NUFFIELD COUNCIL ON BIOETHICS

Conducting research and innovation in the context of global health emergencies: what are the ