> See, for example, Social Science in Humanitarian Action (2019) *Social science and behavioural data compilation, DRC Ebola outbreak, November 2018-February 2019*, available at:

[https://reliefweb.int/sites/reliefweb.int/files/resources/SSHAP%20Data%20compilation%20brief%20-%20Ebola%20response%2C%20DRC\\_0.pdf](https://reliefweb.int/sites/reliefweb.int/files/resources/SSHAP%20Data%20compilation%20brief%20-%20Ebola%20response%2C%20DRC_0.pdf), where such initial exclusion of pregnant and breastfeeding women from the experimental Ebola vaccine in the DRC was reported to be a source of significant concern in community feedback.

<sup>505</sup> See, for example, the Council’s earlier critique of vulnerability in this context in: Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/project/children-research>.

<sup>506</sup> See, for example, Pakenham JP, Rosselli RT, Ramsey SK *et al.* (2017) Conducting science in disasters: recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research *Environmental Health Perspectives* **125(9)**: 094503.

<sup>507</sup> Global Alzheimer’s and Dementia Action Alliance (2019) *Forgotten in a crisis: addressing dementia in humanitarian response*, available at: [https://www.gadaalliance.org/wp-content/uploads/2019/05/Forgotten-in-a-Crisis\\_report\\_2019.pdf](https://www.gadaalliance.org/wp-content/uploads/2019/05/Forgotten-in-a-Crisis_report_2019.pdf), at page 4. See also: Hikichi H, Aida J, Kondo K *et al.* (2016) Increased risk of dementia in the aftermath of the 2011 Great East Japan Earthquake and Tsunami *Proceedings of the National Academy of Sciences of the United States of America* **113(45)**: E6911-E8, which highlights how humanitarian disaster may be associated with increased dementia risk in the future.

<sup>508</sup> CGTN (30 May 2019) *Congo’s Ebola epidemic inflicts heavy toll on children*, available at: <https://news.cgtn.com/news/3d3d674d7841444d35457a6333566d54/index.html>.



## Ethical review processes

### Capacity of ethics committees to respond in emergencies

#### *Timeliness and flexibility*

- 6.23 While the West Africa Ebola outbreak put exceptional pressure on RECs to review multiple studies in short timeframes, it also demonstrated the scope for ethical review to be flexible and supportive of researchers' needs in emergencies. The WHO Research Ethics Review Committee (WHO-ERC), for example, established a subcommittee to focus specifically on Ebola studies, and was able to offer accelerated review within an average of six working days.<sup>509</sup> Similarly quick turnaround times, including an urgent amendment agreed in five hours, were described in responses to our call for evidence relating to a range of emergencies.<sup>510</sup>
- 6.24 Qualitative research with REC members engaged with a broad range of humanitarian research has identified "timeliness, responsiveness and rigorousness" as key elements in effective review of studies in a wide range of disasters.<sup>511</sup> Such responsiveness might include the use of phone or online meetings, willingness to discuss protocols with researchers at development stage and provide informal feedback, and the ability to respond quickly to protocol modifications, for example in response to community feedback.<sup>512</sup>
- 6.25 Respondents to our call for evidence were in broad agreement that it should be possible to expedite reviews in response to the urgency involved, but that such flexibility should not lead to compromises in the quality of the review (see Box 6.6). It was, however, recognised that it would be unlikely that even well-supported RECs could continue to operate in such a way indefinitely, and that, by definition, processes for expediting some protocols meant that others had to take a backseat. It was also widely felt that 'standard' processes were far from perfect, and that in general the review process would benefit from streamlining, quite independent of the emergency or non-emergency context.

#### **Box 6.6: Combining robustness of review with flexible processes: examples from call for evidence respondents**

"During the [Ebola] outbreak, the GET consortium benefited from a pool of experts drawn from a diverse background from all over Africa. In addition, we held virtual meetings, where protocols for investigational products were discussed promptly, without compromising the quality and standard of ethics and review. Our experience demonstrates that with the right combination of expertise in your committee, reduction in unnecessary and redundant bureaucracy such as the need for multiple review and the appropriate use of technology such as the use of online review system/holding virtual meetings can maintain optimal research participants 'protection and avoid compromising

<sup>509</sup> Alirol E, Kuesel AC, Guraib MM *et al.* (2017) Ethics review of studies during public health emergencies - the experience of the WHO ethics review committee during the Ebola virus disease epidemic *BMC Medical Ethics* **18(1)**: 43.

<sup>510</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.

<sup>511</sup> Hunt M, Tansey CM, Anderson J *et al.* (2016) The challenge of timely, responsive and rigorous ethics review of disaster research: views of research ethics committee members *PLoS One* **11(6)**: e0157142.

<sup>512</sup> See, for example, Aarons D (2018) Research in epidemic and emergency situations: a model for collaboration and expediting ethics review in two Caribbean countries *Developing World Bioethics* **18(4)**: 375-84; and Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26.

on the quality and standard of ethics and review process during a global health emergency.” *The Ethics, Community Engagement and Patient Advisory (ECEPAS) Working Group of the Global Emerging Pathogens Treatment (GET) Consortium*

“research protocol review during emergencies can be fast-tracked but all due diligence for proper review of the protocol needs to be maintained.” *Network of Ethics Committee Members in West Africa*

“Waiting months for an ethics committee meeting is clearly inappropriate, but if much of this red-tape is reduced, the key elements including appropriate engagement with design, consent etc can be acted on very fast. Badly designed studies that the community pushes back against / produce poor data are themselves unethical.” *Anonymous respondent*

“[Deadlines] should be significantly shortened, as we have had here in Brazil during the epidemic by Zika virus. This does not mean giving up principles but giving the appropriate response at the appropriate time in an exceptional situation.” *Oswaldo Cruz Foundation*

“this is not necessarily about changing the ‘standard’ of review – but rather of accelerating the process, and trying to look more searchingly at the whole, rather than piecemeal. This would be good practice in non-emergency situations too. What’s needed is a system as accelerated, frugal and safe as possible.” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

“However, we can wonder how long the ethics (and regulatory) review bodies could keep on working under emergency conditions, with rapid turnaround time, without negative effects on the quality of the review.” *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

### **Capacity and procedural challenges**

6.26 Despite the efforts made by RECs to ensure time-sensitive responses to research proposals during emergencies, relatively high numbers of studies are still published without reference to whether they have received ethical review. A 2018 scoping review of research among refugees and war-affected populations in the Arab world, for example, found over 60 per cent of social science studies and 45 per cent of public health studies did not mention ethical review, compared with eight per cent of biomedical studies.<sup>513</sup> A review of studies undertaken during the armed conflict in Darfur between 2004–12 found that only 13 per cent of studies reported gaining ethical approval.<sup>514</sup> Possible reasons cited for failure to mention approval processes included: that studies were exempt from review; that citing the review was not required (but it might still have taken place); or that researchers were using ‘pre-approved’ generic protocols (see paragraph 6.30). However, it is also plausible that some studies were not reviewed at all, whether because review was perceived as unnecessary (and was not required by some journals as a pre-condition of publication), or because of difficulties in accessing appropriate approval processes.

<sup>513</sup> Makhoul J, Chehab RF, Shaito Z *et al.* (2018) A scoping review of reporting ‘ethical research practices’ in research conducted among refugees and war-affected populations in the Arab world *BMC Medical Ethics* **19(1)**: 36, at page 4 of the paper.

<sup>514</sup> Hussein G, and Elmusharaf K (2019) Mention of ethical review and informed consent in the reports of research undertaken during the armed conflict in Darfur (2004–2012): a systematic review *BMC Medical Ethics* **20(1)**: 40.

- 6.27 Questions of capacity remain a challenge for RECs in many countries. While there has been significant investment in establishing more RECs in LMICs and in enabling REC members to access training – alongside valuable initiatives mapping review capacity and supporting networking in sub-Saharan Africa and Latin America – this remains a work in progress.<sup>515</sup> In the context of emergencies, RECs in countries affected by major outbreaks have been put under significant pressure to deal with the sudden large increase in the number of protocols presented to them, and we were told that they would have valued some kind of prioritisation process, especially where multiple and uncoordinated studies were forwarded from the RECs of institutions from HICs (see paragraph 5.16). Similar questions of capacity were raised in the reviews of research in conflict cited above.
- 6.28 In addition to review by either local or national committees in the country (or countries) where the research is taking place, research in emergencies will often involve research institutions or funders based in other jurisdictions, with their own review requirements. This presents a further challenge: even where all such committees are in place, coordinating responsive and timely reviews is clearly more complex and time-consuming across multiple committees, with scope for duplication and contradiction. Further difficulties arise in circumstances such as where emergencies are linked with internal conflict, where there may be no body available with local legitimacy to undertake ethical scrutiny. Alternative suggested approaches in such cases include seeking input from local advisory groups, or from local academics able to provide a complementary structured review of protocols.<sup>516</sup>
- 6.29 The value of multi-country review, including the opportunities for complementariness through sharing of different perspectives, and potential for mutual learning, was emphasised by a workshop of REC members from across five continents, convened in 2018 by WHO and the African coalItion for Epidemic Research, Response and Training (ALERRT) network (see paragraph 3.28 and Box 3.9) to explore effective review in infectious disease outbreaks.<sup>517</sup> Participants highlighted the importance of definitive national approval before a study could go ahead, rather than supporting a single multi-country approach, and recommended that individual national RECs, or other in-country competent bodies, should prepare by developing standing operating procedures for emergency review.<sup>518</sup> They also emphasised the value of greater harmonisation of criteria and procedures, particularly at regional level, supported by legitimate umbrella bodies such as the African Vaccine Regulatory Forum (see also Box 6.7 for a Caribbean

<sup>515</sup> Mokgatla B, Ijsselmuiden C, Wassenaar D *et al.* (2016) Mapping research ethics committees in Africa: evidence of the growth of ethics review of health research in Africa *Developing World Bioethics* **18**: 341-8. See also: COHRED (2014) *Mapping of ethics review capacity in sub-Saharan Africa*, available at: <http://www.cohred.org/marc/> for further details of the MARC project, mapping ethics committees in sub-Saharan Africa and Latin America; and OSIWA, WATER, and IRESSEF (2017) *Training meetings for ethics committee members in West Africa on emerging and re-emerging infectious disease epidemics: Diamniadio, 25-27 September*, available at: <http://nhvmas-ng.org/site/wp-content/uploads/2018/03/Report-WATER-Bioethics-training-meeting.pdf>.

<sup>516</sup> Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26.

<sup>517</sup> ALERRT (2018) *“Ethics preparedness”: facilitating ethics review during outbreaks - recommendations arising from a joint ALERRT & WHO workshop*, available at: [https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt\\_workshop\\_recommendations\\_final\\_30may18\\_0.pdf](https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt_workshop_recommendations_final_30may18_0.pdf); and Saxena A, Horby P, Amuasi J *et al.* (2019) Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel *BMC Medical Ethics* **20(1)**: 29. See also: Tangwa G (2018) Ebola vaccine trials, in *Ethics dumping: case studies from North-South research collaborations*, Schroeder D, Cook J, Hirsch F, Fenet S, and Muthuswamy V (Editors) (Cham, Switzerland: Springer Open) who make the case for procedures that are seen to be genuinely independent and robust, in order to maintain trust among potential participants.

<sup>518</sup> See also: Biddison LD, Berkowitz KA, Courtney B *et al.* (2014) Ethical considerations: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement *CHEST* **146(4)**: e145S-e55S, who similarly emphasise the need for national guidance on standards for review.

example). It was also noted that such a regionally harmonised approach to review procedures need not be limited to infectious disease emergencies.

### Box 6.7: Ethics preparedness for emergencies in the Caribbean

The Ethics Unit of the Caribbean Public Health Agency (CARPHA) has sought to establish the best model for coordination and communication between the region's RECs in emergency situations.

CARPHA talked to REC members in Jamaica and St. Lucia to discuss what this model might comprise, leading the Ethics Unit to conclude that an *ad-hoc* REC convened specifically for epidemics and emergencies should be convened when emergency situations occur. The REC, it suggests, should be comprised of six or seven members, including chairs of RECs in the Caribbean, representatives from the region's Ministries of Health, and community members. The *ad-hoc* REC should have legislative support, secretarial support, and terms of reference, and should be implemented by the local Ministry of Health. It should only function for epidemic and emergency situations.<sup>519</sup>

The Ethics Unit has also developed a template that *ad-hoc* RECs might use to evaluate research proposals during emergencies.<sup>520</sup>

- 6.30 Where novel research designs are presented for approval in an emergency, this creates additional challenges for RECs: these designs may not be covered by existing guidance, nor familiar to RECs. The idea of the 'pre-approval' or 'pre-review' of generic protocols, or of particular aspects of protocols, has been mooted as one possible way of enabling studies to go ahead speedily in emergencies, especially where less familiar designs are involved.<sup>521</sup> However, caution for such an approach was advised at the 2018 WHO / African coalition for Epidemic Research, Response and Training (ALERTT) workshop: participants noted that while early sight of possible study designs could play a positive role in enabling RECs to familiarise themselves with novel methodologies and their ethical implications, close scrutiny of final proposals would still be required before ethical approval could be granted, and further work could be done on clarifying terminology and expectations.<sup>522</sup> A related 'staged' approach has been reported by the ethics committees of MSF and the International Rescue Committee (IRC), who describe being willing in some cases to approve a generic or 'shell' protocol in advance to enable focused and timely review of the details at the time.<sup>523</sup>
- 6.31 Suggestions from respondents to our call for evidence for how ethical review processes could be supported to be as flexible and responsive as possible in global health emergencies are set out in Box 6.8. In addition to identifying various ways in which RECs could prepare in advance of emergencies, as explored above, respondents emphasised

<sup>519</sup> Aarons D (2018) Research in epidemic and emergency situations: a model for collaboration and expediting ethics review in two Caribbean countries *Developing World Bioethics* **18**(4): 375-84, at 6.1.

<sup>520</sup> *ibid.*, at appendix 1.

<sup>521</sup> Hunt M, Tansey CM, Anderson J *et al.* (2016) The challenge of timely, responsive and rigorous ethics review of disaster research: views of research ethics committee members *PLoS One* **11**(6): e0157142.

<sup>522</sup> ALERTT (2018) "*Ethics preparedness: facilitating ethics review during outbreaks - recommendations arising from a joint ALERTT & WHO workshop*", available at: [https://www.alertt.global/sites/www.alertt.org/files/2018-06/alertt\\_workshop\\_recommendations\\_final\\_30may18\\_0.pdf](https://www.alertt.global/sites/www.alertt.org/files/2018-06/alertt_workshop_recommendations_final_30may18_0.pdf); and Saxena A, Horby P, Amuasi J *et al.* (2019) Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel *BMC Medical Ethics* **20**(1): 29.

<sup>523</sup> Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43**(4): 711-26; also citing Schopper D, Upshur R, Matthys F *et al.* (2009) Research ethics review in humanitarian contexts: the experience of the independent ethics review board of Médecins Sans Frontières *PLoS Med* **6**.



the importance of committees finding ways to build in community input or learn from those with past experience of being participants in research in emergencies.<sup>524</sup>

### Box 6.8: Planning for emergencies: contrasting approaches and perspectives

#### Setting up systems in advance

“... existing good practices should be encouraged and facilitated: for instance, efforts should be put during the research preparedness phase (i.e., before a GHE occurs) to establish procedures for accelerated reviews, to coordinate in-country and multi-country reviews, etc.” *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“In relation to regulatory and ethical processes, preparedness means establishing flexible regulatory and ethical approval processes in advance of any global health emergency to ensure they can be applied in different contexts and outbreaks, rapidly as needed.” *Wellcome*

“There is a talk about ‘pre-approved protocols’, to enable timely research in complex emergencies. One of the reasons is that communities affected would be too busy attending to other crucial matters, for instance saving lives in hospital’s isolation units—and so, reviewing and approving research protocols may take longer than expected. In my view, pre-approved protocols are going to promote unethical researches.” *Anonymous respondent*

“[In] practice, a combination of advance discussion of prototype protocols... or key trial design choices... with timely centralised expert support is likely most sensible. This is because advance discussion, while helpful, cannot anticipate the situation at hand and there is independent value to adhering to a predetermined decision-making process to determine whether studies are acceptable.” *Annette Rid, King’s College London*

#### Finding ways of building in community involvement in advance, including through survivor experience:

“communities and individuals who survived Ebola should be invited to explore these issues and offered opportunities to participate in global efforts to plan for further health emergency responses.” *Bridget Haire, Kirby Institute, UNSW Sydney, Australia*

“Another important consideration for ethical review in GHE is engagement of the community IN that ethical review. IRBs often have requirements to have at least one ‘community’ member on the board. But that person may not have a clear sense of the GHE issues. I have often wondered if it is possible to create a GHE ethical review committee within/of the affected population (at least for protracted emergencies). How can voice of those affected be enhanced in decisions about research that happen in their contexts/communities?” *Anonymous respondent*

#### Supporting ethics board members

“A toolkit for ethical board to refer to for GHE contexts might also be helpful. It will not take the place of ethical reviews but provide some guidance that might be helpful in advancing debates. And yes, it will never be a complete toolkit as new methods, new GHEs... will always arise but it will be a support, and a continuously evolving kit.” *Anonymous respondent*

<sup>524</sup> The importance of such input was also emphasised in Pakenham JP, Rosselli RT, Ramsey SK *et al.* (2017) Conducting science in disasters: recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research *Environmental Health Perspectives* **125(9)**: 094503.

### Thinking across the research spectrum

“Preparedness research involving animals may have an important role to play in producing animal models and animal data that will enable the licensing and distribution of medical treatments in an emergency, without going through the conventional stages of clinical trials.” *Animals in Science Committee (ASC)*

### Support and guidance for committee members

- 6.32 The confidence and expertise of committee members is clearly essential for RECs to be confident in operating in the flexible and responsive ways described above. This is important for RECs in countries directly affected by an emergency and, where applicable, in countries where overseas researchers or funders are based. While there is often a focus on the need for better support and training for committee members in low- and middle-income settings, lack of relevant expertise and inflexible approaches may equally be a feature of academic committees in high-income settings.<sup>525</sup> The features of a ‘global health emergency’ described in Chapter 1 – such as the disruptive and dangerous nature of the situation, and the associated fear and distress – may also make the role of ethical review more challenging for members of local committees, who in some cases may themselves be directly affected personally or professionally by an emergency.
- 6.33 Justified anxiety about the need to ensure that participants in research are not exploited, alongside lack of training or confidence, may also lead to decisions that are overprotective, or not in the interests of participants in other ways. For example, contributors to the community engagement workshop co-hosted by the Nuffield Council in Dakar in 2019 expressed concerns from their own experience of RECs being so concerned about the risks of ‘undue inducement’ that they permitted no reimbursements for travel or time involved in research, despite clear international guidance that such reimbursements may be ethically permissible, and indeed in some cases essential.<sup>526</sup> Similar anxieties have been raised with reference to concerns about risk, where lack of local knowledge or expertise in emergencies may lead REC members to underestimate or overestimate the risks to which participants might be exposed (see paragraph 6.18 and Box 6.5).

## Working group approach

### Ethics committee processes

- 6.34 Structured scrutiny of research proposals by independent committees provides an important focus and opportunity for ethical consideration – by researchers as well as committees. It is not, however, an end in itself; and approval on the part of relevant RECs should never be seen as a substitute for ongoing ethical reflection throughout the research project (see paragraph 6.40).
- 6.35 Several respondents to our call for evidence highlighted issues in ethical review – in particular with respect to committee capacity across the globe and the value of

<sup>525</sup> See, for example, *ibid.* (regarding the need for specialised committees or disaster-specific training in the US context); and Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26 (regarding academic committees).

<sup>526</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>. See also: CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guideline 13.



streamlining procedures to avoid unnecessary bureaucracy – that also apply to research across the board. In our comments below, we focus on the particular challenge of research in global health emergencies, while endorsing the importance of ongoing attention and investment in developing both a comprehensive network of review committees and in ensuring processes are fit for purpose.

6.36 In Chapter 4, we explored different approaches to ethical considerations in emergencies: from the default starting point of following identical principles, to consideration both of ‘interpretive’ approaches, and of ways in which other parts of the ethics ecosystem might, where necessary, help support the underpinning values in our ethical compass (see paragraphs 4.16–4.30). In the case of ethical review, we conclude that there is no reason for diverging from the standard principle that research proposals should be subject to ethical scrutiny by an independent body before they should be permitted to go ahead. The *manner* in which this scrutiny is achieved should, however, be sensitive to context, as indeed it should be in non-emergency circumstances. **We endorse the following desirable features of review during emergencies, identified by our call for evidence respondents and others as clearly attainable:**

- **Flexibility.** The overarching aim is to ensure that there is good scrutiny, and not necessarily to follow set processes. There may, for example, be scope in emergencies for relevant ethics committees (or designated committee members) to be involved informally from an early stage in questions of design so that the approach becomes one of dialogue rather than a one-off ‘pass / fail’ test. Given the importance of local engagement and scope for local ownership of research projects, committee processes need to facilitate rapid responses to proposals for changes in protocols, particularly where these emerge as a result of community feedback. Even more flexibility of process will be required where genuine co-production of research is envisaged, as this is likely to involve a more extended process of refining study aims and processes in collaboration with local partners.
- **Support for local engagement.** Ethics committees can and should play an important role in encouraging researchers to involve local populations in the development of their studies (see paragraph 7.9). Such involvement, while requiring flexibility in committee procedures as described above, has added value in providing assurance to the committee that risks and benefits have been considered sensitively in context, and that the proposed study is feasible in that context. It should also alert ethics committees to any concerns that a population is being over-researched.
- **Scope for expediting genuinely urgent studies.** Research proposals in some emergencies will require exceptionally prompt scrutiny if they are to achieve their objectives. Committees need to have plans in place that enable them to deal appropriately with such requests, including clear criteria for the exceptional circumstances where these arrangements apply, since inevitably such arrangements have an impact on committees’ ability to scrutinise other competing proposals (see also below regarding capacity). The need to be able to triage applications in accordance with urgency reinforces the importance of funders and research institutions acting collaboratively in prioritising research needs in the acute phase of an emergency (see paragraphs 5.20–5.21 and Recommendation 1).

### **Supporting capacity and facilitating preparedness**

6.37 These examples of flexible and innovative practice are all dependent on sufficient capacity in ethical review. In addition to the widely-acknowledged need to continue to support the general development and confidence of RECs (noted above), an important element of emergency preparedness is the development, at both national and regional level, of the collaborative systems and protocols necessary to facilitate prompt and responsive review when an emergency arises (see paragraph 4.63 and Box 6.7). Such systems might include:

- agreeing standardised procedures and templates, potentially at regional as well as national level; and
- developing ways of drawing in additional ethical expertise within the region to support committees who are struggling or overburdened at the time of an emergency.

6.38 **Lead responsibility for developing such systems will depend on local circumstances, but could include regional REC networks such as the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP), the Latin American Forum of Ethics Committees in Health Research (FLACEIS), the Network of Ethics Committees in West Africa, and the African Vaccine Regulatory Forum (AVAREF). National and regional offices of WHO could also play a valuable facilitative role, as part of supporting emergency planning.**<sup>527</sup>

6.39 Another important part of review capacity is found in the internal RECs that are an increasing feature of the health humanitarian sector, including at MSF, Save the Children (UK and US), and the IRC. In addition to giving ethical guidance within individual organisational structures, such committees can also play a valuable role in providing a tier of scrutiny of research in humanitarian context where local RECs may be struggling or absent. However, genuinely local input in scrutiny, for example from local academics or local NGOs with the necessary experience,<sup>528</sup> in the absence of any formal structures, is also essential. Given financial pressures in such local institutions, funders should consider providing budgetary support to ensure the costs of such review are covered.

### **Beyond review**

6.40 It is important to return to the central point that careful, independent scrutiny, carried out in the spirit of supporting ethically justifiable research, is necessary but not sufficient. Researchers retain ongoing responsibilities throughout their research projects for their ethical conduct. Such responsibilities arise with respect to their own professional conduct and relationships with participants (see paragraphs 4.40 and 7.20–7.24). They also arise in how researchers respond, and support colleagues in responding, to ethical dilemmas that occur as the research progresses (see paragraphs 10.18–10.24). In turn, this focus on researchers' responsibilities elicits the question of how they are supported when facing ethical challenges (see paragraphs 10.25–10.26); and how a culture of respectful, collaborative research is promoted by research institutions and funders (see Chapter 8).

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<sup>527</sup> As recommended in ALERRT (2018) *“Ethics preparedness”: facilitating ethics review during outbreaks - recommendations arising from a joint ALERRT & WHO workshop*, available at: [https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt\\_workshop\\_recommendations\\_final\\_30may18\\_0.pdf](https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt_workshop_recommendations_final_30may18_0.pdf); and Saxena A, Horby P, Amuasi J *et al.* (2019) Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel *BMC Medical Ethics* **20(1)**: 29.

<sup>528</sup> See, for example, Pillai V (25 March 2019) *The role of beneficence in humanitarian research: presentation to PREA conference, Ohio State University*, available at: [http://streaming.osu.edu/knowledgebank/PREA/PREA\\_Session2\\_Pillai\\_20190325.mp4](http://streaming.osu.edu/knowledgebank/PREA/PREA_Session2_Pillai_20190325.mp4).

- 6.41 There are often different approaches to ethical review, with different governance arrangements, that may be taken by the professions, organisations, and academic disciplines that all come together when conducting research in an emergency (see paragraphs 4.3–4.6). For some disciplines it has been a matter of concern that the ethical review model in widespread use was designed for interventional biomedical research and does not necessarily meet the needs of those working in other forms of research and their participants.<sup>529</sup> This perception persists despite the development of more light-touch or ‘proportionate’ approaches to research review considered to be low-risk.<sup>530</sup>
- 6.42 Such concerns may underpin the temptation (mentioned repeatedly to us) for evidence-gathering activities to be labelled as ‘evaluations’ or ‘needs assessments’ rather than research, with the critical factor determining review often being whether there is any intention to publish.<sup>531</sup> Yet it is clear that ethical considerations for participants do not just pertain to publication: data collectors in these circumstances may need support in thinking through what may be ethically at stake more broadly, and what action might need to be taken as a result. **Our ethical compass provides a guide for thinking through how evidence-gathering activities may be conducted in ways that show equal respect to those from whom information is being sought, are fair, and are most likely to help reduce suffering. A prompt for explicit discussion of ethical considerations, for example with a manager or colleague, before plans are finalised would help embed such an approach in standard working practices.**

#### Recommendation 8 (directed to humanitarian organisations and their funders)

**We recommend that humanitarian organisations explicitly build in a step of ‘ethical consideration’ when planning needs assessment, evaluations and other forms of data collection not formally classed as research.**

<sup>529</sup> See, for example, Barrett D, Ortmann L, Brown N *et al.* (2016) Public health research, in *Public health ethics: cases spanning the globe*, Barrett D, Ortmann L, Dawson A *et al.* (Editors) (Cham, Switzerland: Springer Open).

<sup>530</sup> See, for example, Hunter D (2007) Proportional ethical review and the identification of ethical issues *Journal of Medical Ethics* **33(4)**: 241–5.

<sup>531</sup> See, for example, Barber R (26 March 2019) *Research with vulnerable populations in humanitarian crises: ethical challenges and overlooked areas - presentation to PREA conference, Ohio State University*, available at: [http://streaming.osu.edu/knowledgebank/PREA/PREA\\_Session13B\\_Barber\\_20190326.mp4](http://streaming.osu.edu/knowledgebank/PREA/PREA_Session13B_Barber_20190326.mp4); and discussions at RECAP, 15–16 January 2019, American University of Beirut.



# Chapter 7

Consent and beyond: the wider ethics ecosystem



## Chapter 7 – Consent and beyond: the wider ethics ecosystem

### Chapter 7: overview

Even in non-emergency situations, the challenges of seeking genuinely informed consent to research are well-documented. In global health emergencies, disruption, family separation, lack of access to basic resources and services, and the fear, distress, and powerlessness associated with these experiences may all exacerbate existing challenges to voluntary and informed decision-making. Research in emergencies may be further complicated by high levels of uncertainty, and by heightened risks for participants, both related and unrelated to the research. In some cases, the situation of potential participants may mean that agreeing to take part in research appears to be their only option.

Culturally appropriate and respectful consent processes that demonstrate equal respect for participants are as important in emergencies as in any other context. There are many examples of innovative practices that can be drawn upon to support these processes.

**Consent alone is never a sufficient requirement for research to be ethically acceptable. Rather, it is one part of the wider ‘ethics ecosystem’ constituting and supporting ethical research conduct.** This ecosystem includes responsibilities on the part of researchers and ethics committees to be confident that benefits and risks have been carefully scrutinised, risks justified, and wider questions of social justice and social value considered. This can be captured in the question: can what is being asked of potential research participants be justified as fair, given the emergency circumstances they are facing?

In circumstances where truly informed consent is challenging because of all the countervailing pressures, research may still be justifiable. However, other parts of the ethics ecosystem will need to be strengthened to make up for the reduced moral role that individual consent can play in that justification. In particular, this involves demonstrating equal respect for communities and community members by developing collaborative and inclusive processes across the lifetime of the research. **Research ethics committees should consider:**

- **Whether the proposed consent processes are the best and most sensitive possible that can be achieved in the circumstances;**
- **What other requirements might be needed to ensure respect for participants as people of equal moral worth and agency; and**
- **Whether, in all the circumstances, what is being asked of participants can be justified as fair.**

There are also recognised exceptions outside the emergency context where individual consent is impossible, for example if a person is unconscious. In some such cases, research with high social value may nonetheless be found acceptable by ethics committees on the basis of other protections designed to promote respect for participants. Any proposed waivers of consent must be particularly closely scrutinised with respect to the question of how equal respect for participants is to be secured.

The central importance of respectful relationships between research teams and participants means **feedback to participants and wider communities about what a study has learned should routinely be required, with ringfenced funding for this purpose.**

## Introduction

### Challenges in seeking consent

- 7.1 Even in non-emergency settings, the challenges of seeking informed consent for research participation are well documented. Even without the pressure of time, it can be difficult to explain essential elements of a complex study to those unfamiliar with health-related research. Language barriers and/or low literacy can be a source of further difficulties in communication and comprehension, as can inappropriate use of unfamiliar language by researchers.<sup>532</sup> Researchers have a responsibility to ensure that potential participants are able to consent, but judgments about a person's capacity, and about their freedom to act voluntarily, can be very finely balanced. Unequal power relationships between prospective participants and researchers can undermine the voluntariness of consent.<sup>533</sup> In contrast, concerns have been raised that standard informed consent processes may be cumbersome, and may deter potential participants who would otherwise have been willing to take part. This may particularly be the case in non-interventional studies that pose low burdens on participants, such as those concerned with improving health systems.<sup>534</sup>
- 7.2 In both high- and low-income settings, participation in health-related research may be desirable as a way of obtaining interventions that are unavailable through standard health services.<sup>535</sup> Where people have poor, or no, access to even basic health services, the ancillary care involved in much health research may be a sufficient benefit itself to motivate people to participate, regardless of other factors (see paragraph 2.23). Particular dilemmas arise for researchers where local decision-making practices are incompatible with international norms – for example where women are excluded from playing a full role.<sup>536</sup> Yet failure to find appropriate ways of seeking consent for participation from those who are most marginalised and disempowered may lead to their needs being overlooked, not only in terms of adequate evidence for the healthcare of particular groups (see paragraph 6.7), but also in terms of funding and programme priorities by governments and humanitarian or development agencies.<sup>537</sup>
- 7.3 Much has been written about the risks of 'therapeutic misconception', where participants wrongly assume that research interventions, such as additional blood draws or data collection, are designed to improve their care, rather than to contribute to longer-term

<sup>532</sup> See, for example, The New Humanitarian (3 December 2019) *We won't achieve zero Ebola cases in Congo until we get language right*, available at: <https://www.thenewhumanitarian.org/opinion/2019/12/03/ebola-epidemic-Congo-language-communication>.

<sup>533</sup> See, for example, Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26. See also: Faden R, and Beauchamp T (1986) *A history and theory of informed consent* (Oxford: Oxford); and Grady C (2015) Enduring and emerging challenges of informed consent *New England Journal of Medicine* **372(9)**: 855-62.

<sup>534</sup> See, for example, Blackburn D (2019) Response: re. low risk pragmatic trials do not always require participants' informed consent *BMJ* **364**: l1092, although it should be noted that this remains a contested issue: Shepherd L, and Macklin R (2019) Erosion of informed consent in US research *Bioethics* **33(1)**: 4-12. In particular, the extent to which consent waivers are suggested as a matter of research convenience, as opposed to consideration of participant / public preference and interest, is disputed.

<sup>535</sup> See, for example, BBC News (25 May 2018) *Cancer patient feels 'privileged to be alive' after NHS trial treatment*, available at: <https://www.bbc.co.uk/news/health-44238136>.

<sup>536</sup> Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries*, available at: <http://nuffieldbioethics.org/project/research-developing-countries>.

<sup>537</sup> See, for example, Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26, who cite the example of collecting data on gender-based violence to ensure that the particular needs of women and girls are not routinely overlooked.

aims of improving the evidence base for the future care of others.<sup>538</sup> Such misunderstandings undermine the basis on which informed consent to participation in research can be said to have been provided by prospective participants. These misunderstandings should be distinguished from cases where consent is given based on accurate perceptions of benefit (for example access to better quality care), or from where experimental interventions are embraced in the knowledge of highly uncertain benefit, because they offer the only source of hope (see paragraph 1.17). In the humanitarian context, there is similarly a growing awareness of the risks of ‘philanthropic misconception’, where potential participants are unclear about the distinctions between humanitarian workers and researchers associated with the humanitarian interventions, assuming for example that they need to agree to research in order to access help.<sup>539</sup>

### **Heightened challenges in a global health emergency**

- 7.4 In a global health emergency, any and all of these challenges to voluntary and informed decision-making may be exacerbated by factors such as disruption, family separation, lack of access to basic resources and services, and the fear, distress and powerlessness that may be associated with these experiences. Lack of alternative options may lead prospective participants to disregard risks that they might, in other circumstances, have considered unacceptable. Existing difficulties in communication, and the impact of unequal power dynamics may be heightened,<sup>540</sup> not least where (as described in Box 7.1) protective equipment creates additional distance between researchers and prospective participants.

#### **Box 7.1: Challenges for consent: responses to the call for evidence**

“Some of the issues the MSF ERB consistently raised in its reviews during the West Africa Ebola epidemics were how to obtain truly informed consent of patients facing a high chance of death (which raises challenges similar to those generally observed in desperately-ill patients); in a high-safety environment (where protective equipment create a “physical distance” between the person and the healthcare worker during the consent interview, and makes the presence of a family member or witness impossible); with a high potential for therapeutic or philanthropic misconception, as MSF was the only healthcare provider for Ebola patients in many instances, etc.” *Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“An issue in SL [Sierra Leone] was that the people did not have the conceptual frameworks to understand what treatment they were being given/offered and the same would be true of a study. If the people believe that the virus is caused by the/a government and involves magic, they will not be easily persuaded about the benefits/risks of a trial medication.” *Anonymous respondent*

“Efforts should also be made to avoid blurring the lines between the role of clinicians and researchers if applicable, especially in terms of clinical research. For example, research onboarding should be done by individuals who are not primarily responsible for the care of a participant or patient.” *Anonymous respondent*

<sup>538</sup> See, for example, Henderson GE, Churchill LR, Davis AM *et al.* (2007) Clinical trials and medical care: defining the therapeutic misconception *PLoS Medicine* **4(11)**: e324.

<sup>539</sup> Ahmad A, and Maum Mahmud S (2010) Philanthropic misconception *Asian Bioethics Review* **2(2)**: 154-61.

<sup>540</sup> Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26.

“... the wording “we recognize that consent is often imperfect” could be replaced with “we recognize that consent is often challenging”, to reflect the fact that difficulties should be seen as a reason to find contextualized procedures, not to short-cut on principles.”  
*Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)*

“It is striking how ‘autonomy’ has emerged as the priority ethical principle in international public health fora and meetings – but for most of the world, and most of the time, individual wishes do not dominate over what is best for a community. For a person to act against prevailing wishes / perceptions may in many cases be almost impossible, and when it happens may lead to harm for that individual.” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

7.5 Additional dilemmas associated with emergencies, particularly those involving novel pathogens or other health threats for which no effective treatments are currently available, include:

- **Dealing with uncertainty:** the uncertainty inherent in any research study is likely to be exacerbated in an emergency. In some emergencies, the risks of waiting for greater certainty – for example through confirmatory findings – may be greater than the risks of proceeding on the basis of imperfect or incomplete information. There is, therefore, a degree to which consent to participate in research in such circumstances is unavoidably ‘broad’ rather than specific: that is, a decision to give consent might be best characterised as a decision to authorise others to act, despite the uncertainty. (See paragraphs 9.12–9.14 for a discussion of broad consent as ‘consent for governance’ in the context of future uses of research data and samples.) Conceptualising consent in this way reinforces the central role played by trust, and (very importantly) the trustworthiness of researchers and research systems in such circumstances, alongside the role of more formal protections offered through the process of ethical review. We come back to the issue of trust and trustworthiness later in this chapter.
- **Heightened risks of participation / non-participation.** When novel interventions are offered in a research study where no effective treatments exist, risks may be higher than usual for participants, and for those who decline or are ineligible to participate (in the sense of lost opportunity to benefit should results be beneficial – see paragraphs 1.16–1.17 and 6.7). These heightened risks add to the challenges of decision-making, particularly where participants are in situations of increased vulnerability. This might include children, especially those who are not supported by those in a parental role; and people with limited or impaired capacity. As noted above, automatically excluding such participants from research because of their vulnerability may in practice render them even more vulnerable (see paragraph 7.2).

### **Consent as part of the ethics ecosystem**

7.6 Finding the most respectful and culturally appropriate ways of seeking consent for research involvement is critically important for many reasons,<sup>541</sup> and particularly as an

<sup>541</sup> Dickert NW, Eyal N, Goldkind SF *et al.* (2017) Reframing consent for clinical research: a function-based approach *The American Journal of Bioethics* 17(12): 3-11.

expression of equal respect for a person's moral agency (see paragraph 4.47 and paragraphs 7.14–7.16). With the exception of certain, very limited, groups of cases where consent waivers may be justified (see paragraphs 7.17–7.19), the challenges for the meaningful consent processes described above should never be an excuse to pay less attention to the value and significance of consent.

- 7.7 However, both in non-emergency and emergency contexts, informed consent is often discussed as if it, and it alone, provides the necessary and sufficient justification for research to be conducted ethically.<sup>542</sup> The Nuffield Council has previously expressed concerns with this position, in particular in its report on the ethical conduct of research with children, where the Council suggested **that focusing only on consent constituted an abdication of responsibility on the part of those professionally engaged in research** who have a prior duty to ensure that any research proposal put to prospective participants is a 'fair offer' for them to consider.<sup>543</sup> Such responsibilities on the part of research professionals and the wider research system are undoubtedly increased in global health emergencies where, as we argued in Chapter 4, the moral burden that consent can bear in justifying research may be substantially less than in other contexts. Where populations – often already disadvantaged – have had their lives and livelihoods disrupted by an emergency, concerns about equity and the need to avoid exploitation take on additional force in considering what might be fair to ask of research participants.
- 7.8 We argue, therefore, that **the emphasis on the core value of consent must be accompanied by the recognition that other essential parts of the 'ethics ecosystem' have a role to play in ensuring that participants' interests are taken properly into account**, alongside consideration of the value research may bring to others. In the following section on 'consent and beyond', we explore how the value of equal respect, understood with respect to individuals and to broader communities, can act as a guide in thinking through how other aspects of the ethics ecosystem can be strengthened in emergency contexts to ensure such respect is fully shown.

## Consent and beyond

### Strengthening the ethics ecosystem

- 7.9 In our earlier consideration of the ethical aspects of study design and review, we reiterated that while the *processes* involved in providing independent scrutiny of research proposals during an emergency could, and indeed should, be responsive and flexible, the emergency circumstances should not detract from the quality of that review (see paragraph 6.36). Indeed, we argued for a 'heightened alertness' to the ethical challenges that might arise, albeit one that is not necessarily embodied in additional or more cumbersome procedures (paragraph 6.11). We suggest that there are at least two important elements of the ethics ecosystem that could help create such heightened alertness, and in so doing support good consent practice in ensuring that the interests of prospective participants are properly taken into account. These are:

- **Explicit consideration by ethics committees of whether what participants are being asked to do in this context is fair.** Addressing this consideration requires a focus on issues of common concern to all ethics committees, such as the social value

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<sup>542</sup> See, for example, Shepherd L, and Macklin R (2019) Erosion of informed consent in US research *Bioethics* **33**(1): 4-12.

<sup>543</sup> Nuffield Council on Bioethics (2015) *Children and clinical research: ethical issues*, available at: <http://nuffieldbioethics.org/project/children-research>. See also: O'Neill O (2003) Some limits of informed consent *Journal of Medical Ethics* **29**(1): 4-7; and Grady C (2015) Enduring and emerging challenges of informed consent *New England Journal of Medicine* **372**(9): 855-62 for nuanced discussions of some of the limitations of consent.



and justification for the study, possible benefits, risks and burdens, and the seriousness of any possible harms, as well as the quality of the proposed information materials and consent processes. However, framing these considerations in terms of whether it is fair to ask this population in this situation to consider taking part provides a valuable prompt to keep the interests of participants as moral agents at the forefront of consideration. Direct input from the communities who are to be asked to take part in this research will be invaluable in helping committees to answer this question.

- **Support from the wider community, and from stakeholders such as local health services and research institutions, for the research project**, providing assurance for ethics committees and prospective participants alike that what is being proposed has local legitimacy. This link between the role of community engagement and the robustness of the wider ethics ecosystem was strongly supported by respondents to our call for evidence (see Box 7.2).

#### **Box 7.2: Consent and other aspects of the ‘ethics ecosystem’: responses to the call for evidence**

“By acknowledging that consent often fails, and may do so particularly in the context of GHEs, the question becomes how we can design the ethics ecosystem of GHEs in such a way that we still protect participants from harm, including harm of exploitation and stigmatization.” *Associate Professor Jantina de Vries, Department of Medicine, University of Cape Town*

“Engaging in widespread and culturally-appropriate dissemination of information about studies + holding consultation and discussion sessions in emergency-affected communities can support meaningful consent.” *Humanitarian Health Ethics Research Group*

“... other elements should primarily focus on restoring some regard for individuals. This argues that we demand more from consent than just welfare and reputational protection.” *Katherine Sahan, Ethox Centre and Wellcome Centre for Ethics and Humanities*

“Quality community engagement where the community as a whole agrees to this research taking place. Consent in many contexts is not an individual decision, it is made in concert with family and community, therefore this will help to ensure that consent is more valid.” *Gillian McKay*

“True community engagement is essential here. This helps to promote better understanding all around, and can ameliorate concerns over informed consent, harms and benefits, etc.” *Dónal O’Mathúna, PhD*

“... an essential element (which unfortunately cannot be readily measured) is intent. If the intent of the researcher in an emergency is to protect the health and wellbeing of affected people, then it’s more likely that the research will be well located within the ‘ethical ecosystem’ referred to.” *William Aldis, Office of International Programs, Faculty of Public Health, Thammasat University (Thailand)*

- 7.10 We therefore suggest that important elements of the wider ethics ecosystem will be found in respectful, collaborative, and inclusive processes with local communities and other local and national stakeholders across the lifetime of the research. This sits alongside the best possible consent practice and careful review procedures. Drawing on our earlier discussions of broad and diverse stakeholder engagement in Chapters 5 and 6, we



reiterate the important role that the following forms of early engagement can play in creating community confidence in research during emergencies:

- diverse community and stakeholder engagement in considering the acceptability of study aims (including exploration of who is likely to benefit from the research) and study design (see paragraph 6.16);
- collaboration with local and national health authorities to ensure the research is compatible with national research agendas and priorities of local health services, along with verification that there are services available for participants' ancillary care and other support needs (see further on this issue paragraphs 8.8–8.11); and
- community and stakeholder engagement, in tandem with engagement with ethics committees, in developing appropriate recruitment procedures (see further below).

7.11 While the form and extent of such engagement will be affected by the particular circumstances of the emergency (particularly the scope for pre-existing relationships to be built upon), commitment to developing meaningful relationships on these lines as the project develops is likely to be a key factor in creating the trustworthy environment necessary for the research to be accepted as legitimate. While time pressure will often be a significant factor, in some emergencies (for example in outbreaks where the possibility of neighbouring areas or countries being affected can be predicted) it may be possible for such relationships to be developed in advance. This would facilitate more meaningful engagement in early research planning, and a less pressured environment for sharing information and raising awareness in the local area.<sup>544</sup>

7.12 Maintaining these respectful relationships over time is also essential, and avoids the lack of respect inherent in using engagement merely as a means to get a project up and running. In practice, this might involve approaches such as establishing an informal community advisory board to feedback any concerns or suggestions as the research progresses (see paragraph 5.39). Scope for front-line workers (who will often have local knowledge as well as being the first to encounter difficulties with a study on the ground) to influence elements of study design in response to participants' feedback is a further important element of a respectful and collaborative approach. Planning, early and transparently, with communities for an 'ethical departure' at the end of the research is crucial, minimising the harms of a sudden loss of workers, expertise, or resources, and where possible ensuring sustainability.<sup>545</sup>

7.13 A final essential element of respectful relationships with communities hosting the research is to ensure research findings are appropriately disseminated at the end of the project. Dissemination should not only extend to participants (see paragraph 7.24), but also through wider community channels in recognition of the part that host communities have played in facilitating that research.<sup>546</sup> Importantly, such dissemination should also

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<sup>544</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>, at page 61. See also a call by WHO for community engagement about Ebola to be strengthened in countries bordering the DRC: WHO (18 October 2019) *Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 18 October 2019*, available at: [https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo](https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo).

<sup>545</sup> See, for example, Humanitarian Health Ethics (2018) *Ethics and the closure of humanitarian healthcare projects*, available at: <https://humanitarianhealthethics.net/ethics-and-the-closure-of-humanitarian-healthcare-projects/>; and Pal NE, Eckenwiler L, Hyppolite S-R *et al.* (2019) Ethical considerations for closing humanitarian projects: a scoping review *Journal of International Humanitarian Action* 4(1): 17.

<sup>546</sup> See, for example, Humanitarian Health Ethics (2017) *Perceptions of EVD research progress report - August 2017*, available at: <https://humanitarianhealthethics.net/perceptions-of-evd-research-progress-report-august-2017/>.

include follow-up engagement with key local and national policy-makers to ensure that relevant research findings can be taken up. We return in Chapter 9 to these points in the context of the ethical implications of sharing data, including findings (see paragraphs 9.38–9.39).

## Achieving the best possible consent processes

- 7.14 Alongside the additional considerations outlined above, it is essential that consent processes themselves are made as contextually appropriate as possible: being sensitive to cultural plurality and diversity within populations is a key part of demonstrating equal respect for prospective participants (see paragraph 4.35). The input of local researchers, and other local stakeholders, through community engagement processes is likely to be central to achieving this, not only in helping develop appropriate information materials and processes at the point of seeking consent, but also in supporting broader awareness and accessible communication at community level. Monitoring whether there are particular patterns in those who decline consent (for example by gender) may also help to identify any failures to be appropriately inclusive.
- 7.15 There is a substantial body of work from other contexts on how to present research information in accessible ways to different audiences, and how to support voluntariness of decision-making. Many examples of innovative practices have been shown to enhance both initial understanding and retention of key information. There are also many sources of practical recommendations such as appropriate forms of consent documentation and the use of distinctive dress to minimise risks of therapeutic or philanthropic misconception (see Box 7.3).

### Box 7.3: Adaptive and flexible approaches to providing information, and seeking and recording consent

- In three studies exploring mental health among Syrian refugee children in Lebanon, the informed consent process was adapted for low literacy levels. Interviewers **read out the consent and assent documents** and used **infographics** to support the process. They took time to check understanding (for example by **asking participants to paraphrase what they understood**) and checked that parents consented, and the child assented to taking part. In one of the studies, a clinical trial, teams sought to increase accessibility for vulnerable families by **conducting home visits** and by **offering appointments over the phone** at times convenient to families, **including evenings and weekends**.<sup>547</sup>
- **Traditional games** have been used for explaining randomisation for clinical trials of a malaria vaccine in Burkina Faso,<sup>548</sup> while **participatory drama**, involving children as well as professional actors, has been used to share information about drug-resistant malaria in Cambodia.<sup>549</sup>
- Guidance from the HIV Prevention Network highlights circumstances where **verbal consent** is more appropriate than written consent: these include for participants with

<sup>547</sup> Personal communication, Fiona McEwen (20 November 2019): see Box 10.4 for further detail of the studies and of the collaborating partners.

<sup>548</sup> Wellcome Trust and CIDRAP (2015) *Recommendations for accelerating the development of Ebola vaccines: report and analysis*, available at: [http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola\\_virus\\_team\\_b\\_report-final-021615.pdf](http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_virus_team_b_report-final-021615.pdf), at page 41.

<sup>549</sup> Lim R, Tripura R, Peto TJ *et al.* (2017) Drama as a community engagement strategy for malaria in rural Cambodia *Wellcome Open Research* 2: 95.

limited literacy; in settings where there is deep cultural distrust about signing official documents; and in cases where waiving written consent can enhance confidentiality protections and reduce risk of stigma.<sup>550</sup>

- Guidance for those responding to public health emergencies in the US urges research teams to distinguish themselves from responders by wearing **vests, shirts, and hats with clear labelling that help distinguish researchers from responders.**<sup>551</sup>

7.16 More subtle elements of the consent process – such as the role that body language, or the relative seating positions of researcher and prospective participant, can play in supporting or undermining voluntary choices – have also been recognised.<sup>552</sup> Apparently unrelated innovations in the humanitarian sector can also play an important role in supporting better consent practice through physical changes to the environment: for example, through the recent development of transparent biosecure ‘cube’ units for use when caring for patients in highly infectious disease outbreaks.<sup>553</sup> These enable patients to see their family members, and to interact with health professionals and researchers without protective equipment, thus playing a significant role in reducing some of the barriers to effective communication and human connection experienced in past outbreaks. In paying close attention to achieving the best possible consent practices, it is also important to ensure that researchers are not expecting *more* of participants in emergencies than they would in non-emergency contexts, for example with respect to competence or understanding.<sup>554</sup>

### Recommendation 9 (directed to ethics committees)

**When reviewing proposed consent processes for research in emergency settings, research ethics committees should consider:**

- **whether the proposed consent processes are the best and most sensitive possible that can be achieved in the circumstances;**
- **what other requirements might be needed to ensure respect for participants as people of equal moral worth and agency; and**
- **whether, in all the circumstances, what is being asked of participants can be justified as fair.**

## Exceptions to consent

7.17 There are a number of recognised exceptions where research may be authorised by ethics committees without requiring informed consent from individuals, although how these exceptions are applied in practice divides opinion, and will also depend on national

<sup>550</sup> HIV Prevention Trials Network (2009) *HIV Prevention Trials Network: ethics guidance for research*, available at: [https://www.hptn.org/sites/default/files/inline-files/HPTNEthicsGuidanceV10Jun2009\\_0.pdf](https://www.hptn.org/sites/default/files/inline-files/HPTNEthicsGuidanceV10Jun2009_0.pdf), pp31-3.

<sup>551</sup> Pakenham JP, Rosselli RT, Ramsey SK *et al.* (2017) Conducting science in disasters: recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research *Environmental Health Perspectives* **125(9)**: 094503.

<sup>552</sup> Faden R, and Beauchamp T (1986) *A history and theory of informed consent* (Oxford: Oxford), at page 315.

<sup>553</sup> ALIMA (2019) *Cube, the biosecure emergency care unit*, available at: <https://www.alima-ngo.org/en/alima-cube>. These were designed by a Congolese doctor in direct response to his experiences of working in the West African outbreak: The Telegraph (20 November 2019) *Congolese doctor honored for game-changing ‘Ebola cube’*, available at: <https://www.telegraph.co.uk/global-health/science-and-disease/congolese-doctor-honored-game-changing-ebola-cube/>.

<sup>554</sup> See, for example, Pucci E, Belardinelli N, Borsetti G *et al.* (2001) Information and competency for consent to pharmacologic clinical trials in Alzheimer disease: an empirical analysis in patients and family caregivers *Alzheimer Disease & Associated Disorders* **15(3)**: 146-54. Even in a carefully designed study in a non-emergency context, 70 per cent of participants did not understand features of the research such as randomisation. See also: Onora O’Neill on the dangers involved in ‘idealisation’: O’Neill O (1996) *Towards justice and virtue: a constructive account of practical reasoning* (Cambridge: Cambridge University Press), pp39-44.

law.<sup>555</sup> Exceptions to individual informed consent requirements include research relating to urgent care such as care for severe head injury where all potential participants are unconscious.<sup>556</sup> Waivers of consent may also be sought from ethics committees if they are convinced that the research would otherwise not be feasible or practicable – for example when using data from population databases – if the research is judged to have important social value.<sup>557</sup> Depending on the circumstances, such waivers may be accompanied by requirements designed to promote participant protection and ensure community acceptability, including scope for discussion with families at the time, and for earlier publicity within communities.

- 7.18 A further class of research where individual informed consent cannot be sought is that which relates to the impact of population-wide public health policy initiatives, where individuals cannot opt-out without in effect vetoing the policy. As in the case of research with unconscious patients, the role of wider community consultation and engagement has been widely discussed in such cases, with respect to implementation of the policy, as well as any associated research.<sup>558</sup>
- 7.19 As Box 7.4 illustrates, examples of these kinds of scenarios (which might or might not meet the criteria set out in particular jurisdictions or guidance such as the Council for International Organizations of Medical Sciences (CIOMS) guidelines for waivers of consent) do feasibly arise in global health emergencies. Where research proposals that would necessarily involve a waiver of consent do arise in emergency contexts, we suggest that it is important for ethics committees to give particular attention to the question of how equal respect for participants is to be secured in these unusual circumstances (see paragraph 4.48 and Recommendation 9 above).

#### Box 7.4: Research in the absence of consent? – examples from the call for evidence

“Arguably there was an element of ‘research’ in medical care during the West African Ebola outbreak in treatment centres (including those outside West Africa, such as the US, the UK and Spain) where clinical teams tried to intensify supportive care to achieve better outcomes. It is important that such endeavours be published. Data about the levels of care in particular treatment centres during outbreaks, and how this related to mortality, should also be published. This kind of data though generally doesn’t require consent even under non-emergency circumstances.” *Bridget Haire, Kirby Institute, UNSW Sydney, Australia*

“Here I would like to point to research undertaken during the Zika outbreak involving the release of *wolbachia* infected mosquitoes... Essentially, the release of mosquitoes strains the ethical traction of individual consent. A person can refuse to be part of the trial, but at some level they (and other citizens in the city) would participate if mosquitoes were released. The constraints of this research for individual consent was reinforced both through processes of collective dialogue and approval, but critically through robust

<sup>555</sup> Shepherd L, and Macklin R (2019) Erosion of informed consent in US research *Bioethics* **33(1)**: 4-12.

<sup>556</sup> See, for example, World Medical Association (2013) *Declaration of Helsinki*, available at: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>, at paragraph 30; and CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guidelines 10 and 16.

<sup>557</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>, guideline 10.

<sup>558</sup> See, for example, WHO (2014) *Guidance framework for testing of genetically modified mosquitoes*, available at: [https://apps.who.int/iris/bitstream/handle/10665/127889/9789241507486\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/127889/9789241507486_eng.pdf); and Burgess MM, Mumford JD, and Lavery JV (2018) Public engagement pathways for emerging GM insect technologies *BMC Proceedings* **12(8)**: 12.

regulatory process, the pragmatic nature of the design and the accountability of a public institution through which the research was implemented.” *Ann H. Kelly, Department of Global Health & Social Justice, King’s College London*

“... take for example the recent emergency conditions in the Gaza Strip. Do severely injured people need to provide consent? Can the family do this instead? Yes I think family can.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

## Research relationships and professional virtues

- 7.20 Developing trusting and trustworthy relationships with the communities where research is due to take place, and with others with an important local or national stake in healthcare and/or research, has a key role to play in the ethics ecosystem. As one respondent to our call for evidence reminded us with his reference to the ‘intent’ of the researcher (see Box 7.2), a further element in the ethical conduct of research is the quality of the direct relationships between researchers and participants throughout the research process. Ethical considerations for researcher-participant relationships do not start and finish with the initial giving of consent, or with the signing of a form.
- 7.21 Taking equal respect seriously requires creating an environment in which all those directly affected (patients / participants, families, professionals) have a clear understanding of what to expect, and as a result can have well-founded trust in the research process (see Chapter 4). Such a trust-based environment can only be created through gradually building up relationships where those affected have reasonable grounds for trusting those running and overseeing the research programme (see paragraph 4.46). These relationships must be conducted on equal terms. On the practical front, researchers need to ensure that participants and their families are kept informed, particularly if there are any changes to initial plans; find ways of hearing and responding to concerns as these emerge; and, critically, ensure that promises are not made that cannot be kept.
- 7.22 Importantly, the quality of relationships also depends on the integrity and dispositions of research workers, and the way these are supported by institutional policies (see paragraphs 4.40 and 10.22). The nature of good relationships in research can be understood in a variety of ways, all of which are underpinned by the need for certain dispositions or virtues.<sup>559</sup> For example, there needs to be a genuine concern for the person and adequate time to establish acquaintance and closeness; a recognition of the power imbalance consequent on a host of factors including dependency (but political, social and economic factors too); and hence the need for mutual respect and trust as a means to compensate for the sense of inadequate control. Research also involves exchange: it can be conceived as a gift relationship.<sup>560</sup> Participants give data, samples, time, and information; researchers give time, concern, advice, and help. The virtue of

<sup>559</sup> For a fuller discussion of this in another context (that of research with older people) see: Hughes J, Haimes E, Summerville L *et al.* (2009) Consenting older adults: research as a virtuous relationship, in *The limits of consent - a socio-ethical approach to human subject research in medicine*, Corrigan O, McMillan J, Liddell K, Richards M, and Weijer C (Editors) (Oxford: Oxford University Press), pp133-49. See also: Nouvet E (26 March 2019) *Consent complexities, Ebola, and the fine line between collaboration and exploitation in research conducted during public health emergencies: presentation to PREA conference, Ohio State University*, available at: [https://kb.osu.edu/bitstream/handle/1811/87662/PREA\\_Nouvet\\_2019\\_presentation.pdf](https://kb.osu.edu/bitstream/handle/1811/87662/PREA_Nouvet_2019_presentation.pdf).

<sup>560</sup> See: Titmuss R (1970) *The gift relationship: from human blood to social policy* (London: George Allen & Unwin); and Tutton R (2004) Person, property and gift: exploring languages of tissue donation to biomedical research, in *Genetic databases: socio-ethical issues in the collection and use of DNA*, Tutton R, and Corrigan O (Editors) (London: Routledge), pp19-38.



fidelity, of being faithful to the other, is crucial and links to the need for there to be honesty and trust between participants and researchers.

- 7.23 Nurturing such relationships will not be easy in the complexities of a global health emergency, and it is important to recognise the time pressures and physical constraints that will inevitably shape research encounters. However, research with survivors of the West Africa Ebola outbreak demonstrates how in many cases it was precisely because of this sense of connection with unit workers that people were willing to take part in research, a finding repeated in research in diverse other settings (see paragraph 2.25). Indeed it has been argued that the ‘recognition’ of others as one’s peers or moral equals expressed through these forms of human connection is fundamental to the sharing of power, and hence to ethical research relationships.<sup>561</sup> This acknowledgment of the extent to which relational and emotional factors may underpin decisions about research involvement presents a challenge in the context of voluntary and informed consent, but cannot simply be ignored or dismissed as an example of undue influence or coercion. Rather, this recognition of the important role of human relationships in decision-making reinforces the importance of other elements of the ethics ecosystem alongside consent processes, in particular the extent to which the research has local support and legitimacy. The extent of this support will affect whether what is being asked of participants can be justified as fair.
- 7.24 Intrinsic to the kind of relationships described above is the importance of recognising the contribution made to research by participants, both in ways as simple as thanking them,<sup>562</sup> and through finding appropriate ways of sharing with them what has been learned through the research.<sup>563</sup> This will not always be straightforward,<sup>564</sup> but it is increasingly recognised as an ethical imperative, both in emergency and non-emergency settings.<sup>565</sup> Such respectful interactions at the individual and community level are a key part of a more equitable approach to research at institutional level, to which we now turn in the next two chapters.

#### Recommendation 10 (directed to ethics committees and funders)

**Funders should provide a ringfenced budget to support researchers in providing meaningful feedback to their participants, and wider communities, about what their study has learned, and should audit whether this take place. Ethics committees should similarly look for communication plans across the lifetime of the research when asked to authorise studies.**

<sup>561</sup> Hhe research, presented by Nouvet E (26 March 2019) *Consent complexities, Ebola, and the fine line between collaboration and exploitation in research conducted during public health emergencies: presentation to PREA conference, Ohio State University*, available at: [https://kb.osu.edu/bitstream/handle/1811/87662/PREA\\_Nouvet\\_2019\\_presentation.pdf](https://kb.osu.edu/bitstream/handle/1811/87662/PREA_Nouvet_2019_presentation.pdf).

<sup>562</sup> Nature (13 November 2018) *How a simple ‘thank you’ could improve clinical trials*, available at: <https://www.nature.com/articles/d41586-018-07410-0>.

<sup>563</sup> ODI (18 October 2019) *Blog: ‘how is your research going to benefit me?’: bringing findings back to communities in Ghana*, available at: <https://www.odi.org/blogs/10803-how-your-research-going-benefit-me-bringing-findings-back-communities-ghana>.

<sup>564</sup> Mootz JJ, Taylor L, Wainberg ML *et al.* (2019) Ethical considerations for disseminating research findings on gender-based violence, armed conflict, and mental health: a case study from rural Uganda *Health and Human Rights Journal* **21(1)**: 81-92.

<sup>565</sup> Pakenham JP, Rosselli RT, Ramsey SK *et al.* (2017) Conducting science in disasters: recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research *Environmental Health Perspectives* **125(9)**: 094503; and Taylor J (2019) Reporting research findings to participants is an ethical imperative *BMJ* **367**: l6324.





# Chapter 8

Collaborations and  
partnerships

## Chapter 8 – Collaborations and partnerships

### Chapter 8: overview

Good research relies on bringing together partners with different kinds of expertise who work together collaboratively to ensure that methods and approaches are coherent across the partnership.

- **Effective cooperation** with the many organisations operating on the ground is essential to ensure that research is well-aligned with emergency response needs, and hence to ensure that it best helps reduce suffering. Without cooperation between research agencies, it is likely that populations may be either under- or over-researched, entailing avoidable harm.
- **Meaningful research collaborations** are much more than cooperation: they involve shared aims and opportunities for all parties involved in the collaboration to shape the research and influence objectives and outcomes. The importance of fair collaborations is underpinned by the ethical imperative to treat others, colleagues as well as research participants, with equal respect.

### *Cooperation between research and response*

Research funders should promote profound engagement from the very beginning between researchers and those directly responsible for emergency response, both at strategic level and on the ground. People should not be asked to take part in research, however good its aims, in circumstances where their basic needs are not being met by the response efforts. Good practice examples in recent emergencies include partnerships between research teams and humanitarian partners, such as the World Food Programme, to ensure that such needs are being met before people are asked to contribute to research.

**Funders must pay particular attention to the need for research collaborations to work with others to help ensure that populations' basic health needs are being met as part of the response effort.**

### *Collaborations within the research sector*

Promoting fairness in the collaborations between research partners, particularly between institutions in high- and low-income settings, is important within two timeframes:

- **During the emergency:** research institutions need to take active steps to ensure that these relationships are as fair as is possible in the circumstances: for example by establishing collaboration agreements early; supporting inclusive authorship criteria; and facilitating access to essential resources such as libraries and training. Funders are well placed to encourage such arrangements within funded collaborations.
- **Over the long-term:** developing fair collaborations is an essential part of **capacity development and strengthening**. Capacity for social science and ethics research is an important, and often overlooked, priority in low- and middle-income settings. Funders have an important part to play in this, including in prioritising long-term sustainable funding models that support LMIC institutions in applying and holding grants directly, as well as through collaborative arrangements. Funders, however, are only one part of the picture, and governments and intergovernmental bodies also have important roles to play.

## The ethical case for cooperation and collaboration

- 8.1 Effective research in global health emergencies involves international cooperation between research-focused stakeholders and those responsible for, or engaged with, other aspects of humanitarian response. These include domestic authorities, health services and other local leaders and agencies, local, regional and international aid organisations (intergovernmental, other governmental, charitable), private sector partners, and sometimes the military (see paragraph 1.6 and Box 1.2). Such cooperation is essential at both individual and organisational level, despite being complicated by often conflicting priorities, responsibilities, and interests.<sup>566</sup>
- 8.2 Increasingly, global health research, and in particular that taking place in emergencies, necessarily also involves *collaborative* approaches. While cooperation is essential for effective working on the ground, genuinely meaningful collaboration is an aspiration, involving not only shared aims but also opportunities for all parties to shape the project from the beginning, and to influence objectives and outcomes (see further, paragraphs 8.20–8.23). In practice, collaborations are most likely to be found *within* the research sector (involving, for example, research institutions from different settings working together on a funded project). However, when there is strong leadership and a shared sense of purpose in response to an emergency, with research firmly embedded as a key element of that response, it may be possible to have meaningful collaborations across these distinct sectors. This is illustrated in Box 8.1.

### Box 8.1: Collaborative approaches to the Zika virus

#### Zika and Related Diseases Specialists Network – Renezika

Few of the pandemics facing the international community in recent decades have had the complexity of Zika virus and associated diseases pandemic that emerged in Brazil in April 2015. Initially, the occurrence was considered to be of no greater threat than dengue or chikungunya. Nonetheless, by the end of October, microcephaly cases started to rise sharply, which triggered a thorough investigation and subsequent declaration of a National Public Health Emergency. On 5 December, the President of Brazil launched the National Microcephaly Response Plan, involving 19 institutions and structured around three pillars: 1) vector control; 2) healthcare; and 3) research and education.

During the implementation of the National Microcephaly Response Plan, the importance of integrating the efforts of different parties became evident, including research institutes and governmental bodies, both national and international. From this need for integration, the Zika and Related Diseases Specialists Network – Renezika – was created. During the emergency, the Network provided information that supported the elaboration of health surveillance and assistance protocols in different contexts. Later, the Network provided a sustainable framework to promote the joint development of virological, clinical, and epidemiological studies; alternative vector control strategies, diagnostic tests, as well as potential vaccines and treatments. These research collaborations were strengthened with support from the Brazilian Ministry of Health, the Centers for Disease

<sup>566</sup> Feldman PH, Nadash P, and Gursen M (2002) Researchers from Mars, policymakers from Venus *Health Affairs* **21**(4): 299–300. See also: Katz R, Blazes D, Bae J *et al.* (2014) Global health diplomacy training for military medical researchers *Military Medicine* **179**(4): 364–9.

Control and Prevention (CDC), the World Health Organization (WHO), the US National Institutes of Health (NIH), and the European Commission.<sup>567</sup>

- 8.3 While many of the challenges of partnership working are logistical and practical, the emphasis on cooperation and collaboration is also inherently ethical, as illustrated with reference to the values of our ethical compass:
- **Helping reduce suffering:** contributing to better response, and hence reducing suffering, is a core justification for conducting research in such challenging environments, as described in Box 8.1. However, where key actors do not cooperate or collaborate with each other, research may not be well aligned with response, and may potentially even interfere with the response effort. This may be associated with direct harms and loss of scope for benefit both for affected and future populations.
  - **Fairness:** the question of the fair distribution of benefits and burdens is a central concern in all ethical research. Lack of coordination between research teams and projects contributes to the risks of populations being either under- or over-researched.<sup>568</sup> This can lead to the needs of particular groups or subgroups being overlooked (see paragraph 6.21), or to people feeling exploited (for example because similar questions are repeatedly asked of them, without ever leading to improvements in their situation).
  - **Equal respect:** the moral imperative to treat others with equal respect (colleagues as well as participants) combines with the emphasis on fairness to underpin ‘fair’ or ‘meaningful’ collaborations. For individual researchers, collaborations founded on equal respect need to take account of factors such as fair opportunities to contribute, and avoidance of exploitation (for example in connection with systems of academic recognition and progression). From a broader perspective, equal respect and fairness provide the foundation for the long-term capacity strengthening of institutions. The strength of a country’s emergency preparedness is inextricably combined with the respective strengths of its health and research systems, and the capacity of these to interact (see paragraph 3.8).
- 8.4 Respondents to our call for evidence overwhelmingly supported the idea that research institutions had an ethical obligation to collaborate (see Box 8.2). The importance of institutions’ willingness to transcend their primary organisational interests – or the desire to gain credit for what is being achieved – in order to prioritise the welfare of those affected by current and future emergencies emerged very powerfully. At the same time, it is important not to be naïve about the factors that can work against such collaborative approaches to research, including the many other institutional and personal motivating factors that affect behaviour, both in research in general and in pressured emergency contexts. It also cannot be taken for granted that all those operating in these environments are acting with good will (see paragraph 10.23).

**Box 8.2: Is there an ethical obligation to work collaboratively? – responses to the call for evidence**

“I strongly believe that it is an ethical obligation to work collaboratively rather than competitively in the context of global health emergencies based on mutual respect and trust, research collaboration for (south-south, north-south) for co-working in development

<sup>567</sup> Vanni T, Chalegre K, Giaretta Sachetti C *et al.* (2016) Zika virus emergency in Brazil: scientific challenges and early developments *F1000Research* **5**(1915).

<sup>568</sup> Omata N (2019) ‘Over-researched’ and ‘under-researched’ refugees *Forced Migration Review* **61**: 15-8.



and implementation. Moreover [it is important to foster] co-funding and co-production partnership, articulated shared benefits based information / data sharing for all, all-inclusiveness". *Ernest Tambo*

"Hell yes. It is limited by the practical constraints of the current system and their potential impact on researchers' livelihoods so should not be underplayed, but a grown-up system should aspire to address these issues. If grant awarding bodies were to strongly support collaboration and if academic institutions were to accept contribution as sign of output rather than just money won and papers authored then the rest should follow."

*Anonymous respondent.*

"Absolutely. Unless the main research aim is not saving lives – or finding innovative solutions for a particular problem. Why for instance should there be over 10 vaccines trials in one micro setting? These resources could be pooled together, and donors have a moral responsibility to ensure that this happens in the near future." *Anonymous respondent*

"I think this obligation exists in all research because there are limited resources available for research. In a GHE, however, there is the added burden of the urgency of trying to find successful solutions. If two research teams are competing with one another when they could work together and find a better solution sooner, then the ethical obligation to benefit participants should take priority over the competition. I know that sometimes competition is good to bring the best out of everyone, but in an emergency, collaboration and benefit much take priority." *Dónal O'Mathúna, PhD*

"I would think so, and not just in emergencies. Insofar as collaboration avoids redundancy of efforts and promotes learning and timely research outcomes, it should be part of the norms for researchers. The obvious counter-argument is that competition fosters innovation, but I'm not sure, at least in global health emergencies with a limited window of opportunity for research, how strong this argument is." *Annette Rid, King's College London*

"Yes, in a context of limited resources, competition is detrimental to health and wellbeing of populations. Research based on competition in these contexts can be harmful in a variety of ways (including duplication of effort), and decrease trust." *Anonymous respondent*

"I am not sure because you cannot force collaboration. Collaboration rests on the idea that partners would have the same approach, inclinations, values etc. I think it good to encourage collaboration should groups have these in common and are willing."

*Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

- 8.5 In this chapter, we consider the implications of this strong ethical drive towards effective partnerships focused on the care and well-being of those affected by emergencies – including how a central focus on reducing suffering can at times come into tension with the other values of our ethical compass. We look first at the relationships between research teams (who may themselves be part of collaborations bringing together multiple research institutions) and those directly engaged in emergency response (paragraphs 8.6–8.13); and then specifically at the ways in which meaningful collaborations between research teams can be supported (paragraphs 8.14–8.34).

## Cooperation and collaboration between research and response

- 8.6 Health-related research in emergencies intersects with the direct emergency response in many different ways.<sup>569</sup> In some cases research elements of humanitarian response may be very closely integrated into healthcare: for example in clinical trials of novel treatments or vaccines;<sup>570</sup> or in operational research, such as the implementation and evaluation of culturally-appropriate ways of delivering mental health support to populations displaced after conflict.<sup>571</sup> In other cases, research activities may be more distinct from everyday care, but can only be effectively carried out with the cooperation and logistical support of those concerned with other aspects of response. In some emergencies, cooperation from the military may be essential, particularly for logistical support, but this is likely to bring additional challenges, especially where concerns about complicity<sup>572</sup> or coercion<sup>573</sup> arise.
- 8.7 Research teams may come from the academic sector (working in temporary or longstanding partnerships with response organisations in order to reach communities and participants); they may include partnerships between academia and other sectors, such as pharmaceutical and biotech companies; they may be based within humanitarian organisations, which are increasingly initiating their own research agendas;<sup>574</sup> or they may include any combination of these elements. Box 8.3 illustrates some of the challenges inevitable in these multifaceted and fast-changing relationships between the many organisations involved in emergency response.

### Box 8.3: Challenges and success factors for cooperation and collaboration: responses to the call for evidence

“A global health emergency might necessitate the building of relationships and partnerships more rapidly and in a more ad-hoc manner. This might mean that collaborations which did not pre-exist have to be set up which may create an amount of difficulty. Particularly, as good collaboration relies on mutual trust which can be challenging to build in such constrained circumstances and tight timeframes. Additionally, global health emergencies require partners from multiple sectors who may not often be brought into discussions such as NGOs, civil society, religious groups and regulators among others to work together.” *Wellcome*

<sup>569</sup> See, for example, National Academies of Sciences, Engineering, and Medicine (2017) *Integrating clinical research into epidemic response: the Ebola experience*, available at: <http://nationalacademies.org/hmd/reports/2017/integrating-clinical-research-into-epidemic-response-the-ebola-experience.aspx>, at chapter 2. See also: IASC (2014) *Recommendations for conducting ethical mental health and psychosocial research in emergency settings*, available at: [https://interagencystandingcommittee.org/system/files/1.\\_iasc\\_recommendations\\_for\\_ethical\\_mhpps\\_research\\_in\\_emergency\\_settings\\_0.pdf](https://interagencystandingcommittee.org/system/files/1._iasc_recommendations_for_ethical_mhpps_research_in_emergency_settings_0.pdf).

<sup>570</sup> Rojek AM, Dunning J, Leliogdowicz A *et al.* (2017) Regulatory and operational complexities of conducting a clinical treatment trial during an Ebola virus disease epidemic *Clinical Infectious Diseases*: cix1061-cix. Such pragmatic integration of systems (avoiding duplicatory data collection) would still require relevant ethical governance and oversight.

<sup>571</sup> See, for example, Sumathipala A (2014) When relief comes from a different culture: Sri Lanka's experience of the Asian tsunami, in *Disaster bioethics: normative issues when nothing is normal*, O'Mathúna D, Clarke M, and Gordijn B (Editors) (Dordrecht: Springer); and Ahmad A, Ahmad L, and Mannell J (2018) *Responding to trauma during conflict: a case study of gender-based violence and traditional story-telling in Afghanistan*, available at: <https://odihpn.org/magazine/responding-to-trauma-during-conflict-a-case-study-of-gender-based-violence-and-traditional-story-telling-in-afghanistan/>.

<sup>572</sup> Buth P, de Gryse B, Healy S *et al.* (2018) 'He who helps the guilty, shares the crime'? INGOs, moral narcissism and complicity in wrongdoing *Journal of Medical Ethics* **44(5)**: 299-304.

<sup>573</sup> See, for example, UNICEF (2018) *Planning for post-Ebola: lessons learned from DR Congo's 9th epidemic*, available at: [https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna\\_Stevens\\_2018\\_Planning\\_Post\\_Ebola\\_Report.pdf](https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/14450/Alcayna_Stevens_2018_Planning_Post_Ebola_Report.pdf), at page 34, where in the context of safe and dignified burials, the risks of possible coercion from military or police are raised.

<sup>574</sup> Benelli P, and Low T (2019) Ethical primary research by humanitarian actors *Forced Migration Review* **61**: 28-9.

“Our collaborative experience (during the EVD outbreak in West Africa) enabled the review of a protocol used for the convalescent plasma clinical trials and also the successful delivery of humanitarian and clinical cargo to ensure all necessary equipment needed for the clinical trials were delivered to the respective countries. Key success factors were / are: strong leadership, effective communications & logistics planning, team of African consultants who knew the terrain and cultures/customs, strong community engagement, building and harnessing the survivor network, including a humanitarian approach in addition to clinical research by partnering with World Food Program and other governmental and non-profit organizations.” *The Ethics, Community Engagement and Patient Advisory (ECEPAS) Working Group of the Global Emerging Pathogens Treatment (GET) Consortium*

“The [UK] military were able to facilitate and access some of the research going on in Sierra Leone which was a definite positive. Unfortunately as the networks were forming on the hoof, these collaborative efforts happened very late in the outbreak after various contacts were formed and preconceptions / biases were overcome. Pre-agreement would have been far more effective. This is not just about research, this is about the entire response, but the problems are the same.” *Anonymous respondent*

“Key successes included the reputation of the research institution, a clear working group with ToR to manage the process, and a willingness for the research institution to hire their own staff to conduct the treatment programme so as not to impede day to day operation of the treatment centre.” *Gillian McKay*

“There must be understanding of all groups concerned, researchers, pharmaceuticals, home country. However, this must be guided by someone with power and authority like the WHO who will provide independent monitoring and guidance.” *Dr Rosmond Adams, Caribbean Public Health Agency (CARPHA)*

- 8.8 Even without taking into account the challenges of integrating research actors into the response effort, the leadership and coordination of humanitarian response more broadly has been strongly criticised as being “too cumbersome, bureaucratic, inadequate in terms of effect and accountability, too dominated by developed countries, and insufficiently adapted to constantly changing environments.”<sup>575</sup> A number of recent major initiatives in the humanitarian sector have sought to respond to such concerns. Emerging from the 2016 Humanitarian World Summit, for example, the Grand Bargain<sup>576</sup> and the Charter for Change<sup>577</sup> emphasised the need to shift to more local ownership of humanitarian response, and to set targets for increasing the amounts of global humanitarian funding going to local and national responders, with an emphasis on direct and flexible funding.
- 8.9 Such a shift clearly represents an important step in moving influence and resources to those with local responsibility and local knowledge (see paragraph 2.21). In the absence of a strong local research infrastructure, it does, however, bring with it further challenges of coordination between the response and (international) research sectors, particularly when partnerships need to be created in an *ad hoc* fashion in response to the particular needs of an emergency. Relationships within and between research teams and direct providers of healthcare in emergencies are likely to be particularly crucial. In practice,

<sup>575</sup> Spiegel PB (2017) The humanitarian system is not just broke, but broken: recommendations for future humanitarian action *The Lancet*. (special series).

<sup>576</sup> Agenda for Humanity (2019) *Grand Bargain initiative*, available at: <https://www.agendaforhumanity.org/initiatives/3861>.

<sup>577</sup> Charter 4 Change (2019) *Homepage*, available at: <https://charter4change.org/>.

humanitarian organisations providing direct healthcare on the ground may be highly influential in facilitating some studies in preference to others, because they act as gatekeepers to many of the potential participants.<sup>578</sup> Research teams in the 2014–16 West Africa Ebola outbreak were criticised for what was described as “an unorchestrated ‘land grab’” for sites and patients;<sup>579</sup> and similar concerns were echoed by our call for evidence respondents.<sup>580</sup> Research in the latest Ebola outbreak in the Democratic Republic of the Congo (DRC), by contrast, has been characterised through a highly coordinated approach involving national health authorities, the humanitarian sector, and diverse research teams, with coordination provided by national, regional, and central offices of the World Health Organization (WHO – see Box 6.1).

8.10 Factors associated with successful partnerships cited to us (see Box 8.3) include strong and respected leadership; effective systems of management and coordination with clear terms of reference; good communication and engagement with affected communities; and, critically, emphasis on the effective delivery of humanitarian support, an issue we come back to in more detail below (see paragraphs 8.11–8.13). The key challenge of developing trust between the various actors in these difficult circumstances, alluded to in a number of those responses to our call for evidence, was explored further in our roundtable meeting with ‘on-the-ground’ researchers.<sup>581</sup> Issues raised included:

- the inherent likelihood of tensions between national and international teams, given that the arrival of the latter is likely to be perceived as ‘taking over’ in response to the inability of the national response to contain the emergency;
- limits to the extent to which lip-service paid to the mainstream role of research in emergency response has yet to become fully operational; and hence
- the need for profound local engagement with those responsible for response from the start, if genuine cooperation between research and response is to be achieved.

8.11 The emphasis placed on ‘profound local engagement’ in our roundtable meeting is of key ethical importance, not only with respect to helping develop the relationships essential for effective joint working, but also, and critically, from the perspective of possible research participants. It is standard practice in health research in any circumstances to plan how ‘ancillary care needs’ (that is, health needs that arise independent of the issues that are being researched) will be taken into account, including having appropriate referral mechanisms in place (see paragraph 7.10). In the context of research in global health emergencies, where existing health services have been disrupted, and in any case may have been insufficient to meet needs, the concept of ‘ancillary care’ is likely to take on a wider meaning. It was argued strongly at the 2019 workshop on community engagement, co-hosted by the working group in Dakar, that if the response is not properly funded, and basic needs are not being met, it is unlikely that ethical research will be possible (see paragraph 2.29).<sup>582</sup> Recent commentaries on research in crises and disasters aimed at ethics committee members have highlighted this issue in similar terms. The commentaries include suggestions that the lack of adequate referral pathways should be taken into account by committees when considering foreseeable

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<sup>578</sup> Rid A, and Antierens A (2017) How did Médecins Sans Frontières negotiate clinical trials of unproven treatments during the 2014–2015 Ebola epidemic?, in *The politics of fear*, Hofman M, and Au S (Editors) (Oxford: Oxford University Press).

<sup>579</sup> Lang T (2015) Ebola: embed research in outbreak response *Nature* **524(7563)**: 29-31.

<sup>580</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.

<sup>581</sup> On-the-ground roundtable, 25 June 2018 (see Appendix 1).

<sup>582</sup> See also very similar arguments made in Parker M, and Allen T (2013) Questioning ethics in global health *Ethics in the Field: Contemporary Challenges* **7**: 24-41, at page 33, in the rather different context of mass drug administration campaigns: where medical assistance and surgery for those suffering from the symptoms of the conditions being targeted was not available, it was “hard to see how a convincing argument could be made that the government was genuinely committed to assisting those suffering from these afflictions.”

risks to participants;<sup>583</sup> and that research may be inappropriate at certain points in a disaster “when prospective research participants may have multiple unmet needs and lack specific survival-related resources.”<sup>584</sup>

8.12 This recognition of the desperate situation that those directly affected by emergencies may in some circumstances face – not only in accessing health services, but also other basic needs such as clean water, food, and shelter – does not mean that all research institutions and research teams have a duty to provide direct care and support, rather than conduct research. There may be particular circumstances when researchers with clinical skills do, exceptionally, contribute to direct care on the basis of need, but many researchers will not have the relevant skills, and would not in any case be the most appropriate people to provide the services required. Rather, **this recognition highlights two crucial responsibilities for researchers and their funders:**

- **First, when planning research in a global health emergency, researchers and funders need to be confident that adequate response services will be in place before prospective participants are approached.** As illustrated by the example from the Global Emerging Pathogens Treatment Consortium (GET) in Box 8.3 above, this may be achieved through the development of close partnerships with organisations such as the World Food Programme, alongside governmental and non-governmental organisation (NGO) providers of health services.
- **Second, research plans must take into account, and plan in advance for, circumstances where partners are not able to fulfil their agreed obligations, (whether for financial or other reasons),** and hence where researchers cannot rely on the agreed arrangements.

8.13 Inevitably, such arrangements will not put an end to the ethically challenging and distressing situations often experienced by front-line workers who are asked for help by people in desperate circumstances with essential needs (see Box 10.1 and paragraph 10.24). However, the more research plans (and funders) explicitly take into account such partnerships (and associated back-up plans) as an ethical prerequisite for research, the more likely it will be that front-line workers will be in a position to refer their participants to accessible sources of help.

#### **Recommendation 11 (directed to funders)**

**In order to ensure that people’s basic needs are being met when they are being asked to take part in research, funders should routinely expect research teams / research collaborations to include clear partnership plans with relevant service-providers, such as humanitarian organisations and national health departments, when seeking funding for research during emergencies. These arrangements should also include clear plans of action if partners prove unable, at any point, to provide the expected services.**

<sup>583</sup> Falb K, Laird B, Ratnayake R *et al.* (2019) The ethical contours of research in crisis settings: five practical considerations for academic institutional review boards and researchers *Disasters* **43(4)**: 711-26.

<sup>584</sup> Pakenham JP, Rosselli RT, Ramsey SK *et al.* (2017) Conducting science in disasters: recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research *Environmental Health Perspectives* **125(9)**: 094503.



## Collaborations within the research sector

### Working towards fair and meaningful collaborations

- 8.14 Responses to our call for evidence, illustrated in Box 8.2, demonstrate the strength of feeling surrounding the ethical importance of different institutions working together, rather than competing, to maximise the benefits that research may be able to bring to emergency response. Formal collaborations between research institutions from different countries, with their scope to bring together a wide range of skills, resources, and experiences, are increasingly seen as offering the most effective and ethical way of addressing the research required to improve response to urgent humanitarian needs. However, given the (often) very different starting situations of each member institution – and the extent to which the research agenda remains dominated by funders, publications, and research institutions in a small number of high-income countries (HICs) – the challenges of making such collaborations ‘fair’ or ‘meaningful’ at the level of either individual researchers or institutions, remain substantial.<sup>585</sup>
- 8.15 A valuable insight into the experiences and motivations of researchers involved in such largescale international collaborative networks is provided by qualitative research carried out in 2016 among research actors involved in networks of ten or more (sometimes 20) partners. The authors identified eight factors that contributors associated with being part of ‘good’ research collaborations:
- Cutting-edge science – the opportunity to contribute intellectually
  - Effective leadership – including an interest in helping young scientists
  - Good scientific practice – scientific rigour and ability to deliver to deadline
  - Capacity building – investing in the skillsets of all members, including early-career researchers
  - Mutual respect – but without pretending that there is scientific equality when there isn’t
  - Opportunities for discussion and disagreement – including open discussion about motivations
  - Trust and confidence in partner’s ability to carry out their responsibilities to the team
  - Fairness – including ensuring that credit was given to both members and participants.<sup>586</sup>
- 8.16 To support active change in the way that research collaborations operate, the Council on Health Research for Development has helped develop the Research Fairness Initiative (RFI), which provides a framework and reporting system for addressing fairness through the whole research endeavour, and addresses many of the issues raised above. The RFI identifies three distinct elements of fairness in international research collaborations: ‘fairness of opportunity’ before the research happens; ‘fair process’ during research; and ‘fair benefit sharing’ after research has been completed. Each of these three headings is broken down further into domains where what constitutes fair conduct between partners can be identified and measured (see Box 8.4). The RFI acknowledges

<sup>585</sup> See, for example, Smith E, Hunt M, and Master Z (2014) Authorship ethics in global health research partnerships between researchers from low or middle income countries and high income countries *BMC Medical Ethics* **15**(1): 42; Hedt-Gauthier B, Airhihenbuwa CO, Bawah AA *et al.* (2018) Academic promotion policies and equity in global health collaborations *The Lancet* **392**(10158): 1607-9; and Forbes (10 November 2019) *Global health research needs more than a makeover*, available at: <https://www.forbes.com/sites/madhukarpai/2019/11/10/global-health-research-needs-more-than-a-makeover/#7d21c357e34d>.

<sup>586</sup> Parker M, and Kingori P (2016) Good and bad research collaborations: researchers’ views on science and ethics in global health research *PloS One* **11**(10): e0163579. See also: Nature Index (2 May 2017) *8 things scientists want from a collaboration*, available at: <https://www.natureindex.com/news-blog/eight-things-scientists-want-from-a-collaboration>; and Hedt-Gauthier B, Airhihenbuwa CO, Bawah AA *et al.* (2018) Academic promotion policies and equity in global health collaborations *The Lancet* **392**(10158): 1607-9.



that, while partnerships often begin at a personal level between researchers, it is the policies and procedures that prevail at institutional and national level that may ultimately determine how fairly the opportunities and benefits of research are shared.

#### Box 8.4: Research Fairness Initiative areas for reporting<sup>587</sup>

##### Fairness of opportunity – ‘before research’

- 1 Relevance to communities – in which research is done
- 2 Early engagement of all partners – in deciding about aims, methods, implementation
- 3 Making contributions of all partners explicit – before projects reach a ‘no-return’ phase, ensuring ‘fair value’ for all before, during and after research
- 4 Ensuring that ‘matching’ and other co-financing mechanisms do not undermine opportunities for fair participation of all partners
- 5 Recognition of unequal research management capacities between partners and providing for appropriate corrective measures – negotiation, contracting, language, financial management systems

##### Fair process – ‘during research’

- 6 Minimizing negative impact of research programmes on health and other systems – divert human and other resources away from essential services and care
- 7 Fair local hiring, training and sourcing – staff, consumables and other support
- 8 Respect for authority of local ethics review system – possible measures to enhance this
- 9 Data ownership, storage, access and use – during and after research
- 10 Encourage ‘full cost recovery’ budgeting and compensation for all partners

##### Fair benefit sharing – ‘after research’

- 11 Research system capacities – improvements to ensure local research systems become more competitive, better able to take the lead in future
- 12 Intellectual property rights and technology transfer – specific measures to share IP rights in collaborative research
- 13 Innovation system capacities – measures to optimize localisation of spin-off economic activities, scaling ability of innovation
- 14 Due diligence efforts – minimizing negative environmental, social and cultural impact; achieving Sustainable Development Goals (SDGs); increasing women in science
- 15 Expectation of all partners to adhere to a best practice standard in research collaborations – such as Research Fairness Initiative or other such efforts

8.17 Recent polling of the International Advisory Board of *The Lancet Global Health* on questions of authorship and recognition illustrated some of the challenges that continue to arise in ensuring fair involvement and recognition of researchers in low-income countries (LICs), given the greater power and resources of their partners; and also the lack of consensus on what is ‘fair’.<sup>588</sup> Respondents agreed that it would be unacceptable to publish papers drawing on primary data collected in another country without recognising the co-authorship of collaborators from that country. However, there were more mixed views about the use of open access datasets, and whether it was acceptable to analyse such secondary data without the involvement, and crediting, of those with the knowledge of the context of which it had been collected.

<sup>587</sup> Research Fairness Initiative (2018) *RFI - in practice*, available at: <http://rfi.cohred.org/how-does-it-work-in-practice/>.

<sup>588</sup> The Lancet Global Health (2018) Closing the door on parachutes and parasites *The Lancet Global Health* 6(6): e593.

- 8.18 While the research and initiatives described above relate to international research collaborations in general, rather than specifically in the context of research in global health emergencies, it seems likely that these challenges of ensuring genuinely fair collaborations and avoiding ‘parachute’ research will be significantly exacerbated during an emergency, with the associated pressures of time and disruption of normal structures. The issues raised by respondents to our call for evidence covered similar concerns to those raised in other contexts (see Box 8.5).

**Box 8.5: Examples of good and bad collaborations: experiences of respondents to the call for evidence**

“We have had several cases of working with internationals during intensified emergency very successfully precisely because such internationals... know what it means to internalize and behave as an equal partner.” *Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“Many studies in Uganda presently have local as well as foreign collaborators. As long as power relations are minimized, it is possible to even integrate more useful objectives in the study – and leave out others.” *Anonymous respondent*

“The PIP Framework is... a good example. It required agreement prior to collaborative work, and builds in obligations for collaboration in public health emergencies.” *Anonymous respondent*

“... ensuring that commercial interests including branding opportunities do not get in the way of achieving optimal outcomes, including optimal outcomes for the most affected communities.” *Bridget Haire, Kirby Institute, UNSW Sydney, Australia*

“Our institution was approached several times to ‘partner’ with academic institutions in the US on projects they were undertaking with refugees residing in Lebanon. Many times, their objectives, protocols, and method were already developed and decided on, they were not open to feedback, did not really seem to acknowledge context, and it often seemed as if they only reached out because (1) they needed a local IRB, (2) they needed language translation.” *Anonymous respondent*

“Outside of the GHE context, but probably equally relevant to them: the somewhat lazy assumption of moral and intellectual superiority on behalf of researchers, universities and organizations based in Higher Income Countries vs those based in Lower Income Countries.” *Associate Professor Jantina de Vries, Department of Medicine, University of Cape Town*

- 8.19 Below, we look first at what action might be needed to support more equitable collaborations from the perspectives of individual researchers working within these networks, given current disparities in funding and influence (paragraphs 8.20–8.23). We then turn to the implications for much longer-term approaches to the support and strengthening of research institutions in low- and middle-income countries (LMICs) as part of emergency preparedness (paragraphs 8.25–8.34). We emphasise that these two approaches belong to two timeframes: the long-term aim of supporting the ability of national health and research institutions to lead the response and research effort in response to future emergencies needs to be considered by funders and others separately from the question of what is realistic to achieve when responding to a particular emergency in the absence of such preparedness (see also paragraph 9.10).

**Supporting fairness among academic collaborations**

8.20 Promoting more equitable approaches within academic collaborations emerged as an important theme throughout our evidence-gathering. Examples cited covered all three of the phases of research identified by the RFI (see Box 8.4), including lack of influence in the choice of funded research topics; being treated simply as ‘data-collectors’ rather than as full partners; and lack of recognition as authors / contributors.<sup>589</sup> Commentaries submitted in response to our call for evidence varied from references to the importance of underlying attitudes within a collaboration to the value brought by different partners, to highly practical references on accessing resources such as reliable internet connections.

**Box 8.6: Elements of good collaborative practice: responses to the call for evidence**

“Recognition and support of investigative capacities and empirical concerns of local investigators”. *Ann H. Kelly, Department of Global Health & Social Justice, King’s College London*

“The local research team should be involved from the beginning of the planning of the research. There should be transparency in the planning process and the objectives.” *Dr Anuradha Rose*

“... partnership that is based on the principles of equitable partnership, acknowledging strengths of both institutions, and co-creating a proposal. There is often an assumption of the need for one-way ‘capacity building’ – north to south, whereas in fact it is a two-way capacity building or learning that is needed.” *Anonymous respondent*

“... mechanisms would need to be in place for researchers to gain adequate recognition for collaborative work, in promotions, fundraising, and so on.” *Annette Rid, King’s College London*

“it should not lead to large (international?) consortia dominating and claiming most of the funding, while excluding others / new comers / outliers from access to study sites or funding, nor to lack of competitiveness to have the better ideas sharpened.” *Raffaella Ravinetto, Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Marianne van der Sande, Head of the Public Health Department, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Anne Buvé, Vice-Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium*

“Good internet [is] critical. Using teams who already know each other is very helpful. A Skype-based Ebola vaccine DSMB [data and safety and monitoring board] worked very well.” *Professor Stephen Gordon, MLW, Malawi*

8.21 A number of practical steps that research collaborations could and should take to facilitate more equitable forms of working – while being honest about the actual current situations and skills of different teams and team members – emerged repeatedly in

<sup>589</sup> On-the ground roundtable, 25 June 2018; Roundtable on sharing data and samples, 3 December 2018; RECAP meeting, American University of Beirut, 15-16 January 2019; and Roundtable on the role of funders, 8 March 2019. See also: NPR (4 November 2019) *This Congolese doctor discovered Ebola but never got credit for it - until now*, available at: <https://www.npr.org/sections/goatsandsoda/2019/11/04/774863495/this-congolese-doctor-discovered-ebola-but-never-got-credit-for-it-until-now>.

discussions,<sup>590</sup> and are listed below (see also paragraphs 9.34–9.35 with reference to protected time to publish for colleagues from less well-resourced settings):

- Clarifying expectations from the very beginning between collaboration partners, for example by holding a joint workshop to facilitate face-to-face contact and ensuring all parties' priorities and concerns are on the table (including finding ways of obtaining input from those who are not fluent in the dominant language of the collaboration). This will be particularly important where collaborations include diverse types of organisation, including non-governmental organisations (NGOs) or the commercial sector, where priorities, systems, and incentive structures may be very different from the academic sector.
- Establishing collaboration agreements at an early stage, with a focus on providing opportunities and support where necessary for LMIC collaborators to meet the necessary criteria for authorship.
- Creating a channel within the collaboration for highlighting concerns and expediting resolution.
- Including provision in budgets to ensure that writing-up time is covered, particularly where workers are on short-term contracts.
- Including elements of mentoring and capacity support for more junior colleagues across the collaboration, including journal clubs, encouragement of different forms of writing (including blogs), and access to other forms of training and to institutional resources such as libraries.
- Finding new ways to recognise contributions within institutional performance management: for example, by giving explicit recognition for mentoring and colleague support, as well as for first authorship.

8.22 It was recognised that while, with goodwill on the part of individual researchers (particularly principal investigators) and their institutions, some of these factors are potentially deliverable straight away, others would require longer-term institutional change across the research sector.<sup>591</sup> In particular, the pressures on academics and institutions in high-, middle-, and low-income countries to demonstrate success in the ways demanded by their funding system (typically senior authorship in prestigious journals) was highlighted as a constraint on achieving meaningful collaboration.<sup>592</sup> Recent high-profile recognition of the importance of tackling these issues – as demonstrated by the launch in September 2019 of the Research on Research Institute with its aim to advance more open, diverse, and inclusive research – represents a welcome step forward.<sup>593</sup>

8.23 Research funders' role in supporting collaborative behaviours was a strong theme in responses to our call for evidence (see Box 8.7 below), and was debated positively by those who contributed to our funders' roundtable meeting.<sup>594</sup> It was argued by some that funders could and should play a much more active 'brokerage' role in bringing together different institutions to work together in collaborations (both in the time-pressured environment in response to a specific emergency, and as part of longer-term research). Mapping existing capacity, drawing on the knowledge and expertise of organisations such as funding networks, national research councils and academic networks, would be

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<sup>590</sup> See also: Elrha (2019) *Lightning talks: South-North research partnerships - what works well?*, available at: <https://www.elrha.org/researchdatabase/lightning-talks-south-north-research-partnerships/>.

<sup>591</sup> See also: Nuffield Council on Bioethics (2014) *The culture of scientific research*, available at: <http://nuffieldbioethics.org/project/research-culture>.

<sup>592</sup> RECAP meeting, American University of Beirut, 15-16 January 2019; and Roundtable on the role of funders, 8 March 2019.

<sup>593</sup> The University of Sheffield (30 September 2019) *Research on Research Institute launches to make research more strategic, open, diverse and inclusive*, available at: <https://www.sheffield.ac.uk/news/nr/research-on-research-institute-launches-to-make-research-more-strategic-open-diverse-inclusive-1.866700>.

<sup>594</sup> Roundtable on the role of funders, 8 March 2019.

an important prerequisite for such an approach. Specific suggestions for how funders might support fairer and more inclusive approaches to collaborative working included:

- providing initial small grants for partnership meetings to support collaborative approaches for more substantial funding bids (including within very tight timescales where necessary);
- ensuring that applications include meaningful input from researchers in-country, while being creative in how this is done, especially where it is likely that leading researchers in LMICs may already be highly committed in other elements of emergency response (thereby avoiding simple tick-box compliance); and
- making provision to cover the costs of capacity support for researchers involved in the collaboration (particularly where those from affected countries are less senior as suggested above), to ensure they can play a full part in the collaboration.

**Box 8.7: The role of funders in supporting more equitable collaborations: responses to the call for evidence**

“Funders are well-placed to bring together people working together in different institutions – even those working as competitors. They can bring together people with a great idea, with others on the ground who are able to implement it... There is a balance to be struck between completely open calls, and actively mandating collaboration (for example through the use of consortia) in applications. The latter risks giving priority to well-funded institutions in high income countries who have the infrastructure, contacts and money to put together such consortia quickly. What are needed are ‘softer’ ways of generating collaboration, including active involvement by funders, taking on a role as a broker matching up expertise, skills and experience from different institutions and places (for example by starting a call inviting brief concept notes, rather than fully-formed consortia and plans). There are lots of different models.” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

“They are the funders, as such they have the mandate to require collaboration, and, ideally, to support the identification of suitable partners in-country. No grant should be signed to a Global North country without a collaborating partner in the Global South if the research is to be conducted in a Global South country.” *Gillian McKay*

“Concretely and directly support first the local and then regional research (not only through other international partners) ... Ensure that local populations are always involved along the way.” *Raffaella Ravinetto, Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Marianne van der Sande, Head of the Public Health Department, Institute of Tropical Medicine (ITM), Antwerp, Belgium; Anne Buvé, Vice-Chair of the Institutional Review Board, Institute of Tropical Medicine (ITM), Antwerp, Belgium*

**Working group approach**

- 8.24 **The emphasis in our ethical compass on equal and mutual respect between research colleagues, and on the demands of fairness, particularly in responding to historic and current inequities, provide a strong moral basis for policies that create and sustain respectful and meaningful collaborations. In the immediate need to establish research in response to an emergency, however, it is important to recognise how the other element of our compass, helping reduce suffering, may**



**act as a partial constraint.** Researchers from non-affected HICs may be better placed and better resourced to complete research and produce the evidence required to support response than countries that may already be overstretched by the emergency. At the same time, they are unlikely to have the local understanding of needs and perspectives that researchers from the country or region can bring. **Honesty between collaboration partners as to the strengths and skills each bring is essential, as is creativity on the part of funders in finding ways to support and incentivise fairer ways of working in the ways described by our respondents (see paragraph 8.15).**

#### **Recommendation 12 (directed to funders)**

**We recommend that funders develop and implement effective and creative ways of promoting and supporting more equitable collaborations, following the principles of the Research Fairness Initiative. In addition to taking account of equity in the review of proposals, these could include taking an active role in linking potential collaborators; providing seed funding for scoping meetings between potential partners from HICs and LMICs to enable more inclusive input into subsequent funding applications; including budget lines for immediately relevant capacity support of less well-resourced partners; and specific prompts within funding calls to describe how all partners have contributed to the proposed research.**

#### **Recommendation 13 (directed to research institutions)**

**We recommend that research institutions review their performance management systems to ensure that mentoring and supporting overseas colleagues, as part of international collaborations, is recognised and credited.**

### ***Supporting capacity strengthening over the long-term***

- 8.25 While time constraints inherent in establishing research collaborations during an emergency inevitably place limits on the priority that can be given at that point to capacity strengthening (see paragraph 8.24), such constraints do not apply when considering the longer-term role of funders, research institutions, and others with a role in conducting or supporting research related to emergency preparedness. **Drawing on the continuing significance of historical injustices that affect research capacity in many LMICs (see paragraph 4.35), we argue that there is a moral imperative to foster capacity in sustainable ways that, over time, enable the generation and ownership of knowledge to be located directly in affected communities.** ‘Duty-bearers’ who have the capacity to make a real difference in how research is funded and led include funders, research institutions, and indeed researchers themselves (see paragraphs 4.64–4.71).<sup>595</sup>
- 8.26 Three distinct levels of research capacity strengthening have been identified, with different actors having scope for influence at different levels, as touched upon earlier (see paragraph 8.22):
- Individual: supporting individual career progression of selected researchers through means such as mentoring and access to opportunities to develop their skills;

<sup>595</sup> See also: The Academy of Medical Sciences, the Medical Research Council (part of UK Research and Innovation (UKRI)), and the Interacademy Partnership (forthcoming) *Interdisciplinary research in epidemic preparedness and response*.



- Organisational: for example at the level of the research institution or NGO: including elements such as backroom support for grant applications and research coordination, as well as sustainable employment opportunities and career progression for researchers; and
- Institutional: concerning the ‘rules of the game’ more broadly, including incentive structures and political and regulatory contexts.<sup>596</sup>

8.27 Despite considerable focus over the last decade and more on capacity strengthening at these different levels for health research in LMICs, concerns have been expressed that this is still an “evidence-lite and fragmented field of practice.”<sup>597</sup> A 2019 review of the current literature on research capacity-strengthening in LMICs highlighted a number of limiting factors, which strongly echoed issues raised with the working group (see, for example, Boxes 8.3 and 8.5). Factors cited in the review included: lack of funding or only short-term research funding; weak scientific leadership and absence of mentoring; poor incentives and conflicting professional priorities; difficulty in publishing in international journals; and low worker retention.<sup>598</sup> In contrast, positive factors associated with successful strengthening of capacity included continuity of funding; appropriate infrastructure and governance, and capable leadership; North-South partnerships and sustained collaborations over time; mentoring and network opportunities; and a focus on research addressing policy gaps and local needs.

8.28 During our evidence-gathering, we came across several examples of substantial investment by research funders in research capacity strengthening. These included the development of infectious disease networks such as the African coalition for Epidemic Research, Response and Training (ALERRT) and the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Disease Epidemics (PANDORA-ID-NET) in Africa and Europe, and the Zika Consortia in Latin America (see paragraph 3.28 and Box 3.9); international research collaborations such as Research Capacity Building and Knowledge Generation to Support Preparedness and Response to Humanitarian Crises and Epidemics (RECAP)<sup>599</sup> and Research for Health in Conflict – Middle East and North Africa (R4HC-MENA)<sup>600</sup> focusing on research preparedness in humanitarian crises and conflict in the Middle East and Africa; and support for the development by the Institute for Research and Development, Sri Lanka of the first twin registry in South Asia.<sup>601</sup> A key challenge arising in all such initiatives, however, is how the funding and structures developed in LMICs on the basis of time-limited grants can be secured on a long-term sustainable basis. Similarly, if research funders focus primarily on individual capacity strengthening – for example, by providing opportunities for LMIC researchers to study at prestigious HIC universities – but do not address the organisational level (such as lack of jobs in the researcher’s home country where their

<sup>596</sup> Bowsher G, Papamichail A, El Achi N *et al.* (2019) A narrative review of health research capacity strengthening in low and middle-income countries: lessons for conflict-affected areas *Globalization and Health* **15(1)**: 23, drawing on DfID (2010) *Capacity building in research*, available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/187568/HTN\\_Capacity\\_Building\\_Final\\_21\\_06\\_10.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/187568/HTN_Capacity_Building_Final_21_06_10.pdf).

<sup>597</sup> Bowsher G, Papamichail A, El Achi N *et al.* (2019) A narrative review of health research capacity strengthening in low and middle-income countries: lessons for conflict-affected areas *Globalization and Health* **15(1)**: 23.

<sup>598</sup> *ibid.*, at table 4. The authors noted particular challenges for research in conflict zones.

<sup>599</sup> LSHTM (2019) *RECAP*, available at: <https://www.lshtm.ac.uk/research/centres-projects-groups/recap>.

<sup>600</sup> R4HC-Mena (2019) *Homepage*, available at: <https://r4hc-mena.org/>.

<sup>601</sup> Fernando B, King M, and Sumathipala A (2019) Advancing good governance in data sharing and biobanking - international aspects *Wellcome Open Research* **4**. See also: Sumathipala A, Siribaddana S, Hotopf M *et al.* (2013) The Sri Lankan Twin Registry: 2012 update *Twin Research and Human Genetics* **16(1)**: 307-12, who suggest that the Sri Lankan Twin Registry, and the establishment of a biobank to support a follow-up study of its registrants, “is a classic showcase of successful North-South partnership in building a progressive research infrastructure in a LMIC.”

skills can be used) or institutional level (such as the difficulties in achieving recognition in high-profile journals), little may change.

- 8.29 The Partnership for Research on Ebola Virus in Liberia (PREVAIL) between the US and Liberia provides one example of how a national research institution, created during an emergency, is looking to create a sustainable basis for its future work (see Box 8.8). Developing systems and governance that enable an institution to seek direct grant funding, rather than relying on partnerships managed by HIC partners, is of particular importance in such long-term sustainability. Not-for-profit organisations such as the International Network for the Availability of Scientific Publications (INASP)<sup>602</sup> and COHRED (Council on Health Research for Development),<sup>603</sup> for example, play an invaluable role in supplying technical expertise and tools to support the shift towards more local and sustainable generation of knowledge; as does the Global Grant Community which has developed the Good Financial Grant Practice standard to enable institutions to demonstrate they have sound financial systems.<sup>604</sup>

#### **Box 8.8: PREVAIL: capacity-building, knowledge-sharing, and development**

*Soka Moses, Bartholomew Wilson, and Joseph Boye Cooper provided the working group with an account of how PREVAIL has developed, and continues to develop, as an organisation after the Ebola outbreak in West Africa in 2014–16.*

PREVAIL was established in response to the outbreak of Ebola in Liberia in August 2014. On the emergence of the outbreak, the country's leaders – concerned that Liberia had no capacity to respond to the virus – contacted the US administration to request assistance. As a result of the request, PREVAIL was launched as a research collaboration between the Liberian Government and the NIH's National Institute of Allergy and Diseases (NIAID) to support the Ebola response in Liberia and to conduct research based on a mutually-agreed research agenda.

A governance structure was developed to ensure coordination and efficient implementation of the research. The governance structure included Liberia's Minister of Health and the US Ambassador to Liberia as the highest decision-making body, and an executive committee of experts from both countries to determine the strategic direction of the partnership. Several technical committees were established as part of PREVAIL, including committees on data and information technology, regulation and ethics, social mobilisation and communication (SMC), laboratory, pharmacy, and training and professional development. Each of these committees were jointly led by experts from both Liberia and the US to ensure mutual respect, collegial partnership, and meaningful input from both partner countries. It provided a mentoring relationship and opportunities for knowledge transfer. These transfers of knowledge were particularly key in the light of the relatively junior status of some Liberian committee members, due to limited capacity in the country.

PREVAIL has developed significantly since its inception: there are now nine iterations of PREVAIL's research programme, extending to other diseases such as malaria and HIV. As a result of these developments, and to ensure its long-term survival as a self-sufficient organisation, PREVAIL's systems have needed to respond through change. These changes include the establishment of a data management office, and the appointment of a new Network Director (a Liberian) who will lead the day-to-day operations of PREVAIL. A grant management office will be established to provide

<sup>602</sup> INASP (2019) *About us*, available at: <https://www.inasp.info/about>.

<sup>603</sup> COHRED (2019) *Homepage*, available at: <http://www.cohred.org/>.

<sup>604</sup> Global Grant Community (2019) *Homepage*, available at: <https://www.globalgrantcommunity.org>.

training and support for applying for and managing research grants (at present, no institution in Liberia is qualified to benefit from an NIH research grant). This development aims to contribute to advance planning and to strengthen local capacity to independently leverage funding to sustain future research.

PREVAIL has also supported its partners at the NIH in understanding the importance of engaging communities before conducting research as a way to address community resistance and concerns. This was a significant learning point for PREVAIL's partners and was based on the organisation's knowledge and experience gained from the Ebola outbreak response. Importantly, it also represents an example of knowledge transfer from local practitioners to international actors.

The changing functions and structures of PREVAIL are also highlighted by a change to its acronym: it is no longer the 'Partnership for Research on Ebola Virus in Liberia', but is instead now the 'Partnership for Research on Vaccines and Infectious Disease in Liberia'.<sup>605</sup>

- 8.30 Issues of capacity also emerged as strong themes in the community engagement workshop we co-hosted in Dakar in April 2019.<sup>606</sup> Participants highlighted the importance of strengthening academic social science capacity alongside scientific capacity, so that countries have their own sources of expertise to draw on, in order to facilitate understanding and promote effective engagement with affected populations. This importance of strengthening national and regional social science expertise has been reiterated by a number of expert commentators, including the Director of the Africa Centres for Disease Control and Prevention (Africa CDC),<sup>607</sup> and a working group established on behalf of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) funders' network.<sup>608</sup> The importance of bioethics capacity has similarly been raised as a key element in creating sustainable national research systems.<sup>609</sup>
- 8.31 Another aspect of capacity raised in Dakar, which resonates with the PREVAIL example above, concerned ensuring that important progress made during an emergency (such as the networks and systems underpinning successful community engagement) should not be allowed to fade away once the emergency was over, and political attention was focused elsewhere. Similar concerns arose around maintaining capacity at the 'micro' level, including those individuals who have been drawn by chance into research because of the emergency. Locally-recruited front-line researchers such as data-collectors and research assistants, for example, may develop valuable research skills, but the opportunities for them to build on these skills, develop careers, and therefore contribute

<sup>605</sup> The word 'Prevail' has special significance in Liberia due to its use in the country's national anthem: "with God above, our rights to prove, will o'er all prevail".

<sup>606</sup> ALERRT, IRESSEF, Wellcome Centre for Ethics and Humanities, and Nuffield Council on Bioethics (2019) *Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises*, available at: <http://nuffieldbioethics.org/wp-content/uploads/Dakar-Workshop-FINAL-note.pdf>.

<sup>607</sup> Nature (11 March 2019) *John N. Nkengasong: how Africa can quell the next disease outbreaks*, available at: <https://www.nature.com/articles/d41586-019-00789-4>.

<sup>608</sup> GloPID-R (2019) *Towards people-centred epidemic preparedness and response: from knowledge to action*, available at: <http://www.glopid-r.org/wp-content/uploads/2019/07/towards-people-centered-epidemic-preparedness-and-response-report.pdf>. See also: Wellcome (18 July 2019) *New funding to boost global research capacity in humanities and social science*, available at: <https://wellcome.ac.uk/news/new-funding-boost-global-research-capacity-humanities-and-social-science>.

<sup>609</sup> See, for example, Wellcome Trust and CIDRAP (2015) *Recommendations for accelerating the development of Ebola vaccines: report and analysis*, available at: [http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola\\_virus\\_team\\_b\\_report-final-021615.pdf](http://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_virus_team_b_report-final-021615.pdf), at page 38.

to valuable local academic capacity, will only be realised with careful planning and a degree of future commitment by funders and research partners.

- 8.32 **Although there has been substantial emphasis on capacity-strengthening by research funders in recent years, there is a need for funders to take further steps to support models that have long-term sustainability for institutions, and that build on gains made in earlier time-limited projects.** This might include moving away from funding research in LMICs primarily through international collaborations headed by a HIC partner, toward direct relationships with LMIC institutions, underpinned by assurance models such as Good Financial Grant Practice standard (see paragraph 8.29). It could also include developing funding partnerships with funders based in LMICs, such as that modelled by the African Academy of Sciences ((AAS) – see paragraphs 3.26 and 5.19).

#### **Recommendation 14 (directed to funders)**

**Research funders should explicitly take a long-term approach to funding capacity strengthening, and in addition to supporting capacity development through international collaborations should aim to shift to direct relationships with research institutions in LMICs. They should also consider how to support maximum flexibility at the micro level – for example enabling project leads to approach local partners and explore mutually beneficial arrangements that strengthen local capacity.**

- 8.33 While major research funders clearly have an important role to play in supporting sustainable research institutions in LMICs, national governments have a responsibility to prioritise the development of research capacity in their countries. This is part of each country's commitments under the International Health Regulations (IHRs) to improve their levels of emergency preparedness. Countries should seek to ensure that capacity gains made during past emergencies are not lost.

#### **Recommendation 15 (directed to national governments)**

**As a key part of national emergency preparedness, national governments should prioritise strengthening academic capacity, including in social science and bioethics, to support the development of national / regional expertise in future. They should also ensure that national ethics committees are adequately resourced and supported.**

- 8.34 Finally, we highlight the role of national governments in supporting the international exchange essential for effective research partnerships and the development of individual and organisational capacity. Considerable concerns have been expressed, both in the UK and elsewhere, regarding the implementation of visa policies that appear to be acting as a significant barrier for LMIC researchers (particularly but not exclusively early career researchers) to travel to HICs for workshops, training, or other forms of academic exchange. This is particularly concerning when they have been invited, vouched for, and funded by respected organisations, and where such face-to-face interchange is a crucial part of delivering more equitable collaborative research.<sup>610</sup>

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<sup>610</sup> See, for example, LSE Impact Blog (28 August 2018) *For some, borders are now an insurmountable barrier to attending international academic conferences*, available at: <https://blogs.lse.ac.uk/impactofsocialsciences/2018/08/28/for-some->

**Recommendation 16 (directed to national governments)**

**National governments are urged to be alert to the importance of international collaboration and exchange as part of research capacity development, and to ensure that visa requirements, for example for attending meetings and training, do not in practice prevent academics, vouched for by funders and partner research institutions in the receiving country, from being able to attend such events.**

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borders-are-now-an-insurmountable-barrier-to-attending-international-academic-conferences/; The Guardian (24 June 2019) *Unesco chair blasts 'discriminatory' UK visitor visa system*, available at: <https://www.theguardian.com/uk-news/2019/jun/24/unesco-chair-blasts-discriminatory-uk-visitor-visa-system>; and Humanitarian Health Ethics (4 January 2020) *Blog: colonial suspicions and hollow partnerships - one African research assistant's failure to obtain a visa for a research seminar*, available at: <https://humanitarianhealthethics.net/category/dispatches-from-the-field/>. See also: Institute of Development Studies (2019) *International research collaborations need solid investment and a fair visa system*, available at: <https://www.ids.ac.uk/opinions/international-research-collaborations-need-solid-investment-and-a-fair-visa-system/>; and BMJ (30 July 2019) *Blog: Ulrick Sidney - visas for global events: too many are losing their seat at the table*, available at: <https://blogs.bmj.com/bmj/2019/07/30/ulrick-sidney-visas-for-global-health-events-too-many-are-losing-their-seat-at-the-table/>.





# Chapter 9

Data and samples

## Chapter 9 – Data and samples

### Chapter 9: overview

The collection, storage, and sharing of biological samples and data are essential parts of effective research in global health emergencies. While many ethical issues raised by these activities are the same irrespective of whether samples or data are being used (for example, the importance of equity), there are also important differences. Some of these relate to the fact that samples often constitute a depletable resource, raising issues about which research should be prioritised. Others relate to the social, cultural, or religious status of samples. Still others arise out of the fact that samples can in many cases relatively easily be transformed into data. When we refer to ‘samples and data’, this should not be taken to imply that there are not ethically important differences between them. We note such differences at several points.

Sharing data and samples between humanitarian actors, or for future research use, can play an important role in helping reduce suffering in many ways, both during emergencies and in the routine surveillance that forms part of emergency preparedness. However, sharing may also bring with it risks of harm and exploitation (often for those already unfairly burdened or disadvantaged) and can undermine trust. ‘Sharing’ at present also comes in many forms, including with or without strict access and governance arrangements. **Sharing is vital for effective research collaboration, but it must not be exploitative. The questions to ask are: ‘What can be done to ensure the kind of environment in which data and samples can ethically be shared? What are the conditions for equitable and responsible sharing?’**

#### ***The role of individuals and communities regarding future use of data and samples***

Action is needed in planning for the long-term, and in response to challenges faced when emergencies arise in the absence of such planning. More evidence is needed to explore culturally appropriate approaches to consent, and to understand what governance arrangements for holding and sharing both data and samples would most effectively minimise unintended harms and underpin community trust. Guidance at national or regional level is urgently needed in many parts of the world.

- Funders and research institutions should prioritise research with stakeholders in different parts of the world to inform the development of regional guidance. Governments and intergovernmental agencies should support such initiatives as an essential part of emergency planning.
- Where emergencies arise in the absence of such guidance or shared understanding, National Research Ethics Committees could consider authorising two-stage approaches to consent for future research uses of data and/or samples, allowing time later for discussions on what approach to sharing might be acceptable at both individual and community level.
- Where samples collected in past emergencies have been held without clear consent, future use should be based on discussions with key stakeholders about what form fair and respectful future uses of these samples might take. For future international collaborative research in emergencies, the existence and scope of sample collections should routinely be registered in a publicly accessible database.

#### ***Exploring professional and institutional barriers to sharing***

**Equitable sharing** requires systems that give researchers in low-income countries (LICs) the same opportunities as those in high-income countries (HICs) to benefit from the data and samples that they have acquired themselves, and from open ‘sharing’ arrangements. **Responsible sharing** includes ensuring that data and samples, once shared, are used to optimum effect. We recommend that:

- Journals should explore innovative ways of crediting significant intellectual input into research short of direct involvement in writing; and should consider publication policies that promote the inclusion of primary researchers in later re-analysis of their data.
- Funders should take a more active role in supporting the effective use of data and samples once shared, including exploring funding streams to incentivise secondary analysis in response to identified needs.
- Funders should explore ways in which they can require, and support, their grantees to share their research findings in accessible and timely ways with key policy stakeholders.

## Introduction

*“[Two] things should be avoided: 1. Not sharing data that could save lives; 2. Use of data shared in an emergency context that results in privatized interventions from which communities from whom the data was generated are shut out.”<sup>611</sup>*

*“Trust is often the key for data sharing, but difficult to develop rapidly in the context of a PHE. Therefore, as a minimum, there is a need to ensure ‘confidence’ in the data sharing system for PHEs. While recognising that there may not be firm consensus on specific issues (such as ownership vs. custodianship of data), this should not prevent sharing if all parties have confidence in the system, consider it fair and support the underpinning principles.”<sup>612</sup>*

- 9.1 Procedures for the ethical and effective sharing of data and of biological samples have been identified as key challenges in conducting research in global health emergencies.<sup>613</sup> The use of data and samples for future research purposes – in addition to the clinical, public health, or research purpose for which they were initially gathered – is an important tool for improving future emergency response and care, as described in Box 9.1. Despite these undisputed benefits of effective sharing arrangements, the repurposing and reuse of data and of samples bring with them significant ethical, as well as logistical, challenges, even outside the emergency context. These challenges may become particularly acute during emergencies.

### Box 9.1: Examples of the role of data sharing and sample sharing

#### Preventing or mitigating the effects of infectious disease outbreaks

The Collaborative Management Platform for Detection and Analyses of (Re-) emerging and Foodborne Outbreaks in Europe (COMPARE) provides a framework for globally-linked pathogen data and also clinical and epidemiological data to be shared on an

<sup>611</sup> Bridget Haire, Kirby Institute, UNSW Sydney, Australia, responding to our call for evidence.

<sup>612</sup> Wellcome, responding to our call for evidence.

<sup>613</sup> GioPID-R (2018) *Data sharing in public health emergencies: learning from past outbreaks*, available at: <https://www.glopid-r.org/wp-content/uploads/2017/02/data-sharing-in-public-health-emergencies-case-studies-workshop-reportv2.pdf>, at page 20 (regarding samples); and Wellcome (2018) *Data sharing in public health emergencies: a study of current policies, practices and infrastructure supporting the sharing of data to prevent and respond to epidemic and pandemic threats*, available at: [https://figshare.com/articles/Data\\_sharing\\_in\\_public\\_health\\_emergencies\\_A\\_study\\_of\\_current\\_policies\\_practices\\_and\\_infrastructure\\_supporting\\_the\\_sharing\\_of\\_data\\_to\\_prevent\\_and\\_respond\\_to\\_epidemic\\_and\\_pandemic\\_threats/5897608](https://figshare.com/articles/Data_sharing_in_public_health_emergencies_A_study_of_current_policies_practices_and_infrastructure_supporting_the_sharing_of_data_to_prevent_and_respond_to_epidemic_and_pandemic_threats/5897608).

accessible platform “for the rapid identification, containment and mitigation of emerging infectious diseases and foodborne outbreaks.”<sup>614</sup>

#### **Supporting effective humanitarian response**

Researchers from the London School of Hygiene and Tropical Medicine (LSHTM) undertook real-time analysis of a diphtheria outbreak among displaced Myanmar nationals in Bangladesh. The researchers collaborated with Médecins Sans Frontières (MSF) teams running a diphtheria treatment centre and provided models to forecast the potential scale of the outbreak and the resulting resource needs.<sup>615</sup>

#### **Providing datasets which become a valuable source for further research**

Israeli researchers have used multiple datasets to ‘reconstruct’ the 2009 H1N1 influenza outbreak in order “to obtain insights that could not have been obtained from each of these datasets in isolation.”<sup>616</sup>

#### **Contributing to understanding the emergence and transmission of disease in real time**

During the 2009 flu pandemic, researchers from Public Health England (PHE) used real-time syndromic surveillance data to provide situational awareness during the pandemic. It enabled public health officials to identify the age groups most affected, and where the impact of the pandemic was at its worst.<sup>617</sup> Syndromic surveillance summaries are shared openly on PHE’s website.<sup>618</sup>

#### **Improving understanding of outbreak prevalence**

The Lassa Diagnostic Laboratory at Kenema Government Hospital, Sierra Leone, granted access to researchers (including those from the US Army Medical Research Institute of Infectious Diseases (USAMRIID) to undertake a retrospective seroprevalence survey of 675 samples collected and stored at the laboratory. The research demonstrated that viral pathogens (e.g., Ebola, Marburg, and Rift Valley fever viruses) in and around Sierra Leone are endemic to the region, suggesting that unrecognised outbreaks of viral infections had occurred. The research sought further to better define the disease burden on the population over time.<sup>619</sup>

9.2 A substantial body of work already exists in this area, both with respect to data and sample sharing in low-income settings, and, more recently, with respect to emergencies. In this chapter, we provide an overview of the key challenges identified in the existing literature and by those who contributed to our inquiry, and consider these in the light of the ethical compass we developed in Chapter 4. In doing so, it is important to keep a number of important distinctions in mind:

- The sharing of data and samples are often discussed together – and several of the issues that arise can be common to both. However the management and use of biological samples raise some distinctive issues from those related to data alone (see,

<sup>614</sup> COMPARE is an EU project that aims to speed up the detection of, and response to, disease outbreaks, with the goal of reducing the cost and impact of those diseases. See: COMPARE (2019) *About COMPARE*, available at: <https://www.compare-europe.eu/about>.

<sup>615</sup> Finger F, Funk S, White K *et al.* (2019) Real-time analysis of the diphtheria outbreak in forcibly displaced Myanmar nationals in Bangladesh *BMC Medicine* **17**(1): 58.

<sup>616</sup> Yaari R, Katriel G, Stone L *et al.* (2016) Model-based reconstruction of an epidemic using multiple datasets: understanding influenza A/H1N1 pandemic dynamics in Israel *Journal of the Royal Society, Interface* **13**(116): 20160099.

<sup>617</sup> Public Health England (6 March 2014) *Blog: syndromic surveillance - our national insurance*, available at: <https://publichealthmatters.blog.gov.uk/2014/03/06/syndromic-surveillance-our-national-insurance/>. Syndromic surveillance is a tool which shows, in real-time, whether diseases follow an unusual trend, such as increasing in prevalence at an unexpected time of year.

<sup>618</sup> Public Health England (2019) *Syndromic surveillance: systems and analyses*, available at: <https://www.gov.uk/government/collections/syndromic-surveillance-systems-and-analyses>.

<sup>619</sup> O’Hearn AE, Voorhees MA, Fetterer DP *et al.* (2016) Serosurveillance of viral pathogens circulating in West Africa *Virology Journal* **13**(1): 163.



in particular, paragraph 9.6), and regulatory approaches may potentially differ substantially.<sup>620</sup> There are also important distinctions between human samples (such as blood, tissue, and saliva) and pathogens such as viral isolates from animals or birds with human pandemic potential (see Box 9.2). At the risk of some repetitive phrasing, we aim to be clear throughout where we are referring to data alone, to samples, or to both (recognising that in practice human samples will also be associated with linked data if they are to have value as a research resource, and also may be transformed into data relatively easily).

- When discussing ‘sharing’ data and samples, it is also important to keep in mind the questions: ‘sharing what, how, with whom, and for what purpose?’ **Data** may potentially be shared at the time of an emergency between those directly involved in response, including public health practitioners, ministries of health, the humanitarian sector, front-line health professionals, and researchers; or by any of these actors with other researchers in the future. At present, datasets may be shared for future research on completely open-access terms; through curated platforms governed by specified access criteria and oversight by an access committee; or solely through direct application to original researchers and/or ethics committees. Research findings can be published only in high-cost subscription journals; or be made available through various forms of open access arrangement, making them more easily accessible to practitioners, policy-makers, and also academics and students in low- and middle-income settings who may not have ready access to journal subscriptions. **Samples** are sometimes made potentially available to any interested researcher through storage in a biobank (subject to the access requirements of the biobank or national law) or can be held in an institutional biorepository with much more limited access. Crucially, one aspect of ‘sharing’ that is often overlooked is the extent to which those who contributed to the research through agreeing to provide their data and their samples get to hear about either the findings of the original research (see paragraph 7.24), or in broad terms about future uses.

9.3 It is also essential to recognise the role of law both in terms of what national law permits or forbids, such as the permissibility of broad consent (see below), and in terms of the relevance of international law and the competing claims of nation states’ sovereign rights and international obligations (see Box 9.2). In some cases, governments may have very good reason – linked with past experience of exploitation – to resist samples in particular being taken out of the country; in others, governments may seek to hold on to information for their own reasons, unrelated to population benefit.<sup>621</sup> Nevertheless, researchers still have to operate within the legal framework of the relevant country, and need to find ways of working with relevant governments, for example by developing shared or mutually beneficial goals.

9.4 Whilst operating within such legal frameworks, the fundamental importance of relationships between front-line researchers and potential research participants must

<sup>620</sup> See, for example, the initial proposals put forward (and subsequently heavily amended) for revising the Common Rule for any research funded by US federal authorities: Lynch HF, Wolf LE, and Barnes M (2019) Implementing regulatory broad consent under the revised Common Rule: clarifying key points and the need for evidence *The Journal of Law, Medicine & Ethics* **47(2)**: 213–31.

<sup>621</sup> See, for example, discussion of ethics committee concerns in Tindana P, and de Vries J (2016) Broad consent for genomic research and biobanking: perspectives from low- and middle-income countries *Annual Review of Genomics and Human Genetics* **17(1)**: 375–93; and community perspectives of the role of the state in Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10(3)**: 264–77.

also be kept in mind, as we explored in Chapter 7 (see in particular paragraphs 7.20–7.23). As we discuss below (see paragraphs 9.9–9.28), the possible future use of a person’s data or their samples raises distinct consent and governance questions for ethics committees and others, alongside those relating directly to the research at hand.

### Box 9.2: Snapshot of international law and frameworks relating to data and samples

#### Data

- The **International Health Regulations 2005** require each signatory state to share with the World Health Organization (WHO) “timely, accurate and sufficiently detailed public health information” of all events that may constitute a public health emergency of international concern in its territory.<sup>622</sup>

#### Samples

- The 1992 **UN Convention on Biological Diversity** recognises “the sovereign rights of States over their national resources” and states that “the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.”<sup>623</sup> Access to genetic resources, where granted, should be on mutually agreed terms (see below under the **Nagoya Protocol**). Where a signatory country carries out research using another country’s resources, they should endeavour to do so with the full participation of the source country, and where possible in that country.<sup>624</sup>
- The 2011 **World Health Organization (WHO) Pandemic Influenza Preparedness (PIP) Framework** was developed in response to Indonesia’s decision not to share H5N1 flu samples in 2007. The framework links access by the international community to flu samples (through the network of influenza laboratories coordinated by WHO) with benefit-sharing arrangements to ensure source countries can access any resulting vaccines or treatments. It covers both human samples and non-human virus isolates but is restricted to those related to pandemic influenza. While an example of ‘soft law’ (a non-binding framework under Article 23 of the WHO Constitution), it includes binding operational agreements, for example through the use of standard material transfer agreements.<sup>625</sup> Concerns have, however, been expressed as to how effectively it is operating in delivering benefits to source countries,<sup>626</sup> and around the implications of the growing importance of genetic sequence data which may fall outside PIP definitions.<sup>627</sup> In response, the WHO has published a draft code of conduct on the open and timely sharing of such sequence data.<sup>628</sup>
- The 2010 **Nagoya Protocol** was negotiated in parallel with PIP and implements the benefit sharing provisions of the **UN Convention on Biological Diversity**.<sup>629</sup> It requires translation into national laws and is currently a work in progress. Contested

<sup>622</sup> WHO (2016) *International Health Regulations: third edition*, available at: <http://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf>, Article 6.

<sup>623</sup> UN (1992) *Convention on Biological Diversity*, available at: <https://www.cbd.int/doc/legal/cbd-en.pdf>, Article 15.

<sup>624</sup> *ibid.*

<sup>625</sup> WHO (2011) *Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits*, available at: [https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf?sequence=1).

<sup>626</sup> Rourke MF (2019) Access by design, benefits if convenient: a closer look at the pandemic influenza preparedness framework’s standard material transfer agreements *The Milbank Quarterly* **97(1)**: 91-112.

<sup>627</sup> Gostin LO, Phelan A, Stoto MA *et al.* (2014) Virus sharing, genetic sequencing, and global health security *Science* **345(6202)**: 1295-6.

<sup>628</sup> WHO (2019) *WHO’s code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease*, available at: [https://www.who.int/blueprint/what/norms-standards/GSDDraftCodeConduct\\_forpublicconsultation-v1.pdf?ua=1](https://www.who.int/blueprint/what/norms-standards/GSDDraftCodeConduct_forpublicconsultation-v1.pdf?ua=1).

<sup>629</sup> UN (2010) *Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity*, available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

issues include the implications of the Convention on Biological Diversity and Nagoya for sharing pathogens; and concerns about increases in bureaucracy, both in regular collaborations such as in the production of the 2019 flu vaccine, and in emergencies such as the Zika outbreak in Brazil.<sup>630</sup> Article 8, in particular, requires due regard to be paid to “cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally.” Signatory states “may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.”

### **Specific challenges of sharing data during or after an emergency**

9.5 The 2016 WHO guidance on ethical issues in infectious disease outbreaks highlights how data sharing in such circumstances takes on increased urgency “because of the uncertain and ever-changing scientific information; the compromised response capacity of local health systems; and the heightened role of cross-border collaboration.”<sup>631</sup> However, different ethical traditions and practices in research and public health (see paragraphs 1.22–1.24) may in practice still hinder or delay such effective sharing of data, especially where researchers are concerned that this may risk breaching confidentiality or the terms of the consent which they have sought for use of the data. Surveillance data held by ministries of health, in particular, potentially provide a valuable research resource for current and/or future patient benefit. However many factors, including political considerations, lack of resource to handle requests, and reported past misconduct by international actors, may hinder effective sharing (see also Box 9.3).<sup>632</sup> Contributors to our roundtable meetings<sup>633</sup> highlighted challenges in sharing data experienced by those working in emergencies. Many of these challenges have been reiterated in detailed case studies of outbreaks in different regions of the world over the last two decades.<sup>634</sup>

- **Time pressures:** time is of the essence to halt the spread of disease or prioritise relief operations in a natural disaster, and to understand enough to enable a meaningful research element of the response. There is a tension between the use of time to seek consent for data use – time that could be spent in patient care – and the role that timely analysis of data may play in informing improved response. This is exacerbated in some infectious disease emergencies where the use of personal protective equipment impedes communication and can also limit the amount of time that staff can safely spend with patients. There is a further fundamental tension between the early release of research data to maximise the impact they can have on controlling the outbreak, and concerns about the quality of that data.
- **The role of confusion and fear:** it is difficult, if not impossible, to come to a consensus on data sharing in a context of fear, tension, and miscommunication, exacerbated by

<sup>630</sup> WHO (2016) *Implementation of the Nagoya Protocol and pathogen sharing: public health implications*, available at: [https://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy\\_full.pdf](https://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf).

<sup>631</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, at page 38.

<sup>632</sup> See, for example, the discussion of the implications of political history in GloPID-R (2018) *Data sharing in public health emergencies: learning from past outbreaks*, available at: <https://www.glopid-r.org/wp-content/uploads/2017/02/data-sharing-in-public-health-emergencies-case-studies-workshop-reportv2.pdf>, at annex 2.

<sup>633</sup> On-the-ground roundtable, 25 June 2018; Data and samples roundtable, 3 December 2018.

<sup>634</sup> GloPID-R (2018) *Data sharing in public health emergencies: learning from past outbreaks*, available at: <https://www.glopid-r.org/wp-content/uploads/2017/02/data-sharing-in-public-health-emergencies-case-studies-workshop-reportv2.pdf>.

the role of multiple organisations and a likelihood of rapid turnover of workers. This difficulty may particularly apply where clear prior agreements and guidance are absent. In some cases, emergencies can change how people practise: data may be shared (for example, by ministries of health) in a way that might not usually happen, as the ‘gatekeepers’ of data may be more willing to make compromises in order to save lives. However, they may worry later if their data had been ‘clean’ enough to share, illustrating further the tension between harm from delay, and harm from inadequate quality control. Concerns about impact on future publications and academic opportunities may also hold back some researchers from readily sharing data, despite clear guidance to the contrary (see Box 9.7).

- The complexities of recognising possible harms to individuals and communities through sharing data beyond initial research** (including fear of harm): in some contexts, the possible harms of sharing data may be overlooked in contrast with the more concrete risks of harm associated with side-effects and adverse incidents in interventional trials. Data can be stigmatising either at individual level (for example regarding disease status or membership of a marginalised group), or at population-level (for example with reference to poverty or exclusion), in ways that only those with deep local knowledge may be able to recognise.<sup>635</sup> Such concerns may arise particularly in the context of narrative data which may have been shared through relationships of trust.

### Box 9.3: Links between public health and research uses of data

An important feature of research conducted in the context of a global health emergency is that while much of the data used will be obtained in the conduct of a ‘research project’ as usually understood – for example, a clinical trial – it will also sometimes have its origins in what might be thought of as routine ‘public health’ or ‘surveillance’ activities.

Guidance issued by the WHO highlights the essential role played by public health surveillance data in emergency response measures to guide the management of the current emergency, and to help prevent and respond to outbreaks in the future.<sup>636</sup> It is not possible to draw a clean line between such ‘public health’ and ‘research’ uses (see also paragraphs 1.19–1.20). Health surveillance is typically conducted on a mandatory basis, on the grounds of the wider public health interests of the community.

While consent for the collection and use of such public health data is therefore not routinely required, the WHO guidance emphasises the importance of safeguarding the confidentiality of personal information, and being transparent as to the nature of the surveillance and the uses to which the data are being put. Aggregated, non-identifiable, surveillance data are routinely used in research with ethics committees granting a consent waiver (see paragraph 7.17).

In some health emergencies, however, more detailed medical information at individual level may be essential – for example to describe treatment outcomes and the natural history of emerging diseases that are not yet well understood. While such information will be anonymised as quickly as possible, there are circumstances when complete

<sup>635</sup> de Vries J, Jallow M, Williams TN *et al.* (2012) Investigating the potential for ethnic group harm in collaborative genomics research in Africa: is ethnic stigmatisation likely? *Social Science & Medicine* **75(8)**: 1400-7. See also: Tindana P, Molyneux CS, Bull S *et al.* (2014) Ethical issues in the export, storage and reuse of human biological samples in biomedical research: perspectives of key stakeholders in Ghana and Kenya *BMC Medical Ethics* **15(1)**: 76.

<sup>636</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, pp23-4. See also: WHO (2017) *WHO guidelines on ethical issues in public health surveillance*, available at: <https://www.who.int/ethics/publications/public-health-surveillance/en/> which highlights the ethical implications of *not* collecting and using surveillance data – in particular the risk that “what doesn’t get counted doesn’t count” (at page 11).

deidentification cannot be guaranteed. The identification of a location such as a village – or, in rarer cases, of a person or household – might be possible because of an unusual combination of features of a cluster of otherwise non-identifiable pieces of information. These data are important in public health contexts, and it is the features that make data useful in this way that create the potential for identification.

The WHO guidance notes the importance of clear national laws limiting the circumstances in which such information may be used for other purposes than those for which it was originally collected. The guidance also requires that the use or sharing of any identifiable data must have the approval of a properly constituted and trained ethics committee.<sup>637</sup> In the UK, for example, any uses of confidential patient information without consent, whether for research or non-research purposes, must be considered by a Confidentiality Advisory Group established under section 251 of the NHS Act 2006 to advise the Health Research Authority and the Secretary of State for Health.<sup>638</sup>

### ***Specific challenges of sharing samples during or after an emergency***

9.6 The sharing of biological samples is particularly challenging because, unlike data, samples represent a limited resource that can be depleted by use, thus raising significant questions of prioritisation of access.<sup>639</sup> Other issues raised with us relating to the use of samples beyond the initial purpose for which they were taken<sup>640</sup> correlated closely with those in the existing literature examining research stakeholders' views in low-income settings.<sup>641</sup> It seems likely that these widely-experienced challenges may be exacerbated by features of an emergency such as extreme time pressures, and the scope for confusion and fear described above. Issues cited included:

- Attachment to blood samples, both because of the particular meanings and value associated with blood in many cultures, and in some contexts concerns about the possible misuse of blood for ritual purposes. Fear of other kinds of misuse of the personal and identifying data that can be derived from samples (not limited to blood) may also arise in research among communities whose legal status is uncertain or who otherwise have reason not to trust authority.<sup>642</sup>
- The scope for research involving samples to lead to the claiming of intellectual property rights, the associated commercial implications, and concerns about actual or perceived profiteering.

<sup>637</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, at page 24.

<sup>638</sup> HRA (2017) *Confidentiality Advisory Group*, available at: <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>.

<sup>639</sup> We recognise that 'immortal' stem cell lines obviously blur these boundaries, but for the most part stored samples are a depletable resource.

<sup>640</sup> On-the-ground roundtable, 25 June 2018; Data and samples roundtable, 3 December 2018; and responses to our call for evidence.

<sup>641</sup> See, for example, Tindana P, and de Vries J (2016) Broad consent for genomic research and biobanking: perspectives from low- and middle-income countries *Annual Review of Genomics and Human Genetics* **17(1)**: 375-93; and Tindana P, Molyneux S, Bull S *et al.* (2019) 'It is an entrustment': broad consent for genomic research and biobanks in sub-Saharan Africa *Developing World Bioethics* **19(1)**: 9-17.

<sup>642</sup> See, for example, the concerns expressed in ABC News (20 June 2019) *Biometric data is increasingly popular in aid work, but critics say it puts refugees at risk*, available at: <https://www.abc.net.au/news/science/2019-06-21/biometric-data-is-being-collected-from-refugees-asylum-seekers/11209274>. See also an account of a response by the humanitarian sector with respect to the appropriate use of biometric data: ICRC Humanitarian Law & Policy (18 October 2019) *Blog: facilitating innovation, ensuring protection - the ICRC biometrics policy*, available at: <https://blogs.icrc.org/law-and-policy/2019/10/18/innovation-protection-icrc-biometrics-policy/>.



- The importance of the physical location of storage, with strong concerns about repeated histories of exploitation and extraction in cases where samples are taken out of the country to be stored and used apparently for the benefit of others. These general concerns are likely to be exacerbated if exports happen during an emergency in a way that appears to take advantage of general disruption and lack of effective controls.
- Sharing samples, particularly when associated with export overseas, also raises concerns for local researchers who may fear that researchers in better resourced environments may get all the academic credit, with local researchers used simply as sample collectors.

### ***Working group approach***

9.7 We noted above that the sharing of data and samples has received a significant amount of attention internationally in the research community, and we provide an overview of important initiatives in the second part of this chapter (see Box 9.7). The concerns we heard illustrated frequent similarities between the challenges in non-emergency and emergency contexts (although often rendered more acute in the latter); and suggested that despite considerable work in this area, more remains to be done. In what follows, we shift the framing of the issue, so that instead of asking whether and when data and/or samples ought to be shared, or critiquing reluctance to share, **we recognise that sharing is vital, but must not be exploitative. The questions to ask are: ‘What can be done to ensure the kind of environment in which data and samples can ethically be shared? What are the conditions for equitable and responsible sharing?’** Such an approach is strongly supported by our ethical values:

- Maximising the potential value of data and samples to improve response and research through effective sharing arrangements may **help reduce suffering** both now and in the future; and conversely an absence of such arrangements may represent a loss of opportunity to reduce such suffering. However, how this is done must demonstrate **equal respect** for the people providing those data and samples through appropriate consent and governance systems.
- A focus on equal respect provides an important tool for thinking through how use of a person’s sample in certain circumstances may wrong them because of its nature (for example, because of cultural or religious meanings associated with particular samples), regardless of whether concrete harm might ensue. It also reinforces the importance of scrutinising possible harms that might accrue from sharing certain forms of data, particularly narrative data, beyond the initial research relationship. While respect might be perceived as a constraint on what can ethically be shared, equal respect also underpins the approach that it can be ethically acceptable to *ask* people, even in very difficult circumstances, to contribute towards the benefit of others, as long as it is done in a way that is respectful and provides a genuine choice. Indeed, not to ask could be seen as patronising and disrespectful.<sup>643</sup>
- **Fairness** requires that those to whom the data and samples relate are not bearing an undue burden for the benefit of others, and that how sharing systems are established and operationalised recognises the contributions and claims of those working in less well-resourced settings.

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<sup>643</sup> See for example the discussion of solidarity-based motivations for taking part in research at paragraph 2.24.



9.8 In the rest of this chapter, we consider what this approach might mean for two distinct, although interdependent, elements of ‘sharing’ data and samples obtained during an emergency:

- **The role of those who provide the data and samples:** questions of consent at the point at which data and samples are collected and the scope for this to include issues of wider sharing; how questions of local and national legitimacy might be addressed; and any justifications / conditions for sharing without explicit consent; and
- **The role of those who collect the data and samples:** the challenges that arise even where there is no doubt about the ethical justification to permit sharing: such as institutional restrictions, personal reluctance, or foreseeable harms to local capacity.

## The role of individuals and communities regarding the future use of data and samples

9.9 Despite considerable debate in recent years, issues of consent for the future use of data and samples for research are still very much unresolved. This is the case at the individual level, and at the community-level of permission and support. Consent challenges include diverse opinions on what models of consent are acceptable and meaningful, particularly in the time-pressured setting of an emergency. Questions of appropriate and achievable engagement between researchers, communities, and domestic authorities in order to develop well-founded trust and provide legitimacy for future sharing are even more complex.

9.10 In exploring ways forward, it is important to keep two distinct timeframes in mind: what is important (even essential) in terms of future preparedness; and what represents an absolute minimum for ethical sharing to take place in the acute phase of any emergency in the absence of such preparedness (see also paragraph 8.19). **Any acceptance of an ‘ethical minimum’ short of best practice in the face of a particular emergency reinforces the moral imperative to take long-term action across the research sector** to ensure that best practices can be securely embedded in future emergencies (see paragraphs 4.62–4.63).

### ***Broad consent and local legitimacy***

#### **Box 9.4: Views on consent for future use of data and samples: responses to the call for evidence**

“Individuals have to be aware of the gravity of the decision they are making and totally understand the impact of the sharing of their personal health/ research data to make an informed choice, prior to consent. To promote personal dignity, autonomy and respect, individuals should be fully informed whenever personal data is collected, whether for public health or research and be given an opportunity to make an informed choice whether or not they are happy for their information to be collected, stored and shared for whatever reason.” *The Ethics, Community Engagement and Patient Advisory (ECEPAS) Working Group of the Global Emerging Pathogens Treatment (GET) Consortium*

“Ignoring local voices means imposing solutions, means solutions to problems that may not exist, means the foreigner knows everything and the local has just to shut up and receive charity, provide data, listen and be good and obedient.” *Dr Najeeb Al-Shorbaji, Consultant*

“Research in different contexts is required to understand what models of consent may be acceptable in emergency circumstances and community attitudes to sample and data sharing.” *Wellcome*

“Consent should be obtained after making sure that the participants are aware that data is collected for public health practice / action purposes and/or for research purposes.”  
*Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine*

“... undue focus on the individual has been deleterious in our approaches to data-sharing, reducing the ability of individuals to have the opportunity to contribute to a better world [...] Important to recognise also the harms of not sharing data – not only to communities but also to individuals.” *Dr Cathy Roth, Senior Research Fellow – Infectious Diseases, Department for International Development, UK, responding in a personal capacity*

“In one emergency situation I have experience of, some people were reticent to share data as they were not sure whether the recipient’s activities constituted research on that data – with concern that the data had not explicitly been collected for research purposes – while the recipient perceived their use to be for direct response purposes (epidemiological analysis to inform response planning). Such uncertainty can impact upon the speed at which the response can take place, and the way in which people work together, as research was viewed as an activity requiring much more oversight, and people were scared of getting caught out, ‘accidentally’ doing research without the appropriate oversight.” *Anonymous respondent*

“In a global health emergency, humanitarian action and public health measures should take priority over research. It is however justifiable to collect data to protect public health, including using individual deidentified health information without individual informed consent, if it is not possible to obtain that consent. (Where this occurs, a debt is owed to the communities in which is occurred.)” *Bridget Haire, Kirby Institute, UNSW Sydney, Australia*

9.11 Possible approaches to consent for the future research use of data or samples range in theory from ‘specific’ consent (where the person concerned would be re-contacted for permission in connection with any future research study) to ‘blanket consent’ (where unconditional permission for literally any future use could be requested) – or indeed, to no consent at all.<sup>644</sup> Between these extremes, there has been increasing interest in – and support for – ‘broad’ consent. Broad consent allows the use of the data and/or samples in specific immediate research, and in future research of a broad but not open-ended nature (for example ‘medical research’, or ‘research on malaria’), with appropriate governance processes in place.<sup>645</sup>

9.12 Empirical work exploring the acceptability of different forms of consent model for the future use of research data and samples is still relatively limited. However, reviews of the

<sup>644</sup> See, for example, the discussion of proposed changes to the US Common Rule, including discussion of circumstances in which it has been argued consent is not required for various ‘secondary’ uses of data: Lynch HF, Wolf LE, and Barnes M (2019) Implementing regulatory broad consent under the revised Common Rule: clarifying key points and the need for evidence *The Journal of Law, Medicine & Ethics* **47(2)**: 213-31.

<sup>645</sup> See, for example, Tindana P, Molyneux S, Bull S *et al.* (2019) ‘It is an entrustment’: broad consent for genomic research and biobanks in sub-Saharan Africa *Developing World Bioethics* **19(1)**: 9-17 for an overview of different forms of consent in the context of biobanking. With specific reference to emergencies, see also: ALERRT (2018) “Ethics preparedness”: *facilitating ethics review during outbreaks - recommendations arising from a joint ALERRT & WHO workshop*, available at: [https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt\\_workshop\\_recommendations\\_final\\_30may18\\_0.pdf](https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt_workshop_recommendations_final_30may18_0.pdf); and Saxena A, Horby P, Amuasi J *et al.* (2019) Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel *BMC Medical Ethics* **20(1)**: 29.

available literature regarding attitudes to both the sharing of individual-level data<sup>646</sup> and of samples<sup>647</sup> in low- and middle-income countries (LMICs) describe broad consent as *potentially* acceptable on the basis of being the ‘best compromise’ available. While, it is suggested, in an ideal world many stakeholders might prefer specific consent for each future use to enable individuals to understand better how their data and/or samples were being used, the limitations this might place on research are also recognised, as is the possible insensitivity of attempting to recontact people in some circumstances. The scope for such contact to be perceived as an “unnecessary inconvenience” for participants as well as for researchers is also raised.<sup>648</sup>

- 9.13 It is, however, not the case that broad consent is universally regarded as acceptable or distinguishable from blanket consent,<sup>649</sup> and national jurisdictions may be silent on whether it is permissible, or explicitly forbid it in particular circumstances. There have, for example, been proposals in South Africa to require specific consent for any future uses of identifiable data.<sup>650</sup> Brazil, on the other hand, permits broad consent for the use of data, but only permits it for future use of samples (in the form of the option for sample donors to provide a waiver of specific consent) when these are stored in national biobanks, rather than institutional biorepositories.<sup>651</sup>
- 9.14 Factors associated in the empirical literature with more positive attitudes to broad consent include both greater awareness and understanding of research processes, and trust, born out of experience of the way existing research programmes are operating locally.<sup>652</sup> These factors reinforce an important feature of the kind of ‘broad’ consent explored in the literature cited above: its conception as ‘consent for governance’. In other words, under broad consent, people are not being invited to consent to possible unknown future uses in the abstract, but rather for the retention and use of their data and/or their samples under specified conditions that provide assurance and legitimacy.<sup>653</sup> Scope for the ethical future use of broad consent is thus reliant on the development of such systems for both data and for samples.

<sup>646</sup> Bull S, Roberts N, and Parker M (2015) Views of ethical best practices in sharing individual-level data from medical and public health research: a systematic scoping review *Journal of Empirical Research on Human Research Ethics* **10(3)**: 225-38. See also: Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10(3)**: 264-77; and Cheah PY, Jatupornpimol N, Hanboonkunupakarn B *et al.* (2018) Challenges arising when seeking broad consent for health research data sharing: a qualitative study of perspectives in Thailand *BMC Medical Ethics* **19(1)**: 86.

<sup>647</sup> Tindana P, and de Vries J (2016) Broad consent for genomic research and biobanking: perspectives from low- and middle-income countries *Annual Review of Genomics and Human Genetics* **17(1)**: 375-93.

<sup>648</sup> Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10(3)**: 264-77, at page 270.

<sup>649</sup> Discussion at *Research, responsibility, and regulation: ethical challenges in global health*, 11 December 2018, Keele University.

<sup>650</sup> Science (20 February 2019) *A new law was supposed to protect South Africans’ privacy. It may block important research instead*, available at: <https://www.sciencemag.org/news/2019/02/new-law-was-supposed-protect-south-africans-privacy-it-may-block-important-research>.

<sup>651</sup> Marodin G, Salgueiro JB, Luz Motta Md *et al.* (2013) Brazilian guidelines for biorepositories and biobanks of human biological material *Revista da Associação Médica Brasileira (English Edition)* **59(1)**: 72-7.

<sup>652</sup> See, for example, Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10(3)**: 264-77 regarding attitudes to data sharing in Kenya; Merson L, Phong TV, Nhan LNT *et al.* (2015) Trust, respect, and reciprocity: informing culturally appropriate data-sharing practice in Vietnam *Journal of Empirical Research on Human Research Ethics* **10(3)**: 251-63 on attitudes to data sharing in Vietnam; and Tindana P, and de Vries J (2016) Broad consent for genomic research and biobanking: perspectives from low- and middle-income countries *Annual Review of Genomics and Human Genetics* **17(1)**: 375-93 on existing literature in LMICs of relevance to both samples and data.

<sup>653</sup> Sheehan M (2011) Can broad consent be informed consent? *Public Health Ethics* **4(3)**: 226-35.

9.15 Proposals from empirical studies on data and sample sharing cited above include an emphasis on governance arrangements that would control future use (including access criteria, such as potential relevance of the research to local needs, and collaborations with local researchers); and on the *process* for the involvement of local voices in such decisions (including improving local awareness, seeking regular input on community concerns, providing community feedback on approved research plans, and non-tokenistic involvement in oversight committees).<sup>654</sup> The importance of ensuring legitimacy through appropriate involvement of national and local governments is also emphasised, particularly regarding the use of samples. One model put forward for biobanks being developed as part of the Human Heredity and Health in Africa (H3Africa) genomic research collaboration is based on the concepts of ‘entrustment’ and ‘stewardship’, and describes the structures and processes that would be needed to underpin trust in such stewardship (see Box 9.5).<sup>655</sup>

**Box 9.5: Entrustment framework (Tindana *et al.*<sup>656</sup>)**

<b>Recommendations</b>	<b>Points to consider</b>
<i>Trustworthy research institutions</i>	<ul style="list-style-type: none"> <li>Develop clear and transparent research goals</li> <li>Strengthen research competence</li> <li>Advocate for sustainable core research funds</li> <li>Strengthen institutional leadership</li> <li>Reciprocity – give appropriate benefits</li> </ul>
<i>Clear institutional guidelines</i>	<ul style="list-style-type: none"> <li>Develop institutional guidelines for sample collection</li> <li>Develop institutional guidelines for sample export and data sharing</li> <li>Develop guidelines for collaborations and access to samples and data</li> </ul>
<i>Effective consent and community engagement processes</i>	<ul style="list-style-type: none"> <li>Obtain informed consent for sample collection and research participation</li> <li>Seek entrustment for sample storage and future uses</li> <li>Seek entrustment for sample export and data sharing</li> <li>Engage community in future uses of samples</li> </ul>
<i>Effective and efficient research ethics committees</i>	<ul style="list-style-type: none"> <li>Develop workable standard operating procedures (SOPs)</li> <li>Provide adequate training</li> <li>Provide adequate resources</li> <li>Develop effective communication between REC and researchers</li> <li>Develop effective communication between local RECs and external RECs</li> <li>Actively monitor approved research</li> </ul>
<i>Governance</i>	<ul style="list-style-type: none"> <li>Set up a board of trustees or community advisory boards with representation from all stakeholders</li> </ul>

<sup>654</sup> Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10(3)**: 264-77. See also: Bull S, Cheah PY, Denny S *et al.* (2015) Best practices for ethical sharing of individual-level health research data from low- and middle-income settings *Journal of Empirical Research on Human Research Ethics* **10(3)**: 302-13.

<sup>655</sup> Tindana P, Molyneux S, Bull S *et al.* (2019) 'It is an entrustment': broad consent for genomic research and biobanks in sub-Saharan Africa *Developing World Bioethics* **19(1)**: 9-17.

<sup>656</sup> *ibid.*, table 2.

**Implications for emergencies**

- 9.16 While the issues raised with us on sharing data and/or samples in emergencies correlate closely with those reported in the wider literature on sharing data and samples in low-income settings, the features of emergencies, and in particular the issue of lack of time, create significant logistical constraints for how those issues can be handled (see paragraphs 9.6–9.7). We were told for example that, in practice, when samples are obtained in epidemics for diagnostic purposes, consent is rarely sought for other uses at the time.<sup>657</sup> Moreover, even in cases where consent processes do make reference to future possible uses of data and/or samples, the amount of ‘moral work’ such contemporaneous consent could achieve might be very limited (see paragraphs 4.24–4.27 and 7.6–7.8). It seems unlikely that possible future uses of data or samples would be an important focus for people in emergencies who are seeking urgent care and treatment (including hoping to access experimental therapies). While such an awareness does not absolve researchers from providing information as clearly as possible (see paragraphs 7.14–7.16), it highlights the importance of other parts of the ethics ecosystem, in particular the role of community engagement and the creation of trustworthy relationships alongside systems that are recognised as having legitimacy. As we have discussed above, any use of broad consent models inherently entails considerations of effective governance and legitimacy, as people are being asked to consent to a *process* by which future use will be determined.
- 9.17 Models such as the ‘entrustment’ model for sharing samples described in Box 9.5 develop as a result of collaborative work over many years, and cannot be created from scratch during an emergency. In particular, creating the infrastructure associated with such a model, such as the creation of biobanks at national or regional level, is a long-term project. However, nor can the values and interests that underpin that model be ignored, even at the acute phase of an emergency. The failure to operate in ways that are acceptable to local communities can destroy trust and undermine the scope for future collaborations and the possibility of benefit for communities affected by emergencies.<sup>658</sup> The export of samples relating to people with Ebola from West Africa to the US and Europe continues to generate strong feelings, as witnessed, for example in the language of ‘biopirataje’.<sup>659</sup>
- 9.18 While these concerns about sharing samples in ways that are *not* perceived as legitimate, and in particular the physical export of material out of the country, relate specifically to samples, parallel issues were raised with us with reference to data.<sup>660</sup> These included fears about the risks of data being misused by people acting in bad faith (illustrating the importance of secure storage and access arrangements), as well as anxiety about how data, if shared with researchers lacking cultural sensitivity and knowledge, might be used to stigmatise individuals and whole communities (see

<sup>657</sup> On-the-ground roundtable, 25 June 2018.

<sup>658</sup> See, for example, Georgetown University Center for Global Health Science and Security (2018) *Data sharing during the West Africa Ebola public health emergency; case study report*, available at: <http://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-during-west-africa-ebola-public-health-emergency-case-study-report-georgetown.pdf>.

<sup>659</sup> Le Monde (22 January 2019) *Où sont les échantillons sanguins infectés par Ebola?*, available at: [https://www.lemonde.fr/afrrique/article/2019/01/22/ebola-l-utilisation-opaque-des-echantillons-sanguins\\_5412571\\_3212.html](https://www.lemonde.fr/afrrique/article/2019/01/22/ebola-l-utilisation-opaque-des-echantillons-sanguins_5412571_3212.html). See also: The Telegraph (6 February 2019) *Ebola's lost blood: row over samples flown out of Africa as 'big pharma' set to cash in*, available at: <https://www.telegraph.co.uk/news/0/ebolas-lost-blood-row-samples-flown-africa-big-pharma-set-cash/>. Discussion at the Global Forum on Bioethics in Research in November 2018 revealed that this issue remained controversial.

<sup>660</sup> Data and samples roundtable, 3 December 2018.



paragraph 9.5).<sup>661</sup> While these fears may not necessarily be borne out in practice,<sup>662</sup> they remain a genuine concern, and reinforce the instrumental and intrinsic importance of involving those affected in making decisions about what constitutes the appropriate use of data and the necessary safeguards.

## Achieving equitable and responsible sharing in emergencies

### *Preparing for future response*

9.19 We suggested above (see paragraph 9.7) that a constructive way forward in what remains a contested debate was to explore the conditions needed to support equitable and responsible sharing – recognising that these may look quite different in different contexts, and may potentially differ between data and samples in the same context. In considering the role of individuals and communities in decisions about the future use of their data and/or their samples in emergencies, we draw on the central importance of equal respect, and the role such respect plays in underpinning trustworthiness, particularly in contexts where those who are being asked to provide such data and/or samples feel relatively powerless (see paragraphs 4.38–4.39).

9.20 Questions of the future research uses of data and samples also bring in the relevance of human values and emotions (see paragraph 4.51). Consent for the use of data for primary research uses, for example, is sought and given in the context of a direct human relationship, while secondary uses inevitably break that chain.<sup>663</sup> One of the questions to consider, therefore, is what systems might be put in place in the context of wider sharing to do equivalent ‘moral work’ to the moral value implicit in the trusting and trustworthy human relationships that should underpin the seeking of consent for primary uses. Just as we argued that invitations to take part in research must be justifiable as fair (see paragraph 7.9), **research teams must be able to justify to communities affected by emergencies that proposals for future uses of data and samples are fair.**

9.21 **We suggest below a number of features that will play an important role in creating trustworthy systems in emergencies and beyond.** We recognise that these systems will need to develop over time, often starting from limited beginnings, and to be effective will rely on preparatory work that is only just beginning now, or may not yet have started. Work on these issues should therefore be prioritised by research leaders at local, national, and regional level, and supported by funders, as a crucial part of the ‘emergency preparedness’ agenda. At paragraph 9.24 we return to the situation of researchers working in emergencies where there is little or no such preparatory work to draw upon. Here, we highlight the importance of:

- **Consideration of what a locally and culturally appropriate consent process would look like**, taking into account what is legally permissible within the relevant jurisdiction, and also what is permissible with respect to the data and samples of those who do not survive. Existing empirical research (see paragraphs 9.12–9.15) on attitudes to consent for future use of data and samples in a number of different contexts and countries provides a valuable starting point. However, much more such research is

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<sup>661</sup> It should be noted that there appears to be little clear evidence to date of such harm eventuating (see, for example, Pisani E, Aaby P, Breugelmanns JG *et al.* (2016) Beyond open data: realising the health benefits of sharing data *BMJ* **355**: i5295), although this does not mean that the expressed fears should be underplayed.

<sup>662</sup> See, for example, Abramowitz S, Giles-Vernick T, Webb J *et al.* (2018) *Data sharing in public health emergencies: anthropological and historical perspectives on data sharing during the 2014-2016 Ebola epidemic and the 2016 yellow fever epidemic*, available at: <http://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-in-public-health-emergencies-yellow-fever-and-ebola.pdf>, at page 29.

<sup>663</sup> Roundtable on data, 3 December 2018.



needed, including research drawing directly on the knowledge of communities who have lived through past emergencies. **Transparency as to those circumstances in which consent is *not* necessary for the use of patient-level data, for public health reasons, is essential** (see Box 9.3 above). Legal clarity about what is permissible in particular jurisdictions is also an important aspect of emergency preparedness, and many countries do not yet have clear legislation that explicitly makes reference to data-sharing.<sup>664</sup>

- Consideration of **which governance arrangements would generate well-founded trust in the appropriate future use of data and samples once donated**. Such arrangements might include the establishment of an access committee with clear criteria to be met before data or samples could be released. They might also, appropriately, differ for samples and for data, with a focus on how requests to access samples might be prioritised, given they are a resource subject to depletion. A further important aspect of trustworthy governance is found in **transparency, clear lines of communication, and commitment to sharing information about research findings**. Those who agree to donate samples or data for future research uses should be able to find out if they wish, in general terms, about any resulting research: for example through channels established to share research findings back to the communities who have directly or indirectly contributed to that research.<sup>665</sup>
- **Local input, achieved in ways that support legitimacy**, in exploring possible approaches to the future uses of any data and samples that may be obtained during research. This is in addition to the role of ethics committees in scrutinising research proposals – particularly where committees might be perceived as remote from those immediately affected. Wherever possible, researchers should aim to develop proposals for consent for data- and sample-sharing that are based on community input as part of the wider community engagement processes discussed in Chapter 5. The empirical research cited earlier (paragraphs 9.12–9.15) emphasises the importance of further research on developing effective and efficient methods for involving communities in these policy decisions.<sup>666</sup>

9.22 National and regional research leaders have an essential part to play in supporting the background work needed to inform the development of inclusive and accountable systems in response to the needs of an emergency. The work of H3Africa,<sup>667</sup> for example, has provided an important baseline of understanding of attitudes to genomic research across Africa. We welcome this, and other regional initiatives such as the project launched in 2019 by the African Academy of Sciences (AAS) to develop the

<sup>664</sup> See, for example, de Vries J, Munung SN, Matimba A *et al.* (2017) Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries *BMC Medical Ethics* **18**(1): 8 who identified just three countries out of these 22 (Cameroon, Ethiopia, and Tanzania) as having explicit legislation at the time of their research.

<sup>665</sup> See, for example, Tindana P, and de Vries J (2016) Broad consent for genomic research and biobanking: perspectives from low- and middle-income countries *Annual Review of Genomics and Human Genetics* **17**(1): 375-93; and Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10**(3): 264-77, whose findings illustrate the strength of interest in such feedback.

<sup>666</sup> See, in particular, Jao I, Kombe F, Mwalukore S *et al.* (2015) Involving research stakeholders in developing policy on sharing public health research data in Kenya: views on fair process for informed consent, access oversight, and community engagement *Journal of Empirical Research on Human Research Ethics* **10**(3): 264-77. See also: Merson L, Phong TV, Nhan LNT *et al.* (2015) Trust, respect, and reciprocity: informing culturally appropriate data-sharing practice in Vietnam *Journal of Empirical Research on Human Research Ethics* **10**(3): 251-63.

<sup>667</sup> H3Africa (2019) *About: vision*, available at: <https://h3africa.org/index.php/about/vision/>.

continent's first cross-disciplinary guidelines for collecting, storing, and sharing data and samples.<sup>668</sup>

**Recommendation 17 (directed to funders, national and regional research leaders, national governments and all levels of the WHO)**

**We recommend that funders and leading research institutions should prioritise further research, in different parts of the world, on stakeholders' views as to what consent and governance mechanisms would create sustainable trust and confidence in the sharing of data and samples for future research use. This evidence should then inform the development of guidance, such as that being developed by the African Academy of Sciences. National governments and intergovernmental agencies should actively support such initiatives as an essential part of emergency planning.**

9.23 For the retention and future research use of samples, the development of laboratory capacity both nationally and (for more specialist facilities designed for safe management of deadly pathogens) at regional level, will play an important role in supporting national and regional scientific capacity, and in alleviating specific concerns about the export of samples out of a country or continent. Significant current initiatives in this field include the development of laboratory capacity across a number of countries in Africa as a key component of the African coalition for Epidemic Research, Response and Training (ALERT) and PANDORA-ID-NET clinical research collaborations (see Box 3.9 in Chapter 3, and Box 9.6); the laboratory network developed as part of Zika Preparedness Latin America Network (ZikaPLAN – see Box 9.7); the establishment of the first African start-up biobank;<sup>669</sup> and work on alternative and sustainable approaches to laboratory biosafety supported by Chatham House (see Box 9.6).

**Box 9.6: Supporting laboratory capacity**

**Building laboratory capacity: the work of PanACEA and PANDORA-ID-NET**

Laboratories to support the diagnosis of infectious diseases are complex environments requiring specialist equipment. They are designed to protect the safety of the laboratory worker and the wider community. Whilst physical infrastructure is important, the expertise and professional standards of workers are critical to the safe operation of the facility and delivery of robust and reliable diagnostic data. Two European and Developing Countries Clinical Trials Partnership (EDCTP) funded research networks, Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA) and PANDORA-ID-NET that aim to strengthen and support infectious disease research capacity in Africa include significant laboratory elements, involving:

- 'cradle to grave' laboratory development;
- initial site evaluation – physical infrastructure and team competence;
- definition of requirements and support for resolution of issues – technical advice, training, and documentation;
- site initiation – training on project specific protocols;
- project monitoring – quality assurance against protocols, and training and guidance in response to issues raised; and
- project closure – quality assurance, review of data, and resolution of data issues.

<sup>668</sup> Nature (18 June 2019) *Africa's science academy leads push for ethical data use*, available at: <https://www.nature.com/articles/d41586-019-01894-0>.

<sup>669</sup> Adepoju P (2019) Africa's first biobank start-up receives seed funding *The Lancet* **394(10193)**: 108.

The development of a professional and expert scientific community is a fundamental part of sustainable capacity:

- Professional networks are essential and are developed through shared activities, both scientific projects and training activities.
- Scientific expertise is developed through undergraduate, postgraduate and research-based programmes, increasingly using local rather than HIC universities, with support from the latter through mentoring and supervision as necessary.

PanACEA is in its second round of funding, moving to African leadership through shared formal decision-making committees. The expectation is that the third wave of the initiative, PanACEA3, will be led by an African principal investigator. PANDORA-ID-NET has been led from the beginning from the Republic of the Congo (DRC) with senior partners from UK and Italy supporting the PI.<sup>670</sup>

### **Sustainable Laboratories Initiative**

This Chatham House initiative aims to support an alternative approach to laboratory biosafety and biosecurity for high-consequence pathogens in Africa. While sophisticated laboratories, using standards and templates applied in HICs, have been developed on the continent as part of global health security initiatives, it can be difficult to sustain these facilities, particularly when financial support from donors is time limited. This initiative takes a different approach based on local risk assessment, so that laboratories are tailored to local risks and resources available, in both the short and longer term, without compromising biosafety and biosecurity. It includes three strands of work: developing a prior-assessment tool to help ensure sustainability of any ensuing laboratory; testing core specifications in the WHO Laboratory Biosafety Manual against sustainability criteria; and investigating the feasibility of a regional training hub for sustainable laboratories in Africa.<sup>671</sup>

## ***Responding in the absence of emergency preparation***

9.24 While the initiatives described above are examples of important progress in developing collaborative and locally-owned approaches to the sharing of data and samples for future research use, there will still be many circumstances where scope for data and/or sample sharing arise (with potential for contemporary as well as future benefit), but where no groundwork exists to support researchers. In such circumstances, there will be a need for the **development of adaptive approaches recognised as having local legitimacy, and that are committed to developing, over time, fair processes and mutually respectful relationships between stakeholders**. One possible approach would be for nationally respected bodies such as national research ethics committees (NRECs) to have the discretion to approve a staged approach to consent for the future use of data and/or samples. This might involve the retention of data and samples collected for a person's treatment (whether within the context of interventional research or in non-research contexts) until it is feasible to establish a legitimate process. While the timeliness of such a process will depend on many structural and political factors, the likelihood of people in the current emergency being able to benefit from any associated

<sup>670</sup> Personal communication, Professor Timothy D McHugh, Professor of Medical Microbiology and Director, UCL Centre for Clinical Microbiology (22 November 2019). See also: PanACEA (2019) *Homepage*, available at: <http://panacea-tb.net/>; and PANDORA-ID-NET (2019) *Homepage*, available at: <https://www.pandora-id.net/>.

<sup>671</sup> Chatham House (2019) *The Sustainable Laboratories Initiative*, available at: <https://www.chathamhouse.org/about/structure/global-health-security/sustainable-laboratories-initiative>.

research will be increased by firm local commitments to develop acceptable processes promptly.

- 9.25 Such an approach is already used in some jurisdictions in the context of treatment in acute illness: for example including an additional step of confirming consent for future research use of clinical data and samples at a time when the patient has stabilised, rather than seeking to have complex discussions when they are acutely ill and first accessing treatment.<sup>672</sup> The feasibility of a two-stage approach in an emergency setting would be strongly dependent on the extent of trust between researchers and key leaders and influencers in affected communities, and relationships developed at the start of the research process (see Chapter 5). **It will also be important to distinguish the holding of data and/or of samples under these arrangements from circumstances in which people will have no choice about their data being used** (for example, for essential public health purposes as described in Box 9.3).
- 9.26 The acceptability of proposals of this kind, or any other planned approaches to future use of data and/or samples, should be subject to scrutiny as part of the routine (if flexible and expedited (see paragraph 6.36)) ethics review of research proposals. We endorse the recommendation of the expert panel convened in 2018 by the WHO ethics team and the ALERRT network, that data and sample sharing plans could similarly be subject to a two-step ethical review stage, with committees expecting to see outline proposals at the point when studies are approved, with the requirement that a full plan be submitted within an agreed period.<sup>673</sup>
- 9.27 Finally, we turn to the sensitive question of ‘legacy’ or archive samples taken and stored in past emergencies where the scope of any consent given is not clear. Such samples may represent a highly valuable (in some cases very rare or even unique) resource with scope to contribute to important developments in understanding and treatment, particularly of rare or novel pathogens. Making responsible use of such samples is strongly supported by the emphasis in our ethical compass of helping reduce suffering. However, such potential benefits can never entirely ‘trump’ the other two elements of our compass: equal respect and fairness (see paragraph 4.73).
- 9.28 In parallel to the two-stage approach suggested above for consent during an emergency itself, we suggest that one respectful way forward regarding the use of contested holdings of samples would be to initiate community-level discussions, alongside other key stakeholders including local health services and research institutions, national research institutions, the NREC, and the Ministry of Health, to devise an agreed approach to future use, including the type of governance and fair access arrangements discussed above (see paragraph 9.21). In the UK context, we note a parallel approach in current proposals to undertake widespread public consultation on the use of the ‘Guthrie card’ archive of new-born blood samples from Scotland for research purposes – recognising the significant research value of the archive and the fact that parents were not at the time asked for consent for these samples to be retained, whether for research

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<sup>672</sup> See, for example, the approach used in the MalariaGEN study in seeking consent from the parents of children acutely ill with malaria for future use of data and samples in genomic research: Tindana P, Bull S, Amenga-Etego L *et al.* (2012) Seeking consent to genetic and genomic research in a rural Ghanaian setting: a qualitative study of the MalariaGEN experience *BMC Medical Ethics* **13**(1): 15.

<sup>673</sup> ALERRT (2018) “Ethics preparedness”: *facilitating ethics review during outbreaks - recommendations arising from a joint ALERRT & WHO workshop*, available at: [https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt\\_workshop\\_recommendations\\_final\\_30may18\\_0.pdf](https://www.alerrt.global/sites/www.alerrt.org/files/2018-06/alerrt_workshop_recommendations_final_30may18_0.pdf); and Saxena A, Horby P, Amuasi J *et al.* (2019) Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel *BMC Medical Ethics* **20**(1): 29, recommendations 5a and 5b.

or any other purposes.<sup>674</sup> Transparency about where and how samples are being held will be particularly important for any future trust.

### **Recommendation 18 (directed to research institutions holding ‘legacy’ or archive samples, and to the WHO)**

**We recommend that all research institutions currently holding substantial sample collections share this information on an inventory (to be held by a body such as the WHO or a regional Centre for Disease Control). Where the scope of the consent provided is unclear, they should commit to discussions with relevant national governments, national and regional research leaders, and community representatives such as survivor organisations, about what form fair and respectful future use of these samples might take.**

### **Recommendation 19 (directed to funders, governments and other regulators, and WHO)**

**We recommend that, in the future, any international research collaborations that intend to collect and store samples prospectively for future research use, should be required to register that collection (including information, for example, about the relevant disease, the number of samples, and the location of the biorepository) in a publicly available database.**

## **Facilitating the wider use of data and samples**

9.29 Even where the conditions for ethical sharing of data and/or samples have been achieved through culturally appropriate consent and governance processes, further challenges (both ethical and logistical) may arise with respect to facilitating access to these resources by other researchers. Barriers to sharing either data or samples during (and in the aftermath of) global health emergencies identified to us include:<sup>675</sup>

- **Concerns about the quality of one’s own data**, making people reluctant to share the data they have collected for fear of being exposed, particularly in the absence of institutional data-sharing policies that protect the institution’s interests as well as those of other prospective users and give assurance to the institution’s members.<sup>676</sup>
- **Holding on to data or to samples because this is perceived to be the only form of control a researcher may have.** Such perceptions may arise, for example, where researchers in low- or middle-income environments have few opportunities to conduct their own research, to gain credit for their work or for career development. Researchers working in less well-resourced settings may need a relatively long time to prepare articles for publication because of lack of research support and/or competing pressures and expectations. In the context of non-emergency research, there have

<sup>674</sup> Nuffield Council on Bioethics (24 June 2019) *Blog: what should be done with the Guthrie cards?*, available at: <http://nuffieldbioethics.org/blog/what-should-be-done-with-the-guthrie-cards>.

<sup>675</sup> Global Forum on Bioethics in Research, Stellenbosch, 15 November 2018; Roundtable on sharing data and samples in emergencies, 3 December 2018; and Nuffield Council on Bioethics (2020) *Research in global health emergencies: call for evidence analysis*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.

<sup>676</sup> Waithira N, Mutinda B, and Cheah PY (2019) Data management and sharing policy: the first step towards promoting data sharing *BMC Medicine* 17(1): 80.



been initiatives to protect researchers working in low-income settings – for example through publication embargos, which grant investigators exclusive rights to publish analyses of their datasets for a set period after these have been made available on platforms, before others may publish.<sup>677</sup> In emergencies, however, such an approach – if not carefully managed through appropriate pre-publication sharing with those responsible for public health response – could present serious opportunity costs with regard to findings that might contribute more immediately to care for affected populations.

- **Data being shared but not in any useable form:** for example because of the lack of the necessary metadata, or the cost of the curation involved in standardising datasets for repositories.<sup>678</sup> Parallel issues may arise in the absence of standard operating procedures for sample collection.
- **Limited commitment to research by some governments:** many collaborations are established between institutions rather than governments. Lack of government interest and support may make sharing either data or samples very difficult, particularly in the context of concern about samples leaving the country.

9.30 A substantial number of recent initiatives have set out to identify, promote, and support good practices in data sharing, both in general and specifically in emergencies (less so for samples, at least in the public domain). These include ‘roadmaps’ and tools; publishing initiatives to encourage the early sharing of data without researchers being penalised regarding subsequent journal publication; and the development of platforms to host (and in some cases help curate) data and facilitate access to samples. An overview of a selection of these is given in Box 9.7.

### Box 9.7: Examples of initiatives to facilitate ethical sharing of data in emergencies

#### Practical ‘roadmaps’ providing guidance, tools, and model materials for sharing data

- The Chatham House *Guide to sharing the data and benefits of public health surveillance* sets out seven key principles that should be taken into account when considering the need to share public health surveillance data and includes a model data-sharing agreement.<sup>679</sup>
- The EDCTP *Data-sharing toolkit* includes data management basics, data-sharing steps, a repository finder, and an extensive collection of resources.<sup>680</sup>
- Technical guidance and standards developed to support the effective reuse of datasets include: the *FAIR data principles* (findable, accessible, interoperable and reusable),<sup>681</sup> and associated practical guidance by organisations such as fairsharing.org which provides a curated resource on data and metadata standards.<sup>682</sup>
- The Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) *Roadmap for data sharing in public health emergencies* makes practical

<sup>677</sup> See, for example, the draft policy of H3Africa on data sharing, access, and release, published in 2019 (not available online).

<sup>678</sup> Alter G, and Gonzalez R (2018) Responsible practices for data sharing *The American Psychologist* **73**(2): 146-56.

<sup>679</sup> Chatham House (2017) *A guide to sharing the data and benefits of public health surveillance*, available at: <https://datasharing.chathamhouse.org/>.

<sup>680</sup> EDCTP Knowledge Hub (2019) *Data sharing toolkit*, available at: <https://edctpknowledgehub.tghn.org/data-sharing-toolkit/>.

<sup>681</sup> Go FAIR (2016) *FAIR principles*, available at: <https://www.go-fair.org/fair-principles/>.

<sup>682</sup> See also: Sansone S-A, McQuilton P, Rocca-Serra P *et al.* (2019) FAIRsharing as a community approach to standards, repositories and policies *Nature Biotechnology* **37**(4): 358-67; and Nature Index (11 February 2019) “A love letter to your future self”: what scientists need to know about FAIR data, available at: <https://www.natureindex.com/news-blog/what-scientists-need-to-know-about-fair-data>.

recommendations to funders to facilitate data sharing, both at strategic level (for example, in collaborating to influence key stakeholders such as national governments and the commercial sector) and through funders' own policies and requirements for their grantees.<sup>683</sup> The GLOPID-R data-sharing group has also published six case studies exploring common barriers and enablers in data sharing in past outbreaks, drawing on published literature and stakeholder interviews.<sup>684</sup> Its analysis of these case studies emphasises how most such barriers and enablers are common to different outbreak scenarios (including known and novel pathogens, with and without available interventions), suggesting scope for solutions with global impact.

### Publishing initiatives

- As part of a 2015 initiative by WHO to facilitate effective sharing of research data and results during 'public health emergencies of global significance', the British Medical Journal, the Nature journals, the New England Journal of Medicine, and the seven PLoS journals endorsed a consensus statement that journals should not penalise authors for sharing data in advance of publication "in the interest of resolving an urgent situation, for example with public health authorities or more broadly when warranted."<sup>685</sup>
- A larger group of journals signed up to a subsequent statement during the Zika outbreak in 2016, confirming that unrestricted dissemination of findings by researchers ahead of submission would not pre-empt publication, and that all content regarding the Zika virus would be made free to access.<sup>686</sup> In 2018, Wellcome called upon the signatories of the 2016 statement to adopt the same approach in the context of the Ebola outbreak in the DRC, although at that time this had not been designated by the WHO as a public health emergency of international concern.<sup>687</sup>

### Examples of platforms to promote wider use of data and of samples

- The ***Infectious Diseases Data Observatory*** (IDDO) is a data-sharing platform that aims to act as the central repository for evidence of optimal management and treatment efficacy for selected infectious diseases (building on the work of the WorldWide Antimalarial Resistance Network (WWARN) with its specific focus on malaria). Its remit, in addition to acting as a data repository, includes undertaking collaborative data analysis to address priority questions in infectious diseases research, sharing best practices on data capture and management, and developing policies for fair conditions of use and appropriate recognition of data contributors.<sup>688</sup>
- ***ZikaPLAN***, which brings together 25 leading research and public health organisations in Latin America, North America, Africa, Asia and Europe to tackle Zika virus disease, has built a collaborative platform to develop, validate, and evaluate tools, including point of care tests for diagnosis, surveillance, and research for Zika virus disease. This

<sup>683</sup> GloPID-R (2019) *Roadmap to data sharing in public health emergencies*, available at: <https://www.glopid-r.org/wp-content/uploads/2019/06/glopid-r-roadmap-for-data-sharing.pdf>.

<sup>684</sup> GloPID-R (2018) *Data sharing in public health emergencies: learning from past outbreaks*, available at: <https://www.glopid-r.org/wp-content/uploads/2017/02/data-sharing-in-public-health-emergencies-case-studies-workshop-reportv2.pdf>.

<sup>685</sup> WHO (2015) *Developing global norms for sharing data and results during public health emergencies*, available at: [http://www.who.int/medicines/ebola-treatment/blueprint\\_phe\\_data-share-results/en/](http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/); and Modjarrad K, Moorthy VS, Millett P *et al.* (2016) Developing global norms for sharing data and results during public health emergencies *PLoS Medicine* **13**(1): e1001935.

<sup>686</sup> Wellcome (2016) *Statement on data sharing in public health emergencies*, available at: <https://wellcome.ac.uk/what-we-do/our-work/statement-data-sharing-public-health-emergencies>.

<sup>687</sup> Wellcome (2018) *Sharing research findings and data relevant to the Ebola outbreak in the Democratic Republic of Congo*, available at: <https://wellcome.ac.uk/what-we-do/our-work/sharing-research-findings-and-data-relevant-ebola-outbreak-drc>.

<sup>688</sup> IDDO (2018) *About IDDO*, available at: <https://www.iddo.org/about-us/about-iddo>.

has included setting up a global biobank of specimens, alongside a network of laboratory and clinical sites.<sup>689</sup>

- Platforms to encourage and support the sharing of social science data in response to emergencies include the **Social Science in Humanitarian Action** platform<sup>690</sup> (building on the earlier time-limited Ebola Response Anthropology Platform<sup>691</sup>); and the **Lassa fever resources** online repository led by the Nigeria Centre for Disease Control, Durham University, and the Robert Koch Institut.<sup>692</sup>

9.31 The trend both towards open (free) access for published research findings, and ‘open data’ policies on the part of funders, regulators, and/or journals are also an important part of the research policy landscape (see Box 9.8). While these requirements are increasingly playing an important part in changing embedded assumptions about access to research resources, they are not uncontroversial, and policies vary between mandating and simply encouraging open data. The International Development Research Centre (IDRC), for example, has reported its decision to ‘go slow’ on mandatory open data, highlighting important capacity questions, including the support (financial and other) needed to ensure that grantees are able to comply, while emphasising the need for informed dialogue to improve privacy protections.<sup>693</sup> Particular concerns have been expressed with reference to qualitative datasets, for example those based on very personal one-to-one interviews.<sup>694</sup>

### Box 9.8: Open access and open data

#### Open access

The aim of open access publishing policies is to ensure that anyone, without the need for a journal subscription, can access research findings: whether through individual articles in a subscription journal being freely available online, or entire journals or platforms being available without user charges. As part of the shift towards full open access, Wellcome and the Bill & Melinda Gates Foundation, for example, have launched their own publishing platforms to enable their grantees to share results rapidly,<sup>695</sup> while an increasing number of funding bodies are signing up to ‘Plan S’, under which: “with effect from 2021, all scholarly publications on the results from research funded by public or private grants provided by national, regional and international research councils and funding bodies, must be published in Open Access Journals, on Open Access Platforms, or made immediately available through Open Access Repositories without embargo.”<sup>696</sup>

#### Examples of open data policies

<sup>689</sup> ZikaPLAN (2019) *Platform for diagnostics innovation and evaluation*, available at: <https://zikaplan.tghn.org/zikaplan-at-work/diagnostics-innovation-and-evaluation/>; and Wilder-Smith A, Preet R, Brickley EB *et al.* (2019) ZikaPLAN: addressing the knowledge gaps and working towards a research preparedness network in the Americas *Global Health Action* **12(1)**: 1666566.

<sup>690</sup> Social Science in Humanitarian Action (2019) *Homepage*, available at: <https://www.socialscienceinaction.org/>.

<sup>691</sup> Ebola Response Anthropology Platform (2019) *Homepage*, available at: <http://www.ebola-anthropology.net/>. See also: Sonar Global (2019) *Mapping social sciences research for the Ebola response in DRC and neighboring countries*, available at: <http://sonar-global.eu/mapping-social-sciences-research-for-the-ebola-response-in-drc-and-neighboring-countries/>.

<sup>692</sup> Lassa Fever Resources (2019) *About*, available at: <https://lassafever.info/about>.

<sup>693</sup> SciDev.net (20 February 2019) *Why the IDRC won't rush its open data policy*, available at: <https://www.scidev.net/global/data/opinion/why-the-idrc-won-t-rush-its-open-data-policy.html>.

<sup>694</sup> See, for example, Krystali R (2019) *Negotiating data management with the National Science Foundation: transparency and ethics in research relationships*, available at: [https://connect.apsanet.org/interpretation/wp-content/uploads/sites/60/2015/10/Krystalli-NSF-Data-Sharing-Memo\\_ForPosting\\_March2019.pdf](https://connect.apsanet.org/interpretation/wp-content/uploads/sites/60/2015/10/Krystalli-NSF-Data-Sharing-Memo_ForPosting_March2019.pdf).

<sup>695</sup> Wellcome (5 November 2018) *Wellcome and the Bill & Melinda Gates Foundation join the Open Access coalition*, available at: <https://wellcome.ac.uk/press-release/wellcome-and-bill-melinda-gates-foundation-join-open-access-coalition>.

<sup>696</sup> cOAllition S (2019) *Homepage*, available at: <https://www.coalition-s.org/>. See also: Dyer O (2019) Academic publishers urge Trump not to demand open access for federally funded research *BMJ* **367**: l7064.

- Mandatory open data policies require researchers (for example as a requirement of funding or publication) to deposit the datasets underpinning their research findings in open-access repositories. Several research funders now require their grantees to comply with such policies, subject to restrictions related to safeguarding participants' privacy or in connection with intellectual property.<sup>697</sup>
- The International Committee of Medical Journal Editors has issued a statement that, in order for results to be published in their journals, clinical trials must (from January 2019) include a data-sharing policy in their trial registration. While the policy does not yet mandate open data sharing, editors may take these data-sharing statements into consideration when making editorial decisions.<sup>698</sup>
- In 2016, the European Medicines Agency (EMA) introduced a policy of publishing the clinical data supplied by pharmaceutical companies when they seek marketing authorisations for new pharmaceutical products.<sup>699</sup> The EMA policy aims to foster transparency and trust in its decision-making process as well as promoting use of scientific knowledge for future research. The policy was revised in March 2019, and includes publishing clinical data overview and summary information, as well as clinical study reports submitted by companies, but requires strict data anonymisation procedures in order to comply with personal data protection laws.<sup>700</sup>

9.32 The various initiatives outlined above, among others, are making progress in tackling many of the professional and institutional barriers to sharing data and samples (see paragraph 9.29), and in providing important support in making such sharing a practical reality. However, in the context of data, a further important ethical question arises in connection with the effective future use of this shared information, and the justification for the significant time, effort, and cost required to make it available beyond the initial research use. A strong theme at the Global Forum on Bioethics in Research (GFBR) meeting in November 2018, and reiterated to the working group, was the extent to which stored and curated data are currently underused, both in general, and by researchers from LMICs in particular.<sup>701</sup> Funding streams supporting data sharing do not necessarily target this crucial aspect of promoting and facilitating the use of datasets once they have been made available, although there are some unfunded good practice examples (see Box 9.9). Research using secondary data may also be less valued and prestigious, and hence less likely to be embarked upon.

<sup>697</sup> See, for example, Wellcome (2017) *Data, software and materials management and sharing policy*, available at: <https://wellcome.ac.uk/funding/guidance/data-software-materials-management-and-sharing-policy>. Wellcome also explains its policy in: Wellcome (2017) *Our new policy on sharing research data: what it means for you*, available at: <https://wellcome.ac.uk/news/our-new-policy-sharing-research-data-what-it-means-you>. For an overview of policies across Europe, see: European Commission (2017) *Facts and figures for open research data: funders' policies*, available at: [https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/open-science/open-science-monitor/facts-and-figures-open-research-data\\_en#funderspolicies](https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/open-science/open-science-monitor/facts-and-figures-open-research-data_en#funderspolicies). See also: Science (2019) *Why NIH is beefing up its data sharing rules after 16 years*, available at: <https://www.sciencemag.org/news/2019/11/why-nih-beefing-its-data-sharing-rules-after-16-years>, on NIH's draft policy; and AstraZeneca (2019) *Disclosure commitment*, available at: <https://astrazenecagrouptrials.pharmacm.com/ST/submission/disclosure>, on Astra Zeneca's approach to sharing trial data via an access committee.

<sup>698</sup> Taichman DB, Sahni P, Pinborg A *et al.* (2017) Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors *Annals of Internal Medicine* **167**(1): 63-5.

<sup>699</sup> EMA (2016) *Clinical data publication*, available at: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication>; and EMA (2019) *Online access to clinical data for medicinal products for human use*, available at: <https://clinicaldata.ema.europa.eu/web/cdp/home>.

<sup>700</sup> EMA (2019) *European Medicines Agency policy on publication of clinical data for medicinal products for human use*, available at: [https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use\\_en.pdf](https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf), at page 4.

<sup>701</sup> See also: Cheah PY, and Day NPJ (2017) Data sharing: experience from a tropical medicine research unit *The Lancet* **390**(10103): 1642.

### Box 9.9: Example of WorldWide Antimalarial Resistance Network study groups

WWARN is a scientifically independent, global collaboration across the malaria research community. WWARN has aggregated historic malaria data and made it accessible for reuse, to generate new evidence that improves treatment regimens.

WWARN's approach to data reuse employs a collaborative 'study group' model, which operates as follows:

- Members of the malaria community identify a research question which requires the pooling of multiple datasets to reach statistical power.
- A systematic review is conducted to identify existing studies which collected data that can inform the research question.
- The investigators responsible for these studies are approached and invited to participate in the study group by sharing their individual patient data, planning, and executing the analysis and writing the manuscript.
- Those who accept send their data to the central WWARN repository, where data are cleaned and standardised. All investigators collaborate to develop a data analytical plan, ensuring that use of their data is appropriately integrated.
- The analysis is conducted either by WWARN or external partners and the results are published in a collective group including data contributors.<sup>702</sup>

### *Working group approach*

9.33 How, then, might our approach of focusing on the conditions for equitable and responsible sharing (see paragraph 9.7) help respond to the barriers and challenges experienced by research teams, in ways that complement the many existing developments summarised above? We suggest that:

- **Equitable sharing between researchers and research teams** requires systems that give researchers in LMICs the same opportunities as those in HICs to benefit both from the data and samples that they have acquired themselves, and from open 'sharing' arrangements. At the same time, fairness with respect to potential beneficiaries of that research (particularly those who are already disadvantaged, or who have already borne particular research risks) must be taken into consideration.
- **Responsible sharing** raises questions of researchers' responsibilities to those who have participated in the initial research (as discussed in the first part of this chapter); and of minimising waste and duplication of research effort. On the one hand, the aim of maximising research use through others' access to data and/or samples collected during emergencies is a key aim of data and sample sharing policies. On the other hand, these aims are not achieved in cases where data or samples are stored in repositories, but then rarely or never found or used. **In brief, data sharing and sample sharing must be seen as means, rather than goals in themselves.**

9.34 In non-emergency settings, or in the context of pre- or post-emergency research, the model developed by H3Africa offers a valuable example for how to move towards more equitable sharing over time. It ensures that local researchers have privileged access for a time-limited period to data and/or samples to compensate for additional challenges and

<sup>702</sup> See: Humphreys GS, Tinto H, and Barnes KI (2019) Strength in numbers: the WWARN case study of purpose-driven data sharing *The American Journal of Tropical Medicine and Hygiene* **100(1)**: 13-5; and personal communication, Philippe Guérin (13 November 2019).



constraints experienced in getting to publication.<sup>703</sup> Such an approach can help prioritise research that is most likely to benefit populations in the relevant country or region. It can also help develop the longer-term capacity of individual researchers and of institutions, thus contributing to the long-term institutional approaches to capacity development discussed in Chapter 8 (see paragraphs 8.25–8.34).<sup>704</sup> As part of our earlier discussion of fair partnerships, we have also endorsed the need for planned research collaborations to ensure early discussion of roles and responsibilities between team members, including opportunities for authorship and mentoring support where necessary (see paragraph 8.21).

- 9.35 However, where there is a case for data and/or samples to be shared urgently for public benefit during an emergency, the imperative to help reduce suffering may at times make such protections for local researchers temporarily unjustifiable. If, in any particular case, immediate public benefit is sufficient to justify moving away from these supportive approaches prioritising the interests of local researchers, at least during the acute phase of an emergency, then fairness requires that researchers who are potentially disadvantaged have the opportunity to be fairly recognised by other means. In addition to the longer-term aims to redress academic inequities described above, we suggest that it is essential for journals to explore innovative ways of ensuring that researchers in less well-resourced settings can be credited for their contributions, and for their expertise to be appropriately used (and credited) in later secondary analyses. Such involvement by original researchers and/or by researchers with expertise in the culture and context where the research was originally conducted would help to mitigate the risk of information being used, however inadvertently, in stigmatising ways (see paragraph 9.5). Allocation of a digital object identifier (DOI)<sup>705</sup> to a dataset could also provide a route for the creator of that dataset to be credited in any future reuse.<sup>706</sup>

#### Recommendation 20 (directed to journals and research institutions)

**We recommend that journals and research institutions explore innovative ways to recognise significant intellectual input into research findings short of direct involvement in writing: for example through more inclusive authorship criteria or other forms of recognising primary research contributors on a named basis. We further recommend consideration of publication policies that actively promote the inclusion of primary researchers in any later re-analysis of shared data and/or samples, and ensure that those working in LMICs can access research findings freely.**

- 9.36 The current limited use – particularly by researchers in LICs – of data made available through shared platforms, and the link between this and lack of funding incentives for such use, connects back to concerns about sustainable capacity development. We noted in Chapter 8 that initiatives to support capacity often focus on access to training and

<sup>703</sup> H3Africa draft policy on data sharing, access, and release: published in 2019 (not available online).

<sup>704</sup> Health research in conflict and complex environments, King's College London: 25 June 2019. Attendees at this conference, for example, raised the need for 15-20-year timescales, rather than four-year grants.

<sup>705</sup> See: DOI (2018) *Homepage*, available at: <https://www.doi.org/>; and Science (2020) *What is a DOI?*, available at: <https://www.sciencemag.org/site/misc/doi.xhtml>.

<sup>706</sup> See also: Smith R (2012) Let's simply scrap authorship and move to contributorship *BMJ* **344**: e157 for a view on 'contributorship' over 'authorship'. Note also examples within the existing system of authorship of how deceased researchers have been acknowledged as authors on papers in order to credit their earlier contributions: Reynolds MG, Wauquier N, Li Y *et al.* (2019) Human monkeypox in Sierra Leone after 44-year absence of reported cases *Emerging Infectious Diseases* **25(5)**: 1023-5.

other opportunities for individuals, and not on the longer-term sustainability of the institutions required to offer those individuals opportunities for jobs, research support, funded research time, or routes to academic recognition (see paragraph 8.28). Yet in the absence of such opportunities, the skills created through training and other forms of capacity building will not lead to the desired end of sustainable institutional research capacity.

- 9.37 Given these existing pressures on longer-term sustainability of academic capacity in LMICs, the current lack of structures and incentives in place to enable and promote the use of shared data is a particular challenge. Attendees at the 2018 GFBR, for example, argued that there was a need for concrete policies on the part of funders and research institutions to help shift resources (of all kinds) to where priority research needs arise, in a similar way to that achieved by H3Africa: including considerations of factors such as who should be the PI, who carries out the analysis, and where sample and data platforms are physically located.<sup>707</sup> Concerns about the longer-term funding of key data- and sample-sharing platforms also highlight the central importance of greater government commitment and ‘buy-in’ to the importance of such infrastructure as part of emergency preparedness (see paragraphs 3.5–3.10).

#### **Recommendation 21 (directed to funders)**

**We recommend that funders consider how they can take a more active role with respect to the future responsible use of data and samples, once these have been made more widely available. In addition to monitoring how their grantees meet any existing obligations to make data not only available but useable (for example through requiring compliance with the FAIR principles), this could include specific funding policies to support secondary analysis, building, for example on the model of the WWARN study groups.**

- 9.38 Finally, we consider the question of the wider dissemination and impact of initial study findings: sharing information gained during research with those directly concerned in order to promote uptake of relevant findings. We have reiterated the ethical importance of demonstrating respect to research participants, and to wider communities who have supported research, through finding appropriate means of sharing research findings at the end of a study (see paragraphs 7.14 and 9.2). We further emphasise here the need for funders, as part of their increasing concern with impact, to expect researchers to take positive action to make their findings accessible and available to key policy stakeholders such as local health services and ministries of health. There should be a particular focus on reaching those stakeholders who are unlikely to read academic papers regardless of open access arrangements.
- 9.39 For this focus on dissemination and uptake of research findings to be realised in practice, explicit funding for this aspect of research projects will be required. We support the example of the funding body Elrha, for example, who have included dissemination requirements – along with associated funding to support uptake activities – in grants made under their Research for Health in Humanitarian Crises (R2HC) programme.<sup>708</sup> A particularly important element of such dissemination includes sharing outcomes where an intervention has been shown *not* to be effective, in order to reduce the risk of wasted research effort and unnecessary participant burden if others explore the same question

<sup>707</sup> Global Forum on Bioethics in Research, Stellenbosch, 13-14 November 2018.

<sup>708</sup> Elrha (2018) *6th call for proposals: frequently asked questions*, available at: [https://www.elrha.org/wp-content/uploads/2017/06/R2HC-6thCall\\_FAQsMarch\\_18.pdf](https://www.elrha.org/wp-content/uploads/2017/06/R2HC-6thCall_FAQsMarch_18.pdf), at FAQ 29.

elsewhere. While there are clear requirements for such reporting for clinical trials,<sup>709</sup> these are not always followed,<sup>710</sup> and the principle is in any case equally applicable for much wider forms of research. Curated platforms that bring together both positive and negative findings in accessible forms for policy-makers (as with, for example, the Social Science in Humanitarian Action platform cited in Box 9.7) can play an invaluable role in ensuring research findings are genuinely accessible to those who could best act on them.

#### **Recommendation 22 (directed to funders)**

**We recommend that funders explore ways in which they can require, and support, their grantees to share their research findings in accessible and timely ways with key policy stakeholders. We further recommend that they consider ways in which they could help ensure findings, including negative findings, are publicly accessible in non-academic formats, for example through the development of shared platforms.**

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<sup>709</sup> WHO (2015) *WHO statement on public disclosure of clinical trial results*, available at:

<https://www.who.int/ictrp/results/reporting/en/> notes that the latest version of the Declaration of Helsinki states: "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." and that "Researchers have a duty to make publicly available the results of their research... Negative and inconclusive as well as positive results must be published or otherwise made publicly available".

<sup>710</sup> See, for example, All Trials (13 September 2018) *Half of European clinical trials haven't reported results*, available at: <http://www.alltrials.net/news/eu-ctr/>.



# Chapter 10

Practical ethical issues  
faced by front-line  
workers



## Chapter 10 – Practical ethical issues faced by front-line workers

### Chapter 10: overview

Those working on the front-line of research in global health emergencies – which may include those with professional health or other academic qualifications, research assistants, drivers, security personnel and volunteer healthcare workers – can face particularly challenging, often dangerous, working conditions. There is an increasing awareness of the need to support front-line workers better in dealing with ethical challenges that emerge during their involvement with a study, accompanying the recognition that ethical review cannot resolve all issues.

#### **Welfare and fair treatment of front-line workers**

The role of front-line workers may be inherently risky, and there can be a tension between respect for the welfare of research workers, and effective conduct of the planned research. **Funders, employers, and research ethics committees have a duty to consider the welfare of workers, alongside the welfare of participants and the value of the research, and to ensure action is taken to mitigate foreseeable risks.** Local knowledge will be crucial in recognising such risks, and in identifying how to prevent or mitigate them.

Differential terms of employment between local and international workers, or between different staff groups such as those with or without professional qualifications, can be exploitative, are a source of concern to many in the field, and may undermine scope for respectful collaboration. While equal respect underpins equality of treatment, how this is realised in practice is not straightforward, as in lower-income settings this creates other sources of inequality: paying all workers international rates, for example, could seriously undermine local health systems and economies.

**Employers should be completely transparent about the basis for any differential treatment of local and international workers.** They should have an inclusive approach – involving domestic ministries of health, for example – to determine relevant terms and conditions. For some aspects of employment, such as responsibility for personal security, it is hard to see how any differential treatment could be justified.

#### **Ethical support for front-line workers**

While careful review processes and collaborative work with local communities to understand local needs and sensitivities can play a part in reducing ethical dilemmas facing front-line workers, such dilemmas are still an inevitable part of working in an emergency. **Those on the front-line (who are often the least well-supported) need to have access to timely, high quality ethics support in a variety of forms. There is a particular need for a flexible platform to provide timely ethics advice and support for those involved in all aspects of research in emergencies, including those funding, planning, and carrying out research. The launch by the World Health Organization of the pilot Public Health Emergency Ethics Preparedness and Response (PHEEPR) Network is therefore welcome.**

## Introduction

- 10.1 The role of front-line workers in research – who directly interact with participants and wider communities, both through direct data collection and related facilitation – is often overlooked, and yet is critical. A number of the features of a global health emergency

may exacerbate the challenges these workers face, in particular disruption and time pressure to act, combined with the nature and degree of the risks of harm. The complex and changing situations faced by front-line research workers – potentially involving many different (at times unfamiliar) nationalities and organisations, competing lines of command, and varying standard operating procedures – often need to be managed and reconciled in real time. The risk of unclear lines of accountability, lack of support for paid and volunteer front-line research workers alike, and associated disparities of power and financial remuneration between national, international, and local workers, can increase tensions and decrease the morale of front-line research workers. For instance, in circumstances where the value of research in emergency contexts might not be recognised by all stakeholders, front-line research workers can find themselves stigmatised for being involved in research. They may also have to manage local-level misunderstandings. Whilst often the lowest paid in the research hierarchy, they can face greater demands for financial, medical, and emotional support than others in the research team. There are also important safeguarding issues experienced by front-line research workers who might find themselves in greater physical danger.<sup>711</sup>

- 10.2 The term ‘front-line workers’ involved in research in global health emergencies, as used here, includes a wide range of different people from different sectors who undertake a variety of roles, often including front-line humanitarian health professionals. While one definition of a ‘humanitarian health professional’ is an individual with a combination of skill-specific competencies such as those obtained through a degree held by nurses, doctors, psychologists, and pharmacists,<sup>712</sup> this group might also include those occupying other care roles, security personnel, drivers, and interpreters / facilitators. Some of these roles will be filled by volunteers, whether those volunteering to work unpaid, or existing workers agreeing to take on particular responsibilities in the light of the emergency facing them. In practice, such apparent choices to volunteer may be highly constrained: roles may be accepted in the hope of further (paid) employment or educational opportunities, for example, or as a result of pressure from others.<sup>713</sup>
- 10.3 Close cooperation from the beginning between research teams and those responsible for emergency response; and respectful and meaningful collaborations between research teams from high-income countries (HICs) and local research institutions are of central importance in global health emergencies (see Chapter 8). The success, or otherwise, of such arrangements may have direct impacts on how front-line research workers are treated: many challenges experienced by workers arise as a direct result of the different nationalities and organisations involved, multiple lines of command and, in turn, the different forms of responsibility which these generate. In the event of security concerns in a global health emergency, for example, international front-line research workers might be treated very differently from their local colleagues. This can create ethical tensions. Similarly, access to scarce medicines and medical facilities might vary, and undermine collaborative working goals and practices. Such differential treatment may also arise between different categories of locally employed worker, as well between

<sup>711</sup> Cronin-Furman K, and Lake M (2018) Ethics abroad: fieldwork in fragile and violent contexts *PS: Political Science & Politics* **51(3)**: 607-14; and UKCDR (2019) *Safeguarding in international development research: evidence review*, available at: [https://www.ukcdr.org.uk/wp-content/uploads/2019/06/20190603-UKCDR-Evidence-Review\\_updated.pdf](https://www.ukcdr.org.uk/wp-content/uploads/2019/06/20190603-UKCDR-Evidence-Review_updated.pdf).

<sup>712</sup> Burkle FM (2013) The limits to our capacity: reflections on resiliency, community engagement, and recovery in 21st-century crises *Disaster Medicine and Public Health Preparedness* **5(S2)**: S176-S81.

<sup>713</sup> See, for example, Kpanake L, Dounamou T, Sorum PC *et al.* (2019) What motivates individuals to volunteer in Ebola epidemic response? A structural approach in Guinea *Human Resources for Health* **17(1)**: 81.

local and international workers, and indeed between international workers from different countries.

### Box 10.1: Challenges faced by front-line workers

Examples of challenges faced by front-line workers, drawn to the working group's attention, include:

**Violence and physical threats:** researchers sought to gather data on children living with disabilities in Syria. However, the violent targeting of health services in Syria meant that it was difficult for the researchers to later identify the same children with more detailed follow-up surveys: the children, and their families, had often moved elsewhere within Syria, or to another country (e.g., Turkey).<sup>714</sup>

**Association with factions** in the country of operation may also raise challenges for front-line workers. For example, workers could face arrest if they interview people associated with terrorism in that country.<sup>715</sup> An anonymous respondent to our call for evidence also observed: "in [South Sudan], tribe plays a big factor. The most competent research assistant cannot work in an area where his tribe is not welcomed."

**Meeting needs:** front-line workers may also be faced with challenges about what they bring with them. Should they go empty-handed into a place that is in great need? Do they take food, and risk bias?<sup>716</sup> Or is it more important to address basic needs to gain trust?<sup>717</sup>

**Being a source of danger for participants:** for an international team of front-line workers involved in the 'Do No Harm' digital initiative in Myanmar to monitor conflict-related incidents and displacement, 'simply being there' raised challenges for stakeholders they were aiming to support. There was a significant security risk for the team (themselves monitored by Myanmar's military intelligence), raising issues for how they could safely hold confidential data about their participants in this context of conflict.<sup>718</sup>

**Emotional impact:** front-line workers focused on gender-based violence in Ethiopia indicate that they are changed through their work with affected people: "sometimes you cry with them".<sup>719</sup>

**Unfair or exploitative treatment, including travel restrictions:** a Syrian woman working in Lebanon as a community worker was invited to Europe to undertake a training course on sexual and gender-based violence (SGBV). On leaving an airport in Lebanon to fly to Europe, she was told that she would not be able to return to the country unless she paid \$400. The woman decided to leave for the training course, and subsequently her children are now living alone in a refugee camp in Lebanon.<sup>720</sup> More generally, in the event of security concerns international travel restrictions can mean that "whereas American and European academics are often able to mobilize foreign

<sup>714</sup> Discussions at Health research in conflict and complex environments conference, King's College London: 25 June 2019.

<sup>715</sup> Discussions at PRO-RES workshop on research ethics in disaster and conflict settings, Dublin City University: 16-17 May 2019.

<sup>716</sup> *ibid.*

<sup>717</sup> Kingori P (2013) Experiencing everyday ethics in context: frontline data collectors perspectives and practices of bioethics *Social Science & Medicine* **98**: 361-70.

<sup>718</sup> Presentation on Ethics and humanitarian innovation: different approaches and learning from humanitarian research: Post-Research Ethics Analysis (PREA) conference, Columbus, Ohio: 25-26 March 2019.

<sup>719</sup> Discussions at Post-Research Ethics Analysis (PREA) conference, Columbus, Ohio: 25-26 March 2019.

<sup>720</sup> Discussions at PRO-RES workshop on research ethics in disaster and conflict settings, Dublin City University: 16-17 May 2019.

passports or take advantage of humanitarian networks to evacuate rapidly if a security situation deteriorates, local interlocutors rarely can.<sup>721</sup>

The distinction between **different roles of front-line workers** may also raise challenges: “I was on the response side, and there were times that responders seemed suspicious of people who were primarily doing research”.<sup>722</sup>

**Financial issues:** front-line workers can be the last to be paid for their efforts as well as being the paid the least, or indeed sometimes never paid.<sup>723</sup> Restrictive university policies regarding bank or cash transfers may result in front-line researchers having to make otherwise unnecessary journeys into a conflict zone in order to visit an ATM.<sup>724</sup>

- 10.4 Front-line research workers frequently find themselves dealing with ethical dilemmas that emerge during their involvement with a study, partly arising out of challenges of the kind outlined above, and partly out of the inherent nature of the work itself. There is an increasing awareness that workers can experience moral distress because of unresolved ethical issues in emergency contexts;<sup>725</sup> and that prospective ethical review cannot and will not answer all issues. Workers from the diverse professions and roles described above may also bring with them different implicit or explicit ethical approaches (see paragraphs 4.3–4.6 and Appendix 4), and different priorities, expectations, and experiences.<sup>726</sup> These may become a source of tension between colleagues and for individuals who are fulfilling multiple roles. For example, a front-line research nurse in a global health emergency might be conflicted by the fact that the standard of general nursing care provided as part of a clinical trial was higher than could be offered outside the research context to other patients. While in this example, the role of nurse or researcher may be clearly defined within the research protocol, in practice, demarcations can become blurred and appear artificial to those affected by emergencies and in need of assistance.<sup>727</sup> Such a blurring of roles can be a source of ethical challenge for those seeking to conduct research procedures according to a strict protocol, especially if their work brings them face-to-face with acute needs that they are not in a position to meet.
- 10.5 In what follows, we consider first the question of what is owed to all front-line workers with respect to their own welfare; and second what support needs to be in place to enable those directly engaged in the research to manage and respond to the ethical challenges that inevitably arise in their work.

<sup>721</sup> Cronin-Furman K, and Lake M (2018) Ethics abroad: fieldwork in fragile and violent contexts *PS: Political Science & Politics* **51(3)**: 607-14, at page 608.

<sup>722</sup> Anonymous respondent to our call for evidence.

<sup>723</sup> Shepler S (2017) “We know who is eating the Ebola money!” Corruption, the state, and the Ebola response *Anthropological Quarterly* **90(2)**: 451-73.

<sup>724</sup> Discussions at PRO-RES workshop on research ethics in disaster and conflict settings, Dublin City University: 16-17 May 2019.

<sup>725</sup> See, for example, Jewkes R, Sikweyiya Y, and Jama-Shai N (2014) The challenges of research on violence in post-conflict Bougainville *The Lancet* **383(9934)**: 2039-40; and Jenkins SA (2018) Assistants, guides, collaborators, friends: the concealed figures of conflict research *Journal of Contemporary Ethnography* **47(2)**: 143-70.

<sup>726</sup> See, for example, Hunt MR (2008) Ethics beyond borders: how health professionals experience ethics in humanitarian assistance and development work *Developing World Bioethics* **8(2)**: 59-69; and Aubé N (2011) Ethical challenges for psychologists conducting humanitarian work *Canadian Psychology / Psychologie Canadienne* **52(3)**: 225-9.

<sup>727</sup> Schwartz L, Sinding C, Hunt M *et al.* (2010) Ethics in humanitarian aid work: learning from the narratives of humanitarian health workers *AJOB Primary Research* **1(3)**: 45-54.

## Welfare and fair treatment of front-line workers

### Taking front-line worker welfare seriously

*“We need brave researchers”<sup>728</sup>*

- 10.6 The role of the front-line worker in research during a global health emergency is inherently risky. Risks of physical harm may derive directly from the nature of the emergency, such as the diverse risks associated with working in conflict zones, in an area still destabilised by natural disaster, or from inadequately protected exposure to infectious disease.<sup>729</sup> As these examples imply, the nature and extent of such physical risks arise from a combination of the danger inherent in the particular situation, and from failures to provide or use appropriate protections where these exist. However, as illustrated by some of the examples in Box 10.1 above, the wider harms to which front-line workers may be exposed may be exacerbated, or indeed caused, by a number of other factors. These include the (sometimes highly sensitive) nature of the research itself; the expectations placed on front-line workers; and failures on the part of others (including managers, employers, or funders) to ensure that the research has been planned in ways that are sensitive to culture and context.
- 10.7 For instrumental and intrinsic reasons, effective engagement with affected populations as early as possible in the research process is of central importance (see paragraphs 5.26–5.28 and 6.15). The risks to front-line workers that may result from a failure to ensure that the planned research is both acceptable to, and valued by, local populations reinforce this approach. In addition, there is a need for clear risk assessments of the challenges likely to be faced by those working on the ground in each specific research site, accompanied by strategies to ensure the best possible mitigating measures. Local knowledge will be essential, both in identifying the likely challenges, and finding the most appropriate mitigating measures.
- 10.8 There is no single way in which these assessments could or should be achieved. However, one suggestion made to us proposed the creation of a separate ‘research and security committee’ as a subcommittee of one of the research ethics committees (RECs) responsible for scrutinising research proposals, involving both ethical and local expertise.<sup>730</sup> As this suggestion implies, concern for the welfare of front-line research workers is not simply a matter of good employment practice but is also a question of ethics: this recognises that research workers are owed equal respect to the same degree as research participants. At times, there may be a direct conflict between action that would be necessary for the effective conduct of the research, and the dangers this would bring to workers (for example, where there is no safe way of accessing key participants). In such cases, however valuable a contribution the research might make towards the reduction of suffering, respect for the well-being of the research workers must prevent it going ahead in that form and at that time.
- 10.9 **We conclude that, while it is for researchers and research institutions to take the lead on identifying how the safety and welfare of front-line workers should best be protected, funders and RECs have the responsibility to assure themselves that**

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<sup>728</sup> Ahmad A (2019) The trauma of a woman’s words of war *The Lancet Public Health*: Published online: 6 August, who suggests that “we need brave researchers” to receive stories of women living through war.

<sup>729</sup> Moreover, less high status, locally employed workers are more likely to lack such protection: see, for example, (in the context of response, rather than research) Pallister-Wilkins P (2016) Personal protective equipment in the humanitarian governance of Ebola: between individual patient care and global biosecurity *Third World Quarterly* **37**(3): 507-23.

<sup>730</sup> Comments submitted by external reviewers.



**these issues have been properly considered.** Such an approach would rightly bring concern for the welfare of research workers specifically within the remit of RECs. RECs and funders should exercise this responsibility with a degree of humility, recognising the importance of local knowledge with respect to the nature of possible harms and the best ways of avoiding or mitigating them.

## Fair treatment of workers

10.10 Guidance by bodies such as the World Health Organization (WHO) and the UN's Interagency Standing Committee (IASC) has highlighted the responsibilities of governments and others regarding locally-engaged and international front-line workers.<sup>731</sup> These include obligations relating to their safety, access to necessary training and resources, and clarity about their terms of deployment and access to healthcare. However, there remain a number of ethically contentious issues around such responsibilities. These include how and whether differential treatment between international and locally-engaged workers – or between further sub-categories of these workers – can be justified.<sup>732</sup> Responses to our call for evidence demonstrated the strength of feeling among those working in this field about differential treatment between local and international workers.

### Box 10.2: Differential treatment of front-line research workers: responses to the call for evidence

“We understand that expats may come with more resources but the way in which they are treated must not be different.” *Dr Rosmond Adams, Caribbean Public Health Agency (CARPHA)*

“[Expatriates] got 10 times the salary of the local staff in frontline so how do you expect equal commitment and chance / equity.” *Ernest Tambo, Africa Disease Intelligence and Response Institute & Université des Montagnes, Bangangte, Cameroon*

“... differential treatment continues inequitable and unjust global social, economic, and political determinants. All front-line workers should be offered / promised the same treatment (including pay).” *Anonymous respondent*

“For the case of professional expatriates like myself, it is my duty to give fair treatment. For example, my research assistance may not have a very good understanding of research but they can speak the local language. I have to go the extra mile and teach them additional research skills”. *Anonymous respondent*

“... it is absolutely essential that both receive the best possible care, and that any sub-standard care or treatment of local staff is ethically unjustifiable [...] the care and training that expatriates receive should be extended to local staff, and this cost should be covered by the international organizations or donors.” *Associate Professor Jantina de Vries, Department of Medicine, University of Cape Town*

<sup>731</sup> WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at: <http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf>, pp47-9; and IASC (2014) *Recommendations for conducting ethical mental health and psychosocial research in emergency settings*, available at: [https://interagencystandingcommittee.org/system/files/1.\\_iasc\\_recommendations\\_for\\_ethical\\_mhpsr\\_research\\_in\\_emergency\\_settings\\_0.pdf](https://interagencystandingcommittee.org/system/files/1._iasc_recommendations_for_ethical_mhpsr_research_in_emergency_settings_0.pdf).

<sup>732</sup> For a detailed account of these issues in the context of military response and priority access to care by foreign military, international healthcare and local healthcare staff, see: Draper H, Jenkins S, Bernthal L *et al.* (2018) Preparing for Operation Gritrock: military medical ethics challenges encountered in the planning stages of the UK Ebola response mission, in *Ethical challenges for military health care personnel: dealing with epidemics*, Messelken D, and Winkler D (Editors) (London and New York: Routledge).



“Differential treatment is a problem, especially when it comes to med-evac for international staff but not national staff. In these cases, national staff must be provided with a high level of care in country, paid for by the lead partner.” *Gillian McKay*

“If both researchers are living in the same settings and doing the same work, why should there be a big gap between their salaries?” *Anonymous respondent*

“The PI of the research grant should ensure fair treatment of all front-line staff.” *Dr Anuradha Rose*

“On the front-line no differentiation would be ethical. The main difference will be that expatriate staff have the possibility to leave, e.g. be flown out to hospitals, which local staff will not have.” *Anonymous respondent*

“Differential treatment is unpleasant, but given that whatever ethical guidelines we use have to operate in the real world, it is likely to remain the case.” *Anonymous respondent*

10.11 Involvement in research may in practice be an ‘empty choice’ for many participants in an emergency because of the broader demands of their situation (see paragraph 2.23). Locally-engaged front-line workers may be in a similar situation: employment with an international research collaboration (whether through direct or sub-contractual arrangements) may be the best or only source of economic support at a time of extreme difficulty. In emergencies, where participants may foreseeably be placed in such a situation, there is an added onus on researchers and those responsible for scrutinising their work to be confident that participation in research can be justifiable as fair given all the circumstances (see paragraph 7.9). Similarly, in this employment context, **the imbalances of power in such employment relationships impose additional duties of care among employers of front-line workers, to be confident that the terms and conditions they are providing constitute a ‘fair offer’.**

10.12 In considering what might be required for employment terms and conditions to constitute such a fair offer, two values of the ethical compass – equal respect and fairness – provide an important guide. It is important to recognise, however, that they may also be a source of tension. Equal respect demands recognition of the equal moral worth of all workers, and thereby underpins an obligation not to take advantage of the situation in which they happen to find themselves, even if this would lead to them voluntarily taking up employment on highly unfavourable terms. Fairness includes a requirement that ‘likes should be treated alike’, and a concern for the equitable distribution of benefits and burdens: in particular ensuring that it is not those least able to bear burdens who are expected to shoulder them.

10.13 When considering research employers’ duties towards those who work for them, concern for equal respect and fairness both point in the same direction of equivalence of treatment in all aspects of employment. However, fairness is also relevant when considering the treatment of research workers and the many others working in the health sector. For example, any decision to pay salaries for research work that exceed local pay rates for equivalent roles in the health sector may risk undermining the local health system by persuading workers away from essential roles, and by disrupting local economies in ways that will not be sustainable in the long-term. Thus it may inevitably be the case that careful avoidance of differential employment terms between one group of people (locally employed and international) can directly cause equally unfair disparities between other groups of workers. It may also actively cause, rather than reduce, suffering, through unintended but predictable consequences for local health systems.

10.14 A second issue to consider is the question of what duties employers (in the form of the various parts of an international research consortium) and research funders can legitimately be held to bear (see paragraphs 4.64–4.71). It would be unreasonable to assert that the institutions involved in an international research consortium should acquire responsibilities to rectify any and all existing injustices, simply by virtue of their presence in a particular location. On the other hand, such a consortium has clear duties as an employer to the workers carrying out research in its name, including those on temporary contracts or subcontracted through other organisations. It also has a duty not to *add* to existing injustices by its presence or actions, which may in some circumstances translate into positive duties to act. The close interaction between research and response activities may also involve research institutions in obligations to the wider populations affected by the emergency, where basic service provision is an essential prerequisite for an ethical approach to community members to take part in the research (see paragraph 8.11).

10.15 Many of the ethical challenges relating to the fair treatment of front-line workers are foreseeable: several of the examples cited in Box 10.2 above were repeated in similar forms by respondents to our call for evidence.

#### **Recommendation 23 (directed to research institutions)**

**We recommend that research institutions, when setting policies, both in general and for a particular emergency, should explicitly consider whether those conditions represent a ‘fair offer’ in the circumstances. We suggest that elements of a fair offer will include:**

- **being transparent about how rates of pay are set, and the basis for any differential treatment of local / international workers;**
- **working with other partner organisations, in particular those responsible for providing routine health services in the location where the research is planned, to understand the context and potential consequences of employers’ decisions;**
- **aiming to provide the highest attainable standard of care and support for any person working on behalf of the institution, whose care needs arise as a result of that work;**
- **providing explicit justification for any differences in treatment with respect to safeguarding and safety; and**
- **including temporary and indirectly employed (e.g., sub-contracted) workers within these considerations.**

10.16 **While the primary responsibility for the fair treatment of front-line workers rests with employers, research funders also have responsibilities in this area, both to allow for any costs involved, and to ensure that research employers’ responsibilities in this area are scrutinised within the grant system.** We welcome the fact that many major funders are already recognising this responsibility in the work they are doing regarding their role in safeguarding.<sup>733</sup>

<sup>733</sup> UKCDR (10 June 2019) *UKCDR publishes draft briefing paper on evidence review on safeguarding in international development research*, available at: <https://www.ukcdr.org.uk/news-article/ukcdr-publishes-draft-briefing-paper-and-evidence-review-on-safeguarding-in-international-development-research/>.

## Ethical support for front-line workers

10.17 As Box 10.3 illustrates, front-line research workers in global health emergencies can face highly-challenging situations that confront them with ethical dilemmas affecting the welfare of their study participants, their colleagues, and themselves.

### Box 10.3: Front-line worker experiences: ethical challenges in Eastern Democratic Republic of the Congo (DRC) research<sup>734</sup>

“We were working in North and South Kivu in Eastern DRC with a local NGO and a local higher learning institution on a Gender Based Violence intervention study. Our local partners are well established with formal and informal connections to the police, military, and rebel groups. We knew that data collection would be challenging, as we would be working in rebel-controlled territories, with the Ebola outbreak wreaking havoc in villages close by. From the outset, it was clear to us that the best way to manage the security situation was by relying heavily on the knowledge and network of our local partners. It was decided that no external supervisor team should venture out to the field, as this would pose a threat to themselves, but also to the study participants and the data collectors.

Our data collectors went out in teams of four to six people (half of them men, half women), travelling through the region and staying overnight in relatively large local centres. We were in daily connection with them through telephone and WhatsApp. The situation was tense. We were updated on difficult encounters at roadblocks; unpleasant encounters with unknown individuals; and in one case an overall sense of insecurity that made the team decide not to return to a certain village. The pressure on the data collectors was further exacerbated by difficult working circumstances (e.g., travel by motorbike, often eating simple local food, less than ideal accommodation) and psychologically demanding work (listening to participants testifying on their gender-based violence experiences).

In this context, two of our data collectors – one man and one woman - suddenly found themselves in the middle of a gun attack. They were in the lobby of a hotel in a distant village when a military person who was guarding the door was shot dead. A 45-minute shootout ensued. Our female data collector was in shock and did not manage to go up the hotel stairs to look for better safety, so she stayed with her colleague and a hotel staff member hiding behind the hotel counter. Quickly the message was shared through WhatsApp and phone. The two data collectors were evacuated the next day with the help of a local partner. All data collectors were then called back to allow the research team to assess the situation and to provide psychological assistance. After inquiry, we found that the attack was criminal in nature aimed at the military men who were doing a monetary transport. As our research team was not the target of the attack and in agreement with the whole team of data collectors, we continued data collection the week after. The two affected data collectors, at their own request, did not participate in further data collection.

We did not take the decision to go back to the field lightly. It was the DRC data collectors themselves who were most adamant that this was important work. They argued that this is the Congolese reality and daily life for many people living in Eastern DRC. They often cited study participants who expressed gratitude that people were taking an interest in

<sup>734</sup> Personal communication, Stefan Jansen PhD, Ag. Deputy Director, Center for Medical Health; Research Coordinator, Directorate of Research and Innovation, College of Medicine and Health Sciences, University of Rwanda (26 November 2019). More first-hand accounts of the experiences of the data collectors are available via Elrha (2019) *Organisation: University of Rwanda*, available at: <https://www.elrha.org/organisation/university-of-rwanda/>.

their suffering. As the data collectors themselves were mainly from Goma and Bukavu, the regional capitals, also they were struck by how dire the situation was. In the many discussions we had then and after, we came to compare the work of the data collectors with the work of war journalists, as they were revealing a reality that is not very visible. For this brave group of people, continuing data collection after this big incident was self-evident. Life goes on.

Since this round of data collection, we have performed the follow up end line data collection with almost the same team. The affected female data collector was again part of the team. The affected male data collector cited family reasons for not joining.

The data collectors have built strong bonds as the result of this study. We are together in a WhatsApp group where we share stories, jokes, and family happenings on an almost daily basis.”

## Professional values and moral craft

- 10.18 Those who take on the responsibilities and challenges of front-line research work in the context of a global health emergency generally do so because they consider the work important and have a commitment to doing their job well. They come to the role with shared values and commitments as well as some – even many – that differ, reflecting the fact that they work for different organisations, have diverse professional backgrounds, or have other relevant personal commitments and values. It is likely that in the majority of their work together it will be relatively straightforward for them as a team or individually to negotiate the successful completion of their tasks in a way that does not challenge these core values and commitments, even if this may require them to deal with distressing and difficult decisions. This kind of ‘moral craft’ is a fundamental part of the effective work of a team of front-line research workers.<sup>735</sup> The importance of such work needs to be recognised as an important contribution.
- 10.19 However, the situations described above (see Boxes 10.1 and 10.3) make it clear that there will also be some occasions – perhaps many – in which these values and commitments pull in different directions, suggesting competing courses of action. This might take the form of moral tension within an individual or team, between different team members, or perhaps arising in situations where it becomes apparent that the expectations and values (for example, of local communities or participants) are different in important respects. This suggests the need for the day-to-day moral craft of front-line researchers and teams to be reflective, sensitive to moral concerns, and alert to the need at times for practices to evolve and change.
- 10.20 Many ways have been suggested for supporting this kind of critical reflection, both on the part of individual workers of their own practice, and as teams. These include ongoing field monitoring and support; creation of ‘reflective spaces’ to provide opportunity for discussion and debriefing in a safe and supportive environment, possibly involving ethics facilitators; developing case studies based on team experiences; and conducting post-study ethical audits using a structured checklist and involving all members of the

<sup>735</sup> Parker M (2015) Scaling ethics up and down: moral craft in clinical genetics and in global health research *Journal of Medical Ethics* 41(10): 134-7.

research team.<sup>736</sup> A more formal structure for such an approach has been proposed in the form of a model of ‘empirical ethical reflection’ that involves local communities, funders, and ethics review committees from the beginning in identifying and planning for ethical challenges that might arise. It builds in opportunities for ethical reflection by researchers throughout the study, and encourages learning points from the ethical reflection to be shared – along with study findings – with all stakeholders at the end of the study.<sup>737</sup>

10.21 These various reflective approaches contrast with more procedural approaches to ethics which focus on the achievement of ‘sign-off’ through ethical review, and training of front-line colleagues on strict adherence to pre-approved informed consent protocols.<sup>738</sup> There is clearly an important link between recognising the limits of procedural ethical approaches, the value of various forms of reflective practice, and our earlier discussion of the role of professional virtues in ethical research practice in emergencies (see paragraphs 4.40 and 7.21–7.24). Oversight and review procedures will never be sufficient in themselves: there will always be reliance on the probity of individual researchers, and on the extent to which virtues such as fidelity, honesty, compassion, and integrity underpin their relationships with study participants, their colleagues, and other stakeholders.

10.22 Importantly, these virtues cannot be expected to inform practice if they are not embedded in the way institutions themselves operate – especially where those working on the front-line have acquired their role almost by chance or through external pressure (see paragraph 10.2). Employing institutions need to encourage an ethical ethos – part of the ethics ecosystem to which we have referred – that supports the virtuous behaviour of their workers and provides institutional structural support for ethical reflection (see, for example, the case study described in Box 10.4 below). We have already gestured at how institutions can mirror ethical behaviour in their own interactions with each other by being open and cooperative (see Chapter 8). However, they also encourage the right sort of ethics ecosystem and moral behaviour in their workers by themselves showing scrupulous fairness and respect in terms of how they treat their workers. This includes systems of support and accountability within the research hierarchy, so that those with the least experience and authority are not expected to take responsibility for difficult decisions that it is not fair to ask them to make.

10.23 Employers also have a duty to act to prevent or minimise the risk of harmful behaviours by their workers. The importance of effective safeguarding policy and practices on the part of non-governmental organisations (NGOs) and research institutions working in global health emergencies has recently received considerable attention in the light of the exposure of troubling practices in the aid sector, including sexual exploitation, abuse, and harassment.<sup>739</sup> Draft guidance issued by UK research funders for consultation following these revelations emphasises the responsibilities of all parties – funders, research organisations, and researchers – to take all reasonable steps to prevent harm

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<sup>736</sup> See, for example, Chiumento A, Khan MN, Rahman A *et al.* (2016) Managing ethical challenges to mental health research in post-conflict settings *Developing World Bioethics* **16**(1): 15-28 for a helpful overview in the context of mental health research in emergencies. See also: Dawson A, Lignou S, Siriwardhana C *et al.* (2019) Why research ethics should add retrospective review *BMC Medical Ethics* **20**(1): 68.

<sup>737</sup> Chiumento A, Khan MN, Rahman A *et al.* (2016) Managing ethical challenges to mental health research in post-conflict settings *Developing World Bioethics* **16**(1): 15-28.

<sup>738</sup> *ibid.* See also: Chiumento A (2017) *Researchers' construction and management of ethical issues in post-conflict mental health research: a qualitative study (PhD thesis)*, available at: <https://livrepository.liverpool.ac.uk/3020641/>.

<sup>739</sup> See, for example, The Charity Commission (2019) *Charity inquiry: Oxfam GB*, available at: <https://www.gov.uk/government/publications/charity-inquiry-oxfam-gb>.



to those involved with research.<sup>740</sup> The draft principles include the need for safeguarding measures to be proportionate and context-dependent, building on existing measures where these are fit for purpose; adequately resourced; and sensitive to the way that vulnerability to harm arises in contexts shaped by inequalities and power imbalances.

#### **Box 10.4: Support for front-line workers in Lebanon**

*Lessons learned in conducting three research studies exploring mental health among Syrian refugee children in Lebanon, including a longitudinal cohort study (BIOPATH), a clinical trial (t-CETA), and a study focusing on the reliability and validity of mental health measurement tools (VaST). This involves a close collaboration between UK academics at Queen Mary University of London (QMUL; PIs M. Pluess and F. McEwen) and Lebanese academics at the Institute for Development, Research, Advocacy and Applied Care (IDRAAC) / Balamand University Medical School / St George's University Medical Center (co-PI E. Karam), as well as a local field work partner, Médecins du Monde (France) in Lebanon (MdM), the American University of Beirut (AUB), and further international partners.*

##### **Staff recruitment and training**

We recruited teams of local staff to run the studies in Lebanon, using contracts that included paid leave (versus daily contracts) to avoid having local staff on less favourable contracts than expatriate staff. During recruitment, we focused on the ability of candidates to anticipate and respond to challenging situations. Candidates for coordinator positions were given written tasks to complete ahead of the interview and candidates for clinical positions were asked to role play challenging situations with vulnerable individuals (e.g., disclosure of sexual abuse). Training also included roleplay with observation and feedback, which was reviewed at the end of the probation period. If there were concerns that a staff member was not able to work safely and ethically with vulnerable children then their contract was not renewed. All staff received training on ethical research practice, either an internationally recognised course in English (e.g., National Institutes of Health (NIH) / Collaborative IRB Training Initiative (CITI)) or training adapted from these courses and delivered in Arabic. We also trained staff on managing risks such as child protection and suicide safety planning. We aimed for all staff to understand the broader aims of the research and why they were being asked to complete particular tasks to make it easier for them to work out the best approach when faced with challenges.

##### **Creating space to raise ethical issues**

Staff in different roles bring different expertise and experience. Senior staff may be unaware of issues experienced by front-line staff, and we worked to create an environment where front-line staff felt comfortable in bringing concerns forward. Issues were acted on promptly to ensure that front-line staff knew that their concerns were taken seriously and that their ideas contributed to the project. Front-line staff were closely supervised by local coordinators, who were in daily contact with the study coordinator at QMUL to discuss practical and ethical challenges that arose. Various reflective spaces were created, including daily and weekly debriefs following data collection, weekly clinical supervision, and during exit interviews. Concerns about

<sup>740</sup> UKCDR (18 October 2019) *Blog: making research safe*, available at: <https://www.ukcdr.org.uk/making-research-safe/>. See also the draft guidance on safeguarding by UKCDR (2019) *Safeguarding in international development research: briefing paper*, available at: <https://www.ukcdr.org.uk/resource/safeguarding-in-international-development-research-briefing-paper/>. UKCDR subsequently launched a stakeholder survey to obtain feedback on the draft guidance: UKCDR (2019) *Survey: safeguarding in international development research*, available at: <https://www.ukcdr.org.uk/resource/survey-safeguarding-in-international-development-research/>.

specific cases (e.g., a child who initially assented but who then became distressed when asked to do an assessment) were immediately discussed with a clinical supervisor and then with the wider research team. Taking into account the views of front-line staff, as well as experienced clinical and research staff, enabled us to decide on the most appropriate course of action in ethically challenging cases. Exit interviews, when staff were encouraged to be completely honest about all aspects of their job, were used to revise procedures in later stages of the projects.

### **Clear lines of responsibility**

Working with refugees in informal tented settlements (ITS), it is common to experience challenging situations such as protection issues. This included disclosures of child maltreatment, families living in extreme adversity, and children separated from parents. Child protection services are fragmented and there is not a standard process for referral. We developed a protocol that clearly set out the lines of responsibility and the process for reaching case-by-case decisions. Front-line workers were not expected to make decisions, but immediately refer cases to their supervisor. Front-line workers were trained in providing immediate assistance, such as safety planning, to ensure that individuals were safe until further action could be taken. Further decisions were made jointly by the research team, which included the study principal investigator (PI), coordinators, experienced clinical staff, and front-line staff. In some cases, advice was sought from other agencies, but without disclosing the name of the family so as to maintain confidentiality.

### **Study design**

The study design was shaped by both scientific and ethical considerations. For example, our initial sampling strategy was to randomly select families in ITS. In addition, we decided to offer monetary compensation after feedback from stakeholders that this was preferable to compensation in the form of goods (e.g., household products that the family may not need). However, during piloting, it became clear that randomly selecting families was perceived as unfair and had the potential to create conflict in settlements where only some families would participate and receive compensation. We therefore changed our approach in two ways: (i) sampled from small-medium sized settlements and approached all families; (ii) reduced the value of the compensation. To avoid creating disparities between the research and existing mental healthcare systems, we ensured that benefits such as travel expenses for research participants were the same as those offered by MdM so as not to create expectations among beneficiaries that could not be met by standard services. Input from front-line staff on these types of issues was essential and contributed to constructive dialogue with ethical review bodies.

Thorough pilot testing of measures, including review by local experts and focus group discussions (FGDs) with Syrian refugees prior to larger scale pilots, identified culturally sensitive topics and ensured that they were approached appropriately. This avoided putting interviewers in the position of asking questions that were likely to be perceived as insulting or offensive. We sought to find out who participants were comfortable being interviewed by. Syrians who participated in FGDs said that they would be more comfortable being interviewed by a Lebanese than a Syrian interviewer, because of uncertainty about the political affiliation or motivation of a Syrian interviewer. We also checked with individual participants whether they preferred to be interviewed by a male or female interviewer. The informed consent process was adapted for low literacy levels. Interviewers read out the consent and assent documents and used infographics to support the process. They took time to check understanding (e.g., by asking participants to paraphrase what they understood), and checked that both parents consented and that the child assented to taking part. In the clinical trial, we sought to increase accessibility for vulnerable families by conducting home visits and by offering appointments over the phone at times convenient to families, including evenings and weekends.

Finally, the experience of front-line staff has raised new research questions. Discussion during clinical supervision highlighted issues around practical and ethical challenges to diagnosing mental disorders in children living with extreme adversity; front-line staff are contributing to the write-up of this work for publication.

### Safety and security

We take seriously our duty of care to participants and staff. Working with MdM, who have extensive experience in this setting, was essential to understanding security issues and developing standard operating procedures (SOPs) for safe working. MdM's security staff provided training to the fieldwork team, monitored areas the team was working in for security threats, and were available to provide immediate advice if problems arose (e.g., when a fight broke out in an ITS). All staff were provided with phones to communicate while conducting visits and, where possible, interviewers worked in pairs with team leaders providing support. Safety was prioritised over data collection: if necessary for security reasons, interviews were terminated and staff left the ITS.

We were also aware of the potential for moral distress in staff who were interviewing families with multiple needs, without always having the means to help. One member of the team was available to take details of families with mental health and other needs, and forward these details to an MdM case manager to follow up and arrange referral when necessary. We funded additional staff to provide mental health services to families in the communities we visited, whether or not they participated in the research. Finally, self-care plans were discussed during supervision with clinical staff and we aimed to provide access to mental healthcare if front-line staff were distressed by the work.

10.24 There are also important links between recognising the responsibilities of employing organisations in supporting structures for ethical reflection (in particular the model of pre-study reflection with local communities) and our earlier discussion in Chapters 5 and 6 of the need for inclusive approaches to study design. Opportunities for community engagement to contribute to culturally sensitive design and recruitment procedures may significantly reduce the challenges faced by front-line workers: some of the cases cited in Box 10.1, for example, describe circumstances where front-line workers were put in physical danger, or felt their research was exploitative, because of inappropriate study design. Research institutions also need to have clear policies (developed with relevant stakeholders and applicable to the context) on aspects of practice that may lead to moral distress, including where front-line workers may be approached by community members for resources or money. Effective partnerships with other organisations are critical in enabling researchers to be able to make referrals to appropriate services and other sources of support (see paragraph 8.11).

### Sources of ethics support

10.25 In addition to opportunities for structured reflective practice within teams on the ground, there is clearly a need for readily accessible resources – in the form of case studies or training materials – to support such reflection and decision-making in circumstances of ethical difficulty. There has been considerable work in this field in recent years, as illustrated in Box 10.5. **We welcome the increasing awareness of the need for ethical support for front-line workers, and the number of initiatives providing freely accessible toolkits and case studies.** The value of such tools will inevitably be dependent on how they are used, and the priority given by employing organisations, funders, and others to training, ongoing mentoring, and other aspects of implementation.

**Box 10.5: Examples of ethical tools to support front-line research workers**

- The **Research for Health in Humanitarian Crises (R2HC) Research Ethics tool** provides guidance on research ethics for public health researchers interested in applying to the R2HC programme, and also for other researchers working in humanitarian crises.<sup>741</sup> It sets out a series of questions for researchers to consider throughout the course of their research, from early development to dissemination and post-research reflection.
- **Post-Research Ethics Analysis (PREA)** – a research project investigating ethical issues in health research in humanitarian crises – aims to identify good ethical practice from lessons learned in the field.<sup>742</sup> Alongside **case studies**<sup>743</sup> to stimulate discussion and help support ethical reflection, it is developing an online interactive **PREA tool** to assist reflection on ethical issues in humanitarian research and provide links to relevant guidance.
- The World Health Organization’s (WHO) **Ethics in Action** website<sup>744</sup> provides a series of scenarios with questions and commentary, and links to key ethics resources, to support the integration of ethical reflection into epidemic response, and to support public health workers and others in responding to the moral dilemmas they face.
- The **Humanitarian Health Ethics Research Group (hhe)** has developed a **toolbox** for humanitarian healthcare workers, including researchers.<sup>745</sup> Materials include an **ethics analysis tool** to guide ethical decision-making;<sup>746</sup> **fictional case studies** for REC training,<sup>747</sup> a **case study series**,<sup>748</sup> and an **e-learning module**.<sup>749</sup>
- The **Global Health Training Centre** provides access to a wide range of online training materials of relevance to those conducting research in emergency contexts, including, for example, short courses on ancillary care obligations and data-sharing.<sup>750</sup>

10.26 In some circumstances, more active support will be required than such tools can provide, and the ethics expertise and knowledge of individuals and organisations will need to be drawn upon. One example of such a specific tailored and proactive approach was that established by the Pan American Health Organization (PAHO) at the start of the Zika outbreak in Latin America. PAHO first consulted with those on the ground to find out what issues were causing ethical dilemmas, and then worked collaboratively to produce guidance.<sup>751</sup> Similar needs in other emergencies have depended on the existence of personal connections and contacts, or have not been met. In response to this need, a pilot network has been launched in January 2020 by WHO, with the aim of facilitating timely responsive advice in this way; conducting research to inform such advice; and

<sup>741</sup> Elrha (2017) *R2HC ethics framework 2.0*, available at: <https://www.elrha.org/researchdatabase/r2hc-ethics-framework-2-0/>.

<sup>742</sup> PREA (2019) *Homepage*, available at: <http://www.preaportal.org/>.

<sup>743</sup> PREA (2019) *Case studies*, available at: <http://www.preaportal.org/case-studies/>.

<sup>744</sup> WHO (2019) *Integrating ethics in infectious disease outbreaks*, available at: <https://extranet.who.int/ethics/node/8>.

<sup>745</sup> Humanitarian Health Ethics (2019) *Toolbox*, available at: <https://humanitarianhealthethics.net/home/hheat/>.

<sup>746</sup> Humanitarian Health Ethics (2014) *Humanitarian Health Ethics analysis tool*, available at: <https://humanitarianhealthethics.net/home/hheat/hheat/>.

<sup>747</sup> Humanitarian Health Ethics (2018) *Fictional protocol 4: ethics committee training*, available at: <https://humanitarianhealthethics.net/home/hheat/fictional-protocol-4-ethics-committee-training/>.

<sup>748</sup> Humanitarian Health Ethics (2019) *Cases*, available at: <https://humanitarianhealthethics.net/home/hheat/cases/>.

<sup>749</sup> Humanitarian Health Ethics (2019) *E-module - humanitarian health ethics: an online ethics training module*, available at: <https://hhetrainingmodule.wordpress.com/>.

<sup>750</sup> Global Health Training Centre (2019) *Homepage*, available at: <https://globalhealthtrainingcentre.tghn.org/>.

<sup>751</sup> Saenz C (2016) Zika virus: ethics preparedness for old and new challenges *The Lancet Global Health* **4**(10): e686.

developing ethics capacity in low- and middle-income countries (LMICs) to ensure that the network grows to reflect global perspectives (see Box 10.6).<sup>752</sup>

#### **Box 10.6: Public Health Emergency Ethics Preparedness and Response (PHEEPR) Network**

The newly-launched PHEEPR Network is a three-year pilot project supported by the Department for International Development (DfID) and Wellcome to facilitate timely responsive ethics advice in emergencies. As a pilot project, it will focus on infectious disease outbreaks to show proof of concept, with the possibility of drawing other initiatives under its umbrella (and extending beyond outbreaks) if successful. Plans include:

- Establishing a network of ethicists able to support local decision-making when called upon, drawn from institutions in both HICs and LMICs;
- Undertaking empirical and normative ethics research in response to identified needs, starting with the introduction of novel therapeutics and vaccines in outbreaks, and consulting on two other starter areas;
- Building ethics capacity in-country for the needs of preparedness and response, including, but not exclusive to, ethics review processes; and
- Supporting collaborative partnerships with founder network members and institutions in LMICs, to help grow capacity for the future.

#### **Recommendation 24**

**There is a need for a flexible, well-funded platform to provide timely ethics advice and support for those involved in all aspects of research in emergencies, including those funding, planning, and carrying out research. We welcome the launch of the Public Health Emergency Ethics Preparedness and Response (PHEEPR) Network. We welcome, in particular, the planned focus on the support for ethics capacity in low-income settings, and the recognition of the central importance of such sources of ethics advice being widely dispersed around the world.**

<sup>752</sup> WHO (26 January 2020) *Piloting the PHEEPR Network*, available at: <https://www.who.int/news-room/detail/26-01-2020-piloting-the-pheepr-network>.





# Chapter 11

Afterword from the Chair  
of the working group

## Chapter 11 – Afterword from the Chair of the working group

- 11.1 Global health emergencies are not amenable to easy definition. They are complex and complicated events: the result of dynamic constellations of biological, environmental, economic, political, social, cultural, technological, and moral factors. In our deliberations, evidence-gathering, and writing as a working group, we have sought to keep this complexity in mind. Against this backdrop, our focus has been on the ethical aspects of the interactions and interdependencies between preparedness, research, and response. An important feature of global health emergencies in this regard is the fact that they generate obligations – both legal and moral – for multiple actors: governments, intergovernmental bodies, humanitarian organisations, the military, commercial companies, research funders, academic institutions, health professionals, researchers, front-line research workers, volunteers, communities, families, and ethicists.
- 11.2 The agencies, communities, and people who are brought together in the conduct of research within global health emergencies bring with them different moral concerns, commitments, and values. In some cases, these will be enshrined in ethics frameworks, or guidance documents. Engaging seriously with these differences is an important requirement for any attempt to understand the ethical dimensions of research in emergencies: people, institutions, and professions will differ in their views about what is, and what is not, an ethical problem, and about the range of acceptable solutions to them. Whilst acknowledging that these differences are a problem – in that, despite them, difficult decisions do need to be made – it is clear that this diversity is also an important resource. It offers the possibility of identifying, developing, and implementing solutions together that would otherwise not be available. An equally important factor in such contexts – and moral decision-making – are the overlaps, interconnections, and potential for productive conversations between the moral perspectives of those involved on the basis of shared experiences, concerns, and values.
- 11.3 Resisting moral relativism or bioethical paralysis in the face of these problems, our response has been to attempt to offer sensible advice to those who face them in practice. Our contribution has two elements. One of these is crystallised in our concept of an ethical compass. The compass, comprising substantive normative commitments to equal moral respect, contributing to reducing suffering, and fairness, is a strong statement that research which does not, for example, treat all those affected with equal moral respect, is unethical. We emphasise that establishing the precise requirements for ethical research in particular contexts – e.g., for equal moral respect – depends upon inclusive, respectful engagement and deliberation. Our second contribution, illustrated by our choice of focus for Chapters 5–10, has been to identify a number of particularly salient, morally significant, aspects of research in global health emergencies, and to offer an informed, in-depth analysis of the nature of the problems and difficult decisions to be made, in the light of the evidence we received.
- 11.4 Ensuring that research conducted during global health emergencies is ethical is not something that can be achieved by better ethics frameworks, more coherent regulation, community engagement, or independent ethical review. These may be necessary conditions, but they are not sufficient. The successful conduct of research to high ethical standards depends crucially upon the moral and ethical work undertaken every day by front-line research workers, health professionals, and volunteers. In addition to the very real dangers and practical challenges they face in their work, this moral labour is both

demanding – in that it requires great skill and expertise – and a potential source of significant distress and exhaustion. The importance of this work – the moral craft of day-to-day ethical research – is often, very often, not fully appreciated or rewarded. It is, however, essential.

- 11.5 Above all, we have tried to bear in mind throughout our deliberations that research undertaken in the context of global health emergencies involves real people, families, and communities. It asks a great deal of them, primarily in the interests of others, at a time of great distress, fear, and vulnerability. We take this opportunity to acknowledge and celebrate the contribution of those who take part in such research: some of whom, including Yusuf, whose story is included in our report, we were fortunate to meet in person.
- 11.6 The vital importance of properly resourced preparedness between emergencies is a key finding of this report. Preparedness and emergency planning are essential for many reasons: they mean emergencies are less likely to happen and more manageable when they do occur. They also mean that the requirements for valuable, ethical research to be conducted are more likely to be in place. Although the occurrence of events with the potential to lead to global health emergencies cannot yet be very accurately predicted, as the amount of real-time surveillance data increases, and technology and modelling methods improve, so too will the ability to intervene in a timely or pre-emptive manner. The deployment of such technologies and the uses of the data they produce will of course raise many new ethical questions.
- 11.7 One question we have often been asked is about the extent to which the ethical issues arising in research in global health emergencies are radically different to those in global health research more broadly. Our focus here has been very much on research in emergencies and it is to those funding, conducting, or reviewing research in these contexts that this report is addressed. It is nonetheless true that our review of the requirements of ethical research in the particular intensity of emergencies may also have highlighted ethical problems and solutions relevant to research conducted in other settings. Two possible examples of this are, firstly, the requirement to involve and engage communities, and, secondly, the importance of fair, respectful research collaborations. If it is reasonable to judge these as essential for ethical research in global health emergencies, it does not seem unreasonable to expect them in any health-related research in low- and middle-income settings.



**Professor Michael Parker, Chair of the working group**





# Appendices

# Appendix 1: Methods of working

## Background

The Nuffield Council on Bioethics launched its project on research in global health emergencies on 16 November 2017, and appointed a working group for the project in January 2018. The working group met nine times between February 2018 and September 2019.

## Call for evidence

To inform its deliberations, the working group launched a call for evidence in June 2018, which received 58 submissions. Further details of the call for evidence are available in **Appendix 2**.

## Roundtable meetings

The working group held three roundtable meetings with a wide range of individuals and representatives of organisations.

### On-the-ground roundtable, 25 June 2018

- **Akin Abayomi**, Professor of Medicine and Research, Nigeria Institute of Medical Research, Lagos, Nigeria. Emeritus, Faculty of Medicine and Health Science, University of Stellenbosch, Cape Town, South Africa.
- **Sultan Barakat**, Director, Centre for Conflict and Humanitarian Studies, Doha Institute for Graduate Studies; Professor at the University of York
- **Daniel G. Bausch**, Director, UK Public Health Rapid Support Team-UK PHRST, Public Health England / LSHTM
- **Ruchi Baxi**, Nuffield Department of Population Health, University of Oxford (presentation given by Patricia Kingori in Dr Baxi's absence)
- **Shevin Jacob**, Senior Lecturer in Sepsis Research, Liverpool School of Tropical Medicine; Global Health Security Team Lead, Infectious Diseases Institute
- **Janaka Jayawickrama**, Senior Lecturer / Associate Professor in Community Wellbeing, Department of Health Sciences, University of York
- **Beverley Stringer**, Social Science Coordinator, Manson Unit, Médecins Sans Frontières

### Roundtable on sharing data and samples in emergencies, 3 December 2018

- **Najeeb Al-Shorbaji**, President of the eHealth Development Association of Jordan, FIAHSI, Independent Consultant in Knowledge Management and eHealth
- **Annick Antierens**, Médecins Sans Frontières, Operational Centre Brussels
- **Moses Bockarie**, Director of International Cooperation (Africa), European & Developing Countries Clinical Trials Partnership (EDCTP), Cape Town; Adjunct Professor, School of Community Health Sciences, Njala University, Sierra Leone
- **Gail Carson**, GLOPID-R Secretariat; Director of Network Development, International Severe Acute Respiratory & emerging Infection Consortium (ISARIC) Global Support Centre, Oxford University; Consultant in Infectious Diseases (via teleconference link)
- **David Harper**, Senior Consulting Fellow, Centre on Global Health Security, Chatham House; Managing Director, Harper Public Health Consulting Ltd.

- **Ben Hayes**, Director, Data Protection Support & Management Ltd.

## Roundtable on the role of funders, 8 March 2019

- **Prisca Benelli**, Humanitarian Research and Learning Manager, Save the Children UK
- **Mia Bülow-Olsen**, Lead, Global Access to Care, Novo Nordisk A/S
- **Caroline Harris**, Programme Manager for Global Health Strategy, MRC / UKRI
- **Dan O'Connor**, Head of Humanities and Social Science, Wellcome
- **Cathy Roth**, Senior Research Fellow (Infectious Diseases), Department for International Development
- **Barbara Sina**, Program Officer, Fogarty International Center, NIH (via teleconference link)
- **Marta Tufet**, Executive Director, UKCDR
- **David Vaughn**, Senior Program Officer, Integrated Clinical Vaccine Development, Bill & Melinda Gates Foundation
- **Jimmy Whitworth**, Professor, International Public Health, London School of Hygiene and Tropical Medicine; Deputy Director for Research, UK Public Health Rapid Support Team, Chair, R2HC Advisory Group, Elrha

## Meetings with individuals

The working group also met (in person or remotely) with a number of individuals over the course of its inquiry (titles correct at the time of meeting). They included:

- **Olivia Berthon and Sheila Mburu**, UKCDR
- **Gail Carson**, GLOPID-R Secretariat; Director of Network Development, International Severe Acute Respiratory & emerging Infection Consortium (ISARIC) Global Support Centre, Oxford University; Consultant in Infectious Diseases
- **Anna Chiumento**, Research Associate, Psychological Sciences, University of Liverpool
- **Heather Draper**, Professor, Social Science and Systems in Health, University of Warwick
- **Fouad Fouad**, American University of Beirut
- **Nina Gobat**, Platform for European Preparedness Against (Re-)emerging Epidemics (PREPARE)
- **Felicity Harvey**, Chair, Independent Oversight and Advisory Committee, WHO Health Emergencies Programme
- **David Heymann**, Professor, Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine; Distinguished Fellow, Centre on Global Health Security, Chatham House
- **Andy Johnston**, Lt Col RAMC, Consultant in Respiratory Medicine and Critical Care Royal Centre for Defence Medicine, Queen Elizabeth Hospital Birmingham, Birmingham
- **Jill Jones**, Head of Global Health Strategy, Medical Research Council
- **Katherine Littler**, Senior Ethics Specialist, Co-Lead, Global Health Ethics, World Health Organization
- **Mark Marchant**, Research Fellow, Political Theory, London School of Hygiene and Tropical Medicine
- **Gloria Mason**, Coordinator, Liberia National Ethics Review Board
- **Timothy McHugh and Mags Thomason**, PANDORA-ID-NET
- **Amit Mistry and Blythe Becroft**, Fogarty International Center, National Institutes of Health
- **Isadora Quick and Yazdan Yazdanpanah**, REACTing, Inserm

- **Bayard Roberts**, Professor, Health Systems and Policy, London School of Hygiene and Tropical Medicine
- **Amanda Rojek**, Epidemic Diseases Research Group, University of Oxford, Oxford

## Workshops

The working group undertook two workshops which gathered experts together to discuss its approach.

### **Senegal, 17-18 March 2019**

The working group collaborated with colleagues from African coalition for Epidemic Research, Response and Training (ALERRT), Institute for Health Research, Epidemiological Surveillance and Training (IRESSEF), and the Wellcome Centre for Ethics and Humanities to co-host a joint workshop in Dakar, Senegal. The workshop focused on community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises. The attendees were:

- **Sharon Abramowitz**, Consultant, UNICEF
- **Anani Badjé**, WP1 Coordinator, ALERRT Network
- **Bonny Baker**, Project Coordinator, Global Health Network, University of Oxford
- **Aphaluck Bhatiasevi**, Team Lead, Social Science Interventions and Risk Communication, WHO Health Emergencies
- **Primus Che Chi**, Social Scientist, KEMRI-Wellcome Trust Research Programme
- **Sara Dada**, Research Fellow, Vaccine Confidence Project, LSHTM
- **Luisa Enria**, Lecturer, International Development, University of Bath
- **Amb. Patrick Seeco Faley**, Ambassador, National Ebola Survivors' Network, Liberia
- **Morenike Oluwatoyin Folayan**, Coordinator, New HIV Vaccine and Microbicide Advocacy Society
- **Nina Gobat**, Senior Researcher, University of Oxford
- **Theresa Jones**, Senior Research Associate / Clinical Psychologist, Anthrologica
- **Yusuf Kabba**, President, Sierra Leone Association of Ebola Survivors
- **Shelley Lees**, Associate Professor, LSHTM; Co-lead ALERRT WP6
- **Mark Marchant**, Research Fellow, LSHTM
- **Vicki Marsh**, Group Head, Nuffield Department of Medicine, University of Oxford
- **Birahim Pierre Ndiaye**, Director, Clinical Trial Platform, IRESSEF
- **Palmer M. Netongo**, Senior Lecturer, University of Yaounde I, Cameroon; ALERRT WP5 Lead
- **Cheikh Ibrahima Niang**, Social Anthropologist, ISE-University Cheikh Anta Diop
- **Nicole Nkoum**, Research Associate, IRESSEF / EBODAV, World Vision Ireland
- **Elysée Nouvet**, Assistant Professor, Global Health, Western University, Ontario
- **Michael Parker**, Chair, Nuffield Council Working Group; Director, Wellcome Centre for Ethics and Humanities, University of Oxford
- **Julian Sheather**, Ethics Consultant and Adviser, British Medical Association and MSF
- **Khoudia Sow**, Researcher, CRCF
- **Manya van Ryneveld**, Researcher, University of Oxford
- **Samantha Vanderslott**, Postdoctoral Researcher, University of Oxford
- **Bartholomew Wilson**, Social Mobilisation, Communication, and Community Engagement (SMC) Lead, PREVAIL
- **Sophie Wodon**, Health Promotion and Patient Support Education and Counselling Technical Referent, MSF Switzerland
- **Katharine Wright**, Assistant Director, Nuffield Council on Bioethics

**Oxford, 3 July 2019**

The working group organised a workshop with 14 external attendees (listed below) to discuss its preliminary approach to ethical issues in global health emergencies. The workshop invited participants to discuss the working group's general approach and recommendations, and also its ethics framework.

- **Jo Ali**, Associate Director for Global Programs, Johns Hopkins Berman Institute of Bioethics
- **Caesar Atuire**, Lecturer, Department of Philosophy and Classics, University of Ghana
- **Anna Chiumento**, Research Associate, Institute of Population Health Sciences, University of Liverpool
- **Liza Dawson**, Chief of Bioethics, Institutional Review Board Chair, Walter Reed Army Institute of Research
- **Dorcas Kamuya**, Researcher in Ethics and Community Engagement, KEMRI-Wellcome Trust Unit, Kilifi, Kenya
- **Katherine Littler**, Senior Ethics Specialist, Co-Lead, Global Health Ethics, World Health Organization
- **Florencia Luna**, Director, Bioethics Programme, Latin American University of Social Sciences (FLASCO); Principal Researcher, National Scientific and Technological Research Council, Argentina
- **Vicki Marsh**, Group Head, Nuffield Department of Medicine, University of Oxford
- **Gloria Mason**, Bioethicist / Coordinator, National Research Ethics Board / PREVAIL; President, West African Network of Ethics Committees
- **Elysée Nouvet**, Assistant Professor, Global Health, Western University, Ontario
- **Bridget Pratt**, Research Fellow, Centre for Health Equity, University of Melbourne
- **Seema Shah**, Associate Professor, Paediatrics, Northwestern University Medical School; Associate Director, Bioethics Programme, Lurie Children's Hospital
- **Sheila Varadan**, Human Rights Consultant, REACH, University of Oxford
- **Jane Williams**, Postdoctoral Fellow, Sydney Health Ethics and Charles Perkins Centre, University of Sydney

## Contributions to external events

The working group and members of the Nuffield Council's executive also contributed to meetings organised by other organisations, including through presentations and/or participation in workshops or symposia. The events contributed to include:

- **GOARN integrating research into response workshop**, Geneva, 1-2 May 2018
- **Global Forum on Bioethics in Research: ethics of data sharing and biobanking in health research**, Stellenbosch, South Africa, 13-14 November 2018
- **Global Forum on Bioethics in Research: establishing a global ethics response for public health emergencies (satellite meeting)**, Stellenbosch, South Africa, 15 November 2018
- **Philippine Health Research Ethics Board**, Manila, 27-28 November 2018
- **Research, responsibility, and regulation: ethical challenges in global health**, Keele University, 11 December 2018
- **RECAP meeting**, American University of Beirut, 15-16 January 2019, and seminar with the Faculty of Health Sciences, American University of Beirut, 17 January 2019
- **Asian Bioethics Review meeting on Universal Health Coverage**, National University of Singapore, 27-28 January 2019

- **Post Research Ethics Analysis conference on ethics and humanitarian research: generating evidence ethically**, The Ohio State University, 25-26 March 2019
- **International Conference on Silk-road Disaster Risk Reduction and Sustainable Development**, Beijing, 11-12 May 2019
- **Research Ethics in Disaster and Conflict Settings**, Dublin City University, 16-17 May 2019
- **Health research in conflict and complex environments**, King's College London, 25 June 2019
- **Oxford Global Health and Bioethics International Conference**, Oxford, 1-2 July 2019
- **Global Mental Health Research Ethics**, University of Liverpool London campus, 23 September 2019
- **Multidisciplinary research in epidemic preparedness and response**, Academy of Medical Sciences, London, 2-3 October 2019
- **GloPID-R Frontiers Meeting**, London, 17-18 December 2019

## Literature reviews

The working group undertook four literature reviews, all of which focus on community engagement initiatives during and following four diverse emergencies:

- Hurricane Katrina
- The Syrian Civil War
- The Great East Japan Earthquake, tsunami, and nuclear accident
- The Indian Ocean tsunami

The reviews highlight how communities took control of their response to these emergencies through intracommunity initiatives and actions. They also focus on how communities were engaged by organisations after the disasters occurred, including what 'went well', and what problems arose in those engagement efforts. Each of these reviews – which all consider a wide range of academic and grey literature – is available to download from the Council's website.<sup>753</sup>

## External review

A draft version of the working group's report was circulated to external reviewers in July 2019. The reviewers were:

- **Sultan Barakat**, Director, Doha Institute
- **Rita Giacaman**, Professor of Public Health, Birzeit University
- **Kiran Jobanputra and Darryl Stellmach** (joint review), MSF
- **Yusuf Kabba**, President, Sierra Leone Association of Ebola Survivors (SLAES)
- **Ryoma Kayano**, WHO Centre for Health Development, Kobe
- **Carleigh Krubiner**, Policy Fellow, Center for Global Development, Washington, DC
- **Katherine Littler**, Senior Ethics Specialist, Co-Lead, Global Health Ethics, WHO
- **Jutta Reinhard-Rupp**, Head, R&D, Translational Innovation Platform, Merck
- **Bayard Roberts**, Professor, Health Systems and Policy, London School of Hygiene and Tropical Medicine
- **Athula Sumathipala**, Professor, Psychiatry, Keele University
- **Ross Upshur**, Dalla Lana Chair in Clinical Public Health, University of Toronto

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<sup>753</sup> Nuffield Council on Bioethics (2020) *Research in global health emergencies: literature reviews*, available at: <https://nuffieldbioethics.org/publications/research-in-global-health-emergencies/evidence>.



- **Michael Van Rooyen**, Director, Harvard Humanitarian Initiative
- **Bartholomew Wilson**, PREVAIL, Liberia

## Appendix 2: Wider consultation for the report

### Call for evidence: overview

The working group's call for evidence was launched on 20 June 2018 and remained open until 17 August 2018. Extended deadlines were available to respondents who could not respond before that date. We received 58 responses to the questions set out in this document: 44 from individuals; 14 from organisations. A summary of respondents' submissions is available on the Nuffield Council's website.

### Questions posed

The call for evidence invited respondents to comment on 27 questions, which were divided into eight sections.

#### **Section 1: what constitutes a 'global health emergency'?**

**Question 1:** Please comment on this working definition of a global health emergency.

**Question 2:** What might be the ethical implications of defining global health emergencies in this (or other) ways?

#### **Section 2: undertaking research in a global health emergency: whose voices should be heard?**

**Question 3:** Please provide examples of how, despite the urgency and pressure of other aspects of immediate humanitarian response, national governments, local researchers, and affected populations have genuinely been 'at the table' in setting research priorities in a global health emergency.

**Question 4:** Please comment on what you believe are the essential aspects of community engagement in an emergency, their ethical justification, and how these can they be achieved.

**Question 5:** Are there *any* circumstances in which research might be so important, and time so short, that this could outweigh the need for local voices to be heard?

#### **Section 3: study design and review**

**Question 6:** In your view, in what ways, if at all, should decisions about study design and acceptable risk be affected by the fact that the research will be taking place in a global health emergency? On what basis would you justify any variation?

**Question 7:** In what ways, if at all, could it be morally justifiable to change the 'standard' ethical and regulatory review processes to respond to the time pressures inherent in a global health emergency?

**Question 8:** If any differences in approach to study design or review can be justified because of the features of a global health emergency, would safeguards, such as an independent declaration that 'emergency' criteria have been met, be necessary?

**Question 9:** When choosing a study design, is it ever justifiable to prioritise a design that will maximise knowledge and hence scope for benefit for future generations, over a design that maximises the possibility of benefit for people affected by the current emergency; or could this never be justified? On what ethical basis would you justify such a choice?

**Question 10:** Are there any specific kinds of research or innovation that, in your view, raise distinct ethical questions and/or might demand differential ethical treatment?

#### **Section 4: making decisions about participation in research**

**Question 11:** Are you aware of any examples of when an emergency seemed to demand a different approach to making decisions about research participation? If so, please explain how any derogation from standard approaches might be ethically justified, and the relevance of the kind of research concerned (for example research involving physical intervention as opposed to research involving data only).

**Question 12:** If we consider the giving of valid consent as one element in the 'ethical ecosystem' around research in emergencies, and recognise too that consent is often imperfect, what are the other essential elements of the ecosystem necessary for such decision-making to be considered legitimate?

**Question 13:** Are there any circumstances in which participation in research should not be optional?

#### **Section 5: duties at the interface of research, treatment, and public health**

**Question 14:** What, in your experience, are the main ethical challenges that arise as a result of uncertainties in the boundaries between treatment, research, evaluation, and public health? To what extent are these associated with logistical or resource constraints?

**Question 15:** Is it possible to create a meaningful distinction between the collection of personal data for public health purposes, and for research purposes? What does this mean for consent and for data-sharing?

**Question 16:** How could a more coherent approach to the complex relationships between research and other essential services in a global health emergency be developed, so that front-line workers are supported by ethical guidance that reflects the realities they face?

**Question 17:** In the alternative, do you think that there are ethical justifications for maintaining clear distinctions between the activities of 'research', 'health care' and 'public health interventions' in a global health emergency? If so, what are they?

#### **Section 6: obligations to / expectations of front-line research staff**

**Question 18:** Do the exigencies of global health emergencies (for example levels of risk, security requirements, extremity of humanitarian need, rapidity of response) change the obligations on, and expectations of, front-line research staff in any way?

**Question 19:** What constitutes fair treatment of both local and expatriate front-line research staff, and who is responsible for ensuring that they receive such treatment? Can differential treatment ever be justified?

**Question 20:** What mechanisms are there, or should there be, to help ensure that obligations to front-line research staff are honoured?

**Question 21:** What ethical responsibilities do front-line research staff in emergencies themselves hold?

## **Section 7: what are the challenges of effective collaboration in global health emergencies?**

**Question 22:** Can you provide examples of where collaboration has worked well in enabling valuable research to take place in global health emergencies? What were the key success factors?

**Question 23:** Can you give any practical examples of ways in which ethical concerns have impeded successful collaboration in research? What would have helped resolve them?

**Question 24:** Can there be said to be an ethical obligation to work collaboratively rather than competitively in the context of global health emergencies? What might such an obligation entail and what are its limits?

**Question 25:** What are the obligations of funders to promote collaboration in a global health emergency?

**Question 26:** What are the key requirements for good ethical practice in sharing (a) data and (b) samples in a global health emergency?

## **Section 8: other issues / considerations**

**Question 27:** Are there any other ethical issues arising in the context of research in global health emergencies that you would like to draw to the working group's attention?

## **List of respondents to the call for evidence**

### **Organisations (14)**

- *Anonymous (2)*
- Animals in Science Committee (ASC)
- Health Research Authority
- Humanitarian Health Ethics Research Group
- Institute of Tropical Medicine (ITM), Antwerp, Belgium: Raffaella Ravinetto, Chair of the Institutional Review Board; Marianne van der Sande, Head of the Public Health Department; Anne Buvé, Vice-Chair of the Institutional Review Board
- Myriam Henkens, Clair Mills and Greg Elder, on behalf of Médecins Sans Frontières (MSF); Raffaella Ravinetto, Lisa Schwartz, Ross Upshur, and Grace Ku, on behalf of the MSF Ethics Review Board (MSF ERB)
- Network of Ethics Committee Members in West Africa
- Prof Alistair Nichol (lead), Prasanth Sukumar, J-P Byrne, Nina Gobat on behalf of PREPARE WP1
- REACTing (Research and ACTION targeting infectious diseases), Inserm, France
- The Ethics, Community Engagement and Patient Advisory (ECEPAS) Working Group of the Global Emerging Pathogens Treatment (GET) Consortium
- UK Research and Innovation
- Wellcome

- Members of staff of WHO Geneva, responding in a personal capacity

## Individuals (44)

- *Anonymous (4)*
- Dr Rosmond Adams, Caribbean Public Health Agency (CARPHA)
- Dr Alpha Ahmadou Diallo, Ministry of Health, Guinea - Conakry
- Rima Afifi, Professor, College of Public Health, University of Iowa; and adjunct professor, Faculty of Health Sciences, American University of Beirut
- Grace Akello, PhD: Gulu University, Faculty of Medicine
- William Aldis, Office of International Programs, Faculty of Public Health, Thammasat University (Thailand)
- Arsenii Alenichev, The University of Amsterdam
- Jackeline Alger MD, PhD, Facultad de Ciencias Médicas, UNAH
- Tim Allen, London School of Economics and Political Science
- Dr Najeeb Al-Shorbaji, Consultant
- Dr Joseph Kimuli Balikuddembe, Institute for Disaster Management and Reconstruction, Sichuan University, China and Hong Kong Polytechnic University
- Ruchi Baxi
- Associate Professor Jantina de Vries, Department of Medicine, University of Cape Town
- Wissam Doudar - Freelance Consultant (Health, Protection and Refugees)
- Seydou Doumbia, Faculty of Medicine & University Clinical Research Center, University of Sciences, Techniques and Technology of Bamako, Mali
- Professor Rita Giacaman, Institute of Community and Public Health, Birzeit University, Palestine
- Professor Robin Gill
- Professor Stephen Gordon, MLW, Malawi
- Bridget Haire, Kirby Institute, UNSW Sydney, Australia
- Ms. Tausi S. Haruna (BscN, RN, Masters in Bioethics), Hubert Kairuki Memorial University (HKMU) Tanzania
- Lt Col Simon Horne
- Instituto Aggeu Magalhães- Fiocruz-PE, Brazil; Federal University of Pernambuco, Pernambuco, Brazil; MERG - Microcephaly Epidemic Research Group
- Olivia Keiser, University of Geneva
- Ann H. Kelly, Department of Global Health & Social Justice, King's College London
- Dr Adèle Langlois
- Jihad Makhoul, American University of Beirut
- Gillian McKay
- Amit Mistry, US National Institutes of Health
- David B. Morton (Professor Emeritus, University of Birmingham, UK)
- Dr Olive Marie-Nicole Ngaba Mballa Epse Mambo Pouka, Head of Unit for Scientific Network and Promotion of Ethics / DROS / Ministry of Public Health, Cameroon; Mr Nicolas Obam, CA1 CRSPE / DROS; Mr Jean Marie Fouda, CRC / DROS Minsante
- Dr Ana Raquel Nunes, Warwick Medical School, University of Warwick
- Morenike Oluwatoyin Folayan, Obafemi Awolowo University, Ile-Ife, Nigeria
- Dónal O'Mathúna, PhD
- Annette Rid, King's College London
- Dr Cathy Roth, Senior Research Fellow - Infectious Diseases, Department for International Development, UK, responding in a personal capacity
- Dr Anuradha Rose
- Katherine Sahan, Ethox Centre and Wellcome Centre for Ethics and Humanities

- Professor Doris Schroeder and Dr Kate Chatfield, Centre for Professional Ethics, University of Central Lancashire, Co-ordinator of the TRUST project
- Ernest Tambo, Africa Disease Intelligence and Response Institute & Université des Montagnes, Bangangte, Cameroon
- Barthalomew Wilson, PREVAIL
- Haihong Zhang, Peking University Health Science Center

### **Published material submissions**

The working group also received submissions of published materials from Morenike Oluwatoyin Folayan, and Alex John London.



## Appendix 3: Emergency definitions

This appendix does not attempt to represent a full review of definitions of ‘emergency’ or ‘disaster’. Rather it provides a set of illustrative examples of the approaches of organisations, states, and the humanitarian sector.

### Definitions of emergencies by organisations

#### The World Health Organization (WHO)

The WHO’s definition for a public health emergency of international concern (PHEIC) follows a definition set out in the 2005 International Health Regulations (IHR). The IHR states that a PHEIC is “an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response”.<sup>754</sup>

The WHO indicates that this definition “implies a situation that is:

- serious, sudden, unusual, or unexpected;
- carries implications for public health beyond the affected State’s national border; and
- may require immediate international action.”<sup>755</sup>

There are also four subparts of WHO’s grading system for defining emergencies.<sup>756</sup>

- **Ungraded:** “an event that is being assessed, tracked or monitored by WHO but that requires no WHO response at the time.”
- **Grade 1:** a single or multiple country event with minimal public health consequences that requires a minimal WCO [WHO country office] response or a minimal international WHO response. Organizational and/or external support required by the WCO is minimal. The provision of support to the WCO is coordinated by a focal point in the regional office.”
- **Grade 2:** a single or multiple country event with moderate public health consequences that requires a moderate WCO response and/or moderate international WHO response. Organizational and/or external support required by the WCO is moderate. An Emergency Support Team, run out of the regional office, coordinates the provision of support to the WCO.”
- **Grade 3:** a single or multiple country event with substantial public health consequences that requires a substantial WCO response and/or substantial international WHO response. Organizational and/or external support required by the WCO is substantial. An Emergency Support Team, run out of the regional office, coordinates the provision of support to the WCO.”

#### UN Refugee Agency (UNHCR)

UNHCR holds that a humanitarian emergency is “any situation in which lives, rights or well-being of refugees, internally displaced people, asylum-seekers or stateless people are threatened unless immediate action is taken; and which demands extraordinary

<sup>754</sup> WHO (2005) *International Health Regulations*, available at: <https://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf;jsessionid=B759FA6F00C9B6678A5319EDD15B4A25?sequence=1>, at page 9.

<sup>755</sup> WHO (2016) *International Health Regulations and Emergency Committee*, available at: <https://www.who.int/features/qa/emergency-committees/en/>.

<sup>756</sup> WHO (2013) *Emergency response framework*, available at: [https://www.who.int/hac/about/erf\\_.pdf](https://www.who.int/hac/about/erf_.pdf), at 2.2.1.

measures because current UNHCR capacities at country and regional level are insufficient. UNHCR declares an emergency to ensure that, together with its partners, appropriate attention and support are provided when they prepare for and respond to potential, unfolding or escalating emergencies.<sup>757</sup> The organisation has also highlighted the likely characteristics that complex emergencies could include:

- “A large number of civilian victims, populations who are besieged or displaced, human suffering on a major scale;
- Substantial international assistance is needed and the response goes beyond the mandate or capacity of any one agency;
- Delivery of humanitarian assistance is impeded or prevented by parties to the conflict;
- High security risks for relief workers providing humanitarian assistance;
- Relief workers targeted by parties to the conflict.”<sup>758</sup>

In addition, UNHCR sets out levels of emergency:<sup>759</sup>

- **Emergency level 1 – proactive preparedness:** “is activated when a country operation must prepare actively for a likely humanitarian emergency but faces such significant gaps in resources, staffing or expertise that it is unable to plan or implement preparedness actions for a high risk emergency scenario. Activation triggers support by the Regional Bureau, the Division of Emergency, Security and Supply (DESS) and other divisions. Support may include preparedness missions and initiatives to raise human, financial and material resources.”
- **Emergency level 2 – stepped-up Bureau support:** “is activated when an operation requires additional support and resources, mainly from the relevant Regional Bureau, in order to respond in a timely and effective manner.”
- **Emergency level 3 – whole-of-UNHCR response:** “is activated in exceptionally serious situations in which the scale, pace, complexity or consequences of the crisis exceed the existing response capacities of both the relevant country operation(s) and Regional Bureau(x), and require a corporate, whole-of-UNHCR response.”

### The UN Office for Disaster Risk Reduction (UNDRR)

UNDRR – formerly UNISDR – defines a ‘disaster’ as “a serious disruption of the functioning of a community or a society at any scale due to hazardous events interacting with conditions of exposure, vulnerability and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts.” It notes that ‘emergency’ “is sometimes used interchangeably with the term disaster, as, for example, in the context of biological and technological hazards or health emergencies, which, however, can also relate to hazardous events that do not result in the serious disruption of the functioning of a community or society.”<sup>760</sup>

### UN Inter-Agency Standing Committee (IASC)

The IASC defines ‘complex emergencies’ as:

- a) “A humanitarian crisis which occurs in a country, region, or society where there is a total or considerable breakdown of authority resulting from civil conflict and/or foreign aggression;

<sup>757</sup> UNHCR (2017) *UNHCR’s new emergency policy*, available at: <https://www.refworld.org/pdfid/59d4d5354.pdf>.

<sup>758</sup> UNHCR (2001) *Coordination in complex emergencies*, available at: <https://www.unhcr.org/uk/partners/partners/3ba88e7c6/coordination-complex-emergencies.html>.

<sup>759</sup> UNHCR (2017) *Policy on emergency preparedness and response*, available at: <https://emergency.unhcr.org/entry/262881/policy-on-emergency-preparedness-and-response>.

<sup>760</sup> UNISDR (2017) *Terminology on disaster risk reduction*, available at: <https://www.unisdr.org/we/inform/terminology#letter-d>.

- b) A humanitarian crisis which requires an international response which goes beyond the mandate or capacity of any single agency;
- c) A humanitarian crisis where the IASC assesses that it requires intensive and extensive political and management coordination.”<sup>761</sup>

### Intergovernmental Panel on Climate Change (IPCC)

The IPCC defines disasters as “Severe alterations in the normal functioning of a community or a society due to hazardous physical events interacting with vulnerable social conditions, leading to widespread adverse human, material, economic, or environmental effects that require immediate emergency response to satisfy critical human needs and that may require external support for recovery.”<sup>762</sup>

### Definitions of emergencies / disasters by states

Countries also define emergencies that affect their citizens in a variety of ways. These definitions may be set out for financial (e.g., in order to release funding) or health security reasons. A selection of countries’ definitions is set out below.

#### Australia

The Australian Institute for Disaster Resilience – established by the Australian Government – defines a disaster as “a serious disruption of the functioning of a community or a society at any scale due to the hazardous events in interacting with conditions of exposure, vulnerability, and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts. The effect of the disaster can be immediate and localized, but it is often widespread and could last for a long period of time. The effect may test or exceed the capacity of a community or society to cope using its own resources, and therefore may require assistance from external sources, which could include neighbouring jurisdictions, or those at the national or international levels.”<sup>763</sup> The Institute also defines an emergency as “an event, actual or imminent, which endangers or threatens to endanger life, property or the environment, and which requires a significant and coordinated response.”<sup>764</sup>

#### Canada

The Emergencies Act defines an ‘international emergency’ as one which involves Canada “and one or more other countries that arises from acts of intimidation or coercion or the real or imminent use of serious force or violence and that is so serious as to be a national emergency.”<sup>765</sup> A ‘national emergency’ is defined as “an urgent and critical situation of a temporary nature that (a) seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it, or (b) seriously threatens the ability of the

<sup>761</sup> IASC (1994) *Definition of complex emergencies*, available at: [https://interagencystandingcommittee.org/system/files/legacy\\_files/WG16\\_4.pdf](https://interagencystandingcommittee.org/system/files/legacy_files/WG16_4.pdf).

<sup>762</sup> IPCC (2018) *Managing the risks of extreme events and disasters to advance climate change adaptation*, available at: [https://www.ipcc.ch/site/assets/uploads/2018/03/SREX\\_Full\\_Report-1.pdf](https://www.ipcc.ch/site/assets/uploads/2018/03/SREX_Full_Report-1.pdf), at page 5.

<sup>763</sup> Australian Institute for Disaster Resilience (2019) *Knowledge hub: Australian disaster resilience glossary*, available at: <https://knowledge.aidr.org.au/glossary/?wordOfTheDayId=&keywords=&alpha=D&page=3&results=50&order=AZ>.

<sup>764</sup> *ibid.*

<sup>765</sup> *Section 27, Emergencies Act (RSC 1985, c22 (4<sup>th</sup> Supplement))*, available at: <https://laws-lois.justice.gc.ca/eng/acts/e-4.5/page-3.html#h-214010>.

Government of Canada to preserve the sovereignty, security and territorial integrity of Canada”.<sup>766</sup>

### **Cuba**

In 1966, Cuba passed legislation which brought about the formation of the Cuban National Civil Defense (DCN). In 1976, the Cuban Government issued a mandate that required all Cuban adults to receive civil defence training. In 1997, Legal Decree 170 was passed. It describes the role of the country’s ministries, social organisations, and public bodies when emergencies occur, including the use of their resources. It particularly describes the goal of protecting the Cuban population, economy, and environment from the effects of natural disasters through prevention, preparedness, and response.<sup>767</sup> Cuba’s approach to disaster management has been praised by international organisation such as the UN, Red Cross, and Oxfam.<sup>768</sup>

### **India**

India’s Disaster Management Act 2005 defines a ‘disaster’ as “a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man made causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area”.<sup>769</sup> India’s ICMR (see also Appendix 4) also sets out a definition of a humanitarian emergency or disaster and states that it is “an event or series of events that represents a critical threat to the health, safety, security or well-being of a community or other large group of people, usually covering a wide land area... humanitarian emergencies and disasters include both man-made and natural ones, some of which occur at periodic frequency.”<sup>770</sup>

### **South Africa**

The South African Disaster Management Act 2002 defines a ‘disaster’ as follows:

“‘disaster’ means a progressive or sudden, widespread or localised, natural or human-caused occurrence which –

- (a) causes or threatens to cause –
  - (i) *Death, injury or disease;*
  - (ii) *Damage to property, infrastructure or the environment; or*
  - (iii) *Disruption to the life of a community; and*
- (b) is of a magnitude that exceeds the ability of those affected by the disaster to cope with its effects using only their own resources”.

### **US**

“‘Emergency’ means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and

<sup>766</sup> Sections 3(a) and 3(b), *Emergencies Act (RSC 1985, c22 (4<sup>th</sup> Supplement))*, available at: <https://laws-lois.justice.gc.ca/eng/acts/e-4.5/page-1.html#h-213805>.

<sup>767</sup> Oxfam America (2004) *Cuba: weathering the storm - lessons in risk reduction from Cuba*, available at: <https://www.eird.org/isdr-biblio/PDF/Cuba%20Weathering.pdf>.

<sup>768</sup> Kirk EJ (2017) Alternatives - dealing with the perfect storm: Cuban disaster management *Studies in Political Economy* **98(1)**: 93-103.

<sup>769</sup> Section 2(d) *The Disaster Management Act (2005)*, available at: <https://www.ndmindia.nic.in/images/The%20Disaster%20Management%20Act,%202005.pdf>.

<sup>770</sup> Indian Council of Medical Research (2017) *National ethical guidelines for biomedical and health research involving human participants*, available at: [https://icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf), at 12.0.

capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of catastrophe in any part of the United States.”<sup>771</sup>

### Definitions by the humanitarian sector

The humanitarian sector has a number of definitions for ‘emergencies’ or ‘disasters’ (sometimes referred to as ‘complex emergencies’). Examples are set out below.

#### Centre for Research on the Epidemiology of Disaster

Defines a disaster as “a situation or event that overwhelms local capacity, necessitating a request at the national or international level for external assistance; an unforeseen and often sudden event that causes great damage, destruction and human suffering.”<sup>772</sup>

#### Disasters Emergency Committee

“[A] disaster must be on such a scale and of such urgency as to call for swift international humanitarian assistance.”<sup>773</sup>

#### International Federation of Red Cross and Red Crescent Societies

A disaster “is a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community’s or society’s ability to cope using its own resources. Though often caused by nature, disasters can have human origins.”<sup>774</sup> The organisation also defines a ‘hazard’ – encompassing natural, technological, or manmade hazards – as a “threatening event, or probability of an occurrence of a potentially damaging phenomenon within a given time period and area.”<sup>775</sup>

#### World Vision

“[A] humanitarian disaster occurs when the human, physical, economic or environmental damage from an event, or series of events, overwhelms a community’s capacity to cope.”<sup>776</sup>

<sup>771</sup> US Code (2009) *Title 42, chapter 15, section 5122*, available at: <https://www.govinfo.gov/content/pkg/USCODE-2009-title42/pdf/USCODE-2009-title42-chap68-subchapl-sec5122.pdf>.

<sup>772</sup> CRED (2018) *Natural disasters*, available at: <https://www.cred.be/sites/default/files/CREDNaturalDisaster2018.pdf>.

<sup>773</sup> DEC (2019) *When we launch an appeal: appeal criteria*, available at: <https://www.dec.org.uk/article/when-we-launch-an-appeal>.

<sup>774</sup> IFRC (2019) *What is a disaster?*, available at: <https://www.ifrc.org/en/what-we-do/disaster-management/about-disasters/what-is-a-disaster/>.

<sup>775</sup> IFRC (2019) *Types of disaster: definition of hazard*, available at: <https://www.ifrc.org/en/what-we-do/disaster-management/about-disasters/definition-of-hazard/>.

<sup>776</sup> World Vision (2019) *What is a humanitarian disaster?*, available at: <https://www.wvi.org/disaster-management/what-humanitarian-disaster>.

## Appendix 4: Examples of ethical and regulatory approaches

The information set out in this appendix cannot represent a full review of these approaches. Rather it provides a set of illustrative examples of the approaches of states, regulators, government departments, and NGOs.

### Research guidance / codes of practice examples

Source	Guidance overview
<b>Action contre la Faim</b> <sup>777</sup>	Introduces six ethics principles to support its research activities, including the stipulation that ACF research should be responsive to the needs of vulnerable people, ethically justified and scientifically valid, and culturally sensitive. The research should also promote capacity strengthening in host countries, make an effort to ensure research results are shared widely, and avoid research bias.
<b>Australian Council for International Development</b> <sup>778</sup>	The ACFID guidelines for ethical research are underpinned by four core values: respect for human beings, beneficence, research merit and integrity, and justice. The guidelines also set out a range of questions for researchers to consider when planning their research.
<b>Canada</b> <sup>779</sup>	In 2019, three Canadian research councils – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council – launched the second edition of a policy statement on ethical conduct for research involving humans. Guidelines contained in the document are underpinned by three core principles: respect for persons, concern for welfare, and justice.
<b>Council for International Organizations of Medical Sciences</b> <sup>780</sup>	With WHO, CIOMS publishes ethical guidelines for health-related research involving humans. The guidelines extend to observational research, clinical trials, biobanking, and epidemiological studies. Guideline 20 specifically relates to research in disasters and disease outbreaks.
<b>Department for International</b>	DfID has set out ten ethics principles for research and evaluation that must be upheld for all such activity that the Department conducts or funds.

<sup>777</sup> Action contre la Faim (2018) *ACF ethics and research: principles and guidelines*, available at: [https://www.actioncontrelafaim.org/wp-content/uploads/2018/01/ethics\\_guidelines.pdf](https://www.actioncontrelafaim.org/wp-content/uploads/2018/01/ethics_guidelines.pdf).

<sup>778</sup> Australian Council for International Development (2017) *Principles and guidelines for ethical research and evaluation in development*, available at: [https://acfid.asn.au/sites/site.acfid/files/resource\\_document/ACFID\\_RDI%20Principles%20and%20Guidelines%20for%20ethical%20research12-07-2017.pdf](https://acfid.asn.au/sites/site.acfid/files/resource_document/ACFID_RDI%20Principles%20and%20Guidelines%20for%20ethical%20research12-07-2017.pdf), pp4-5, and page 12.

<sup>779</sup> Government of Canada (2018) *Tri-Council policy statement: ethical conduct for research involving humans*, available at: <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>, at page 6.

<sup>780</sup> CIOMS (2016) *International ethical guidelines for health-related research involving humans*, available at: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>.



**Development (UK)<sup>781</sup>**

- 1) Researchers and evaluators are responsible for identifying the need for and securing any necessary ethics approval for the study they are undertaking.
- 2) Research and evaluation must be relevant and high quality with clear developments and practical value.
- 3) Researchers and evaluators should avoid harm to participants in studies.
- 4) Participation in research and evaluation should be voluntary and free from external pressure.
- 5) Researchers and evaluators should ensure confidentiality of information, privacy and anonymity of study participants.
- 6) Researchers and evaluators should operate in accordance with international human rights conventions and covenants to which the United Kingdom is a signatory, regardless of local country standards.
- 7) DfID funded research and evaluation should respect cultural sensitivities.
- 8) DfID is committed to publication and communication of all evaluations and research studies.
- 9) Research and evaluation should usually be independent of those implementing an intervention or programme under study.
- 10) All DfID funded research / evaluation should have particular emphasis on ensuring participation from women and socially excluded groups.

**Médecins Sans Frontières<sup>782</sup>**

MSF's research ethics framework sets out 12 questions to help MSF researchers and ERB members in their deliberations about ethical issues. The questions are divided into three sections: research question and methodology; respecting and protecting research participants and communities; and implications and implementation of the research findings.

**Oxfam<sup>783</sup>**

Oxfam sets out minimum ethical standards required for all the research it conducts or commissions. The charity identified three principles of research ethics:

- Respect: the researcher must recognise the capacity and rights of all individuals to make their own choices and decisions, and their right to be treated with dignity;
- Beneficence: the researcher's primary goal must be to improve the lives of participants and protect their physical, mental and social well-being; and
- Justice: the researchers must ensure that the benefits for participants are at least as great as the risks.

<sup>781</sup> DfID (2011) *DfID ethics principles for research and evaluation*, available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/67483/dfid-ethics-prcpls-rsrch-eval.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67483/dfid-ethics-prcpls-rsrch-eval.pdf).

<sup>782</sup> MSF (2018) *MSF research ethics framework: guidance document*, available at: [http://fieldresearch.msf.org/msf/bitstream/10144/305288/5/MSF+Research+Ethics+Framework\\_Guidance+document+%28Dec2013%29.pdf](http://fieldresearch.msf.org/msf/bitstream/10144/305288/5/MSF+Research+Ethics+Framework_Guidance+document+%28Dec2013%29.pdf).

<sup>783</sup> Oxfam (2012) *Undertaking research with ethics*, available at: <https://oxfamlibrary.openrepository.com/bitstream/handle/10546/253032/ml-guideline-undertaking-research-ethics-221112-en.pdf;jsessionid=332A859C3E3267BE76532C46DAB536BB?sequence=1>.

<b>Trust Equitable Research Partnerships</b> <sup>784</sup>	TRUST have published a global code of conduct for research in resource-poor settings with guidance under four headings: fairness, respect, care, and honesty. Specific requirements include local relevance of research, engagement with communities and participants throughout the research process, respect for cultural sensitivities and requirements, local ethics review wherever possible, and clarity over respective roles within research collaborations.
<b>UNICEF</b> <sup>785</sup>	UNICEF has set out a procedure for ethical standards in research, evaluation, data collection, and analysis. The procedure builds on the organisation's pre-existing guidance on institutionalising ethical practice.
<b>World Medical Association</b> <sup>786</sup>	The WMA's Declaration of Helsinki sets out ethical principles for medical research with people, including research on identifiable human material and data. It is primarily addressed to doctors. Requirements include: that the importance of the research must outweigh the risks / burdens borne by participants; that research should be voluntary and based on informed consent; and that research should be independently scrutinised. There is no specific reference to emergencies.

## Guidance specific to disaster / emergency settings

Source	Guidance overview
<b>Action contre la Faim</b> <sup>787</sup>	Principles and guidelines set out by ACF make the following statement about research in emergencies:  "It should be stressed that research in emergency settings should be avoided as the researchers are unlikely to be able to guarantee fully the basic bioethics principle in relation to the target population. If, however, the researchers deem necessary that research should take place in an emergency context, they should provide concrete arguments for their choice on the emergency setting. They will be asked to communicate these arguments to the ACF Research Department in charge of the research before any decision to implement the research."
<b>Canada</b> <sup>788</sup>	Three Canadian research councils' (see above) statement on ethical conduct for research involving humans includes an article on preparedness plans for research ethics review during publicly-

<sup>784</sup> TRUST (2018) *Global code of conduct for research in resource-poor settings*, available at: <http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf>.

<sup>785</sup> UNICEF (2015) *UNICEF procedure for ethical standards in research, evaluation, data collection and analysis*, available at: [https://www.unicef.org/supply/files/ATTACHMENT\\_IV-UNICEF\\_Procedure\\_for\\_Ethical\\_Standards.PDF](https://www.unicef.org/supply/files/ATTACHMENT_IV-UNICEF_Procedure_for_Ethical_Standards.PDF). For the pre-existing guidance, see: UNICEF (2013) *Strategic guidance note on institutionalizing ethical practice for UNICEF research*, available at: <https://www.ungm.org/UNUser/Documents/DownloadPublicDocument?docId=826374>.

<sup>786</sup> World Medical Association (2013) *Declaration of Helsinki*, available at: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.

<sup>787</sup> Action contre la Faim (2018) *ACF ethics and research: principles and guidelines*, available at: [https://www.actioncontrelafaim.org/wp-content/uploads/2018/01/ethics\\_guidelines.pdf](https://www.actioncontrelafaim.org/wp-content/uploads/2018/01/ethics_guidelines.pdf), at page 20.

<sup>788</sup> Government of Canada (2018) *Tri-Council policy statement: ethical conduct for research involving humans*, available at: <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>.

**Centers for Disease Control and Prevention (CDC)<sup>789</sup>**

declared emergencies (Article 6.21) and a further article on research ethics review policy and procedures during publicly-declared emergencies (Article 6.22).

A report prepared for the CDC's Ethics Subcommittee provides ethics guidance for public health emergency preparedness and response. It includes a list of key points that should be taken into consideration for public health research undertaken during or immediately after disaster events.

**Elrha<sup>790</sup>**

Elrha has set out an ethical framework for research on health interventions in emergencies. The framework is designed as a tool that offers "a practical and easily implementable approach in which key ethical principles are considered in a clustered, hierarchical order." The clusters – in the order of which ELRHA states that they should be considered – are:

- Scientific requirement to conduct protocol in emergency setting
- Clear articulation of benefits / risks / harms
- Protocol design: scientific validity / feasibility
- Research focus: relative priority
- Team strength: competence / collaborative structure
- Declared interests
- Quality of community engagement
- Respect for cultural context / norms / values
- Community and individual benefit
- Confidentiality / data security
- Informed consent

**Indian Council of Medical Research<sup>791</sup>**

How research is undertaken during humanitarian emergencies and disasters forms a section of ICMR's ethical guidelines for research. It includes guidance on preparedness, informed consent, equitable distribution of benefits and risks, privacy and confidentiality, ethics review procedures, and post-research benefit.

**Johns Hopkins<sup>792</sup>**

The Johns Hopkins Berman Institute of Bioethics has published ethics guidance for the public health containment of serious infectious disease outbreaks in low-income settings, following the Ebola outbreak in West Africa. The guidance sets out three guiding ethics principles: respect, justice, and promoting good and

<sup>789</sup> Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (2008) *Ethical guidance for public health emergency preparedness and response: highlighting ethics and values in a vital public health service*, available at: [https://www.cdc.gov/od/science/integrity/phethics/docs/white\\_paper\\_final\\_for\\_website\\_2012\\_4\\_6\\_12\\_final\\_for\\_web\\_508\\_compliant.pdf](https://www.cdc.gov/od/science/integrity/phethics/docs/white_paper_final_for_website_2012_4_6_12_final_for_web_508_compliant.pdf).

<sup>790</sup> Elrha (2014) *An ethical framework for the development and review of health research proposals involving humanitarian contexts*, available at: [http://www.elrha.org/wp-content/uploads/2015/01/FINAL-R2HC-Ethical-Framework\\_Final-Report\\_24-January-2014\\_0.pdf](http://www.elrha.org/wp-content/uploads/2015/01/FINAL-R2HC-Ethical-Framework_Final-Report_24-January-2014_0.pdf). This framework was later subject to review, which suggested five 'points of departure' from this framework. See: Elrha (2017) *Review and revision of the Research for Humanitarian Crises (R2HC) ethics framework*, available at: <https://www.elrha.org/wp-content/uploads/2018/07/A-Revised-Ethics-Framework-for-the-R2HC.pdf>, at page 20.

<sup>791</sup> Indian Council of Medical Research (2017) *National ethical guidelines for biomedical and health research involving human participants*, available at: [https://icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf), at section 12.

<sup>792</sup> Johns Hopkins Berman Institute of Bioethics (2019) *Ethics guidance for the public health containment of serious infectious disease outbreaks in low-income settings: lessons from Ebola*, available at: [https://bioethics.jhu.edu/wp-content/uploads/2019/03/Ethics20Guidance20for20Public20Health20Containment20Lessons20from20Ebola\\_April2019.pdf](https://bioethics.jhu.edu/wp-content/uploads/2019/03/Ethics20Guidance20for20Public20Health20Containment20Lessons20from20Ebola_April2019.pdf).

**UN Inter-  
Agency  
Standing  
Committee<sup>793</sup>**

preventing harm. The guidance applies these principles to eight key aspects of public health containment of outbreaks in low-income settings including community interactions, supporting responders, and providing care and treatment.

The IASC has set out recommendations for conducting ethical mental health and psychosocial research in emergency settings that apply to any systematic collection and analysis of data, including needs assessment. They emphasise the importance of direct benefit to affected communities; meaningful participation of local stakeholders in research design, conduct and dissemination; and robust informed consent processes based on respectful relationships.

**WHO<sup>794</sup>**

WHO's guidance on managing ethical issues in infectious disease outbreaks includes a chapter on research emphasising the importance of close cooperation with the public health response; the role of local research institutions and the creation of trusting relationships with local communities; the importance of flexible and timely review procedures; the challenges to meaningful informed consent; and the necessity of ensuring access to research benefits.

<sup>793</sup> IASC (2014) *Recommendations for conducting ethical mental health and psychosocial research in emergency settings*, available at: [https://interagencystandingcommittee.org/system/files/1.\\_iasc\\_recommendations\\_for\\_ethical\\_mhpss\\_research\\_in\\_emergency\\_settings\\_0.pdf](https://interagencystandingcommittee.org/system/files/1._iasc_recommendations_for_ethical_mhpss_research_in_emergency_settings_0.pdf).

<sup>794</sup> WHO (2010) *Research ethics in international epidemic response: WHO technical consultation*, available at: <http://apps.who.int/iris/handle/10665/70739>.

## Appendix 5: The working group

**Michael Parker** (Chair) is the Director of the Wellcome Centre for Ethics and Humanities and the Ethox Centre at the University of Oxford. His main research interest is in the ethics of collaborative global health research. Together with partners at the Wellcome Africa and Asia Programmes based in Vietnam, Malawi, Thailand, Kenya, and South Africa he established the Global Health Bioethics Network which aims to conduct ethics research and build ethics capacity across the Africa and Asia Programmes. The Network is funded by a Wellcome Strategic Award.

**Sanjoy Bhattacharya** is a Professor in the History of Medicine, Director of the Centre for Global Health Histories, and Director of the WHO Collaborating Centre for Global Health Histories at the University of York. He studied at the University of Delhi (India), Jawaharlal Nehru University (New Delhi, India) and the School of Oriental and African Studies (London, UK). He is a Wellcome Trust Senior Investigator working on the history and contemporary workings of Primary Health Care and the provision of Universal Health Coverage in South Asia. Sanjoy also continues to work on the histories of the worldwide eradication of smallpox, and the migration, experiences and contribution of South Asian doctors in the UK's National Health Service.

**Karl Blanchet** is a Professor at the Faculty of Medicine, University of Geneva, and Director of the Centre for Education and Research in Humanitarian Action (CERAH) in Geneva. Karl currently works in Afghanistan, Lebanon, Jordan and Kenya.

**Simon Caney** is a Council member, and a Professor in Political Theory, University of Warwick. His research interests are in contemporary political philosophy, and in particular global justice, environmental justice and responsibilities to future generations. He was formerly a member of the Council's working party on *Biofuels: ethical issues*.

**Emily Ying Yang Chan** is a Professor and Assistant Dean (Development) at the Faculty of Medicine, Chinese University of Hong Kong; Director of the Collaborating Centre for Oxford University and CUHK for Disaster and Medical Humanitarian Response (CCOUC); Visiting Professor, Oxford University Nuffield Department of Medicine; and Visiting Scholar, FXB Center, Harvard University. Her research interests include disaster and humanitarian medicine, climate change and health, global and planetary health, remote rural health, Human Health Security and Health Emergency and Disaster Risk Management (H-EDRM), and ethnic minority health. In addition to publishing widely on these issues in international peer-reviewed journals, Emily has also had extensive experience as a front-line emergency relief practitioner across 20 countries during the mid-1990s. She is currently Co-chairperson, WHO Thematic Platform for H-EDRM Research Network and a member of the Asia Science Technology and Academia Advisory Group (ASTAAG).

**Beatriz da Costa Thomé** is a paediatrician trained at the Medical School of the Federal University of São Paulo, Brazil, with a Masters in Public Health with focus on Global Health from the University of Washington. Previous roles have included the provision of technical support for HIV research in Kenya and Mozambique (based in ICAP, Columbia University); work as an investigator in vaccine trials in Brazil and as a Clinical Research and Development manager at Butantan Institute, São Paulo, with focus on developing vaccines for the national public health system. Currently affiliated to the Preventive Medicine Department of the Federal University of São Paulo, Brazil, teaching Epidemiology and mentoring medical students.

**Philippe Guérin** is a medical doctor specialising in public health. He is currently Professor of Epidemiology and Global Health at the Centre for Tropical Medicine and Global Health, University of Oxford, and leads an international project, the Infectious Diseases Data Observatory (IDDO). His research interests focus on the feasibility, challenges and impact of establishing global data platforms for poverty related diseases and emerging infections.

**Julian Hughes** is an old age psychiatrist and philosopher. He was a NHS consultant in old age psychiatry for over 20 years and honorary professor of philosophy of ageing at Newcastle University before moving to be professor of old age psychiatry at the University of Bristol. He has had a particular interest in issues around capacity and consent. He retired from clinical work in 2019 to focus on writing. He remains honorary professor at Bristol and visiting professor at Newcastle. He was formerly Deputy Chair of the Council.

**Patricia Kingori** is Associate Professor and Wellcome Senior Investigator at the University of Oxford. Her primary expertise is in sociology, and her current research interests intersect the sociology of science and medicine, and a critical examination of ethics in practice. She leads the qualitative research capacity-building programme of the Global Health Bioethics Network; her own work focuses on the views, values and experiences of fieldworkers and other front-line research staff involved in collecting data and interacting with research participants. Her research has taken place in various African locations but has recently extended to South East Asia, and includes the experiences of first responders in humanitarian crises, and of local volunteers responsible for cremating those who died from Ebola in West Africa.

**Heidi Larson** is Professor of Anthropology, Risk and Decision Science, Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, and Director of The Vaccine Confidence Project.

**Soka Moses** is a physician at the Ministry of Health, Monrovia, Liberia; and site physician for the Ebola survivor Natural History Cohort Study (PREVAIL III) and Partnership for Ebola Virus Research in Liberia (PREVAIL).

**Sharifah Sekalala** is an Associate Professor in the School of Law at the University of Warwick. Her research focuses on the impact of global health institutions on the developing world. She is also interested in the legal and ethical issues relating to the impacts of migration, climate change, rapid urbanisation and the use of new technologies in delivering health outcomes in resource-constrained settings.

**Julian Sheather** is special adviser in ethics and human rights to the British Medical Association and an ethics adviser to Médecins Sans Frontières. His particular interests lie in health and human rights, medical ethics in times of conflict, humanitarian ethics, public health ethics and mental health and mental capacity. He writes widely on issues in ethics and health, including as a co-author of *Medical Ethics Today*, the BMA's handbook on medical ethics and medical law, and as a regular contributor to the *British Medical Journal* and the *Journal of Medical Ethics*. He also sits on the British Medical Journal's ethics committee.

**Paulina Tindana** is a senior lecturer / bioethicist in the Department of Health Policy, Planning and Management, University of Ghana. Her main research interests lie in understanding the ethical dimensions of international collaborative research, particularly the practical ethical issues arising in genetic / genomic research, informed consent, ethics review, community engagement strategies in global health research and health systems research ethics.



## List of abbreviations

- AAS** – African Academy of Sciences  
**AESA** – Alliance for Accelerating Excellence in Science  
**Africa CDC** – Africa Centres for Disease Control and Prevention  
**AFRO** – WHO Regional Office for Africa  
**ALERRT** – African coalition for Epidemic Research, Response and Training  
**ALIMA** – The Alliance for International Medical Action  
**APPRISE** – Australian Partnership for Preparedness Research on Infectious Disease Emergencies  
**ASEAN** – Association of Southeast Asian Nations  
**AU** – African Union  
**AUB** – American University of Beirut  
**AVAREF** – African Vaccine Regulatory Forum  
**CARPHA** – Caribbean Public Health Agency  
**CCOUC** – Collaborating Centre for Oxford University and CUHK for Disaster and Medical Humanitarian Response  
**CDC** – Centers for Disease Control and Prevention  
**CEPI** – Coalition for Epidemic Preparedness Innovations  
**CERAH** – Centre for Education and Research in Humanitarian Action  
**CIOMS** – Council for International Organizations of Medical Sciences  
**CITI** – Collaborative IRB Training Initiative  
**COHRED** – Council on Health Research for Development  
**COMPARE** – Collaborative Management Platform for Detection and Analyses of (Re-) emerging and Foodborne Outbreaks in Europe  
**CUHK** – Chinese University of Hong Kong  
**DfID** – Department for International Development  
**DOI** – digital object identifier  
**DRC** – Democratic Republic of the Congo  
**DSMB** – Data and Safety Monitoring Board  
**ECEPAS** – Ethics, Community Engagement and Patient Advisory Working Group  
**ECTAD** – Emergency Centre for Transboundary Animal Diseases (ECTAD-RAP: see ‘RAP’)  
**EDCTP** – European and Developing Countries Clinical Trials Partnership  
**EMA** – European Medicines Agency  
**EMRO** – World Health Organization Regional Office for the Eastern Mediterranean  
**EMT** – Emergency Medical Team  
**ETC** – Ebola treatment centre  
**ETU** – Ebola treatment unit  
**EUAL** – emergency use assessment and listing (procedure)  
**EVD** – Ebola virus disease  
**FAO** – Food and Agriculture Organization (UN)  
**FEMA** – Federal Emergency Management Agency  
**FERCAP** – Forum for Ethical Review Committees in the Asian and Western Pacific Region  
**FEWS NET** – the Famine Early Warning Systems Network  
**FGD** – focus group discussion  
**FLACEIS** – Latin American Forum of Ethics Committees in Health Research  
**GCP** – good clinical practice  
**GEER** – Geotechnical Extreme Events Reconnaissance Association  
**GET** – Global Emerging Pathogens Treatment Consortium  
**GFBR** – Global Forum on Bioethics in Research  
**GloPID-R** – Global Research Collaboration for Infectious Disease Preparedness  
**GOARN** – Global Outbreak Alert and Response Network

**H3Africa** – Human Heredity and Health in Africa  
**HEDRM** – Health emergency and disaster risk management  
**HHE** – Humanitarian Health Ethics  
**HIC** – high-income country  
**HIV** – human immunodeficiency virus  
**HPAI** – highly pathogenic avian influenza  
**IASC** – Inter-Agency Standing Committee  
**ICESCR** – International Covenant on Economic Social and Cultural Rights  
**ICCPR** – International Covenant on Civil and Political Rights  
**ICRC** – International Committee of the Red Cross  
**IDDO** – Infectious Diseases Data Observatory  
**IDRC** – International Development Research Centre  
**IFRC** – International Federation of Red Cross and Red Crescent Societies  
**IHR** – International Health Regulations  
**INASP** – International Network for the Availability of Scientific Publications  
**IRC** – International Rescue Committee  
**iRCT** – individual randomized controlled trials  
**IRESSEF** – Institute for Health Research, Epidemiological Surveillance and Training  
**ISARIC** – International Severe Acute Respiratory and Emerging Infection Consortium  
**ITM** – Institute of Tropical Medicine (Antwerp)  
**ITS** – informal tented settlements  
**LIC** – low-income country  
**LMICs** – low- and middle-income countries  
**LSHTM** – London School of Hygiene and Tropical Medicine  
**MERS** – Middle East respiratory syndrome  
**MdM** – Médecins du Monde  
**MEURI** – monitored emergency use of unregistered and investigational interventions  
**MSF** – Médecins Sans Frontières  
**MSF ERB** – Médecins Sans Frontières Ethics Review Board  
**NAS** – National Academies of Science, Engineering, and Medicine  
**NCD** – non-communicable disease  
**NGO** – non-governmental organisation  
**NHRS** – national health research system  
**NIAID** – National Institute of Allergy and Diseases  
**NIH** – National Institutes of Health  
**NREC** – national research ethics committee  
**OCHA** – United Nations Office for the Coordination of Humanitarian Affairs  
**OIE** – World Organisation for Animal Health  
**PACTR** – Pan African Clinical Trials Registry  
**PAHO** – Pan American Health Organization  
**PANDORA-ID-NET** – Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Disease Epidemics  
**PEALS** – Policy, Ethics and Life Sciences (Newcastle University)  
**PHE** – Public Health England  
**PHEIC** – public health emergency of international concern  
**PI** – principal investigator  
**PIP** – Pandemic Influenza Preparedness (Framework – WHO)  
**PPP** – public-private partnership  
**PREA** – Post Research Ethics Analysis  
**PREPARE** – Platform for European Preparedness for (Re-)Emerging Epidemics  
**PREVAIL** – formerly ‘Partnership for Research on Ebola Virus in Liberia’; now ‘Partnership for Research on Vaccines and Infectious Disease in Liberia’  
**PTSD** – post-traumatic stress disorder  
**QMUL** – Queen Mary University of London  
**R2HC** – Research for Health in Humanitarian Crises

- R4HC-MENA** – Research for Health in Conflict – Middle East and North Africa  
**RAP** – Food and Agriculture Organization Regional Office for Asia and the Pacific  
**REACTing** – Research and Action Targeting Infectious Diseases (Inserm)  
**RECAP** – Research Capacity Building and Knowledge Generation to Support Preparedness and Response to Humanitarian Crises and Epidemics  
**RFI** – Research Fairness Initiative  
**rVSV-ZEBOV** – Recombinant vesicular stomatitis virus–Zaire Ebola virus (vaccine)  
**REC** – research ethics committee  
**SARS** – severe acute respiratory syndrome  
**SMC** – Social Mobilisation and Communication committee (PREVAIL – see above)  
**SDGs** – Sustainable Development Goals  
**SEARO** – World Health Organization South-East Asia Regional Office  
**SGBV** – sexual and gender-based violence  
**SLAES** – Sierra Leone Association of Ebola Survivors  
**SOP** – standard operating procedure  
**TPRN** – Thematic Platform for Health Emergency and Disaster Risk Management Research Network (WHO)  
**UHC** – Universal Health Coverage  
**UN** – United Nations  
**UNDRR** – The United Nations Office for Disaster Risk Reduction  
**UNESCO** – United Nations Educational, Scientific and Cultural Organization  
**UNHCR** – United Nations Refugee Agency  
**UNICEF** – United Nations Children’s Fund  
**USAID** – US Agency for International Development  
**USAMRIID** – US Army Medical Research Institute of Infectious Diseases  
**WASH** – water, sanitation, and hygiene  
**WHO** – World Health Organization  
**WHO ERC** – World Health Organization Ethics Review Committee  
**WWARN** – WorldWide Antimalarial Resistance Network  
**ZikaPLAN** – Zika Preparedness Latin America Network

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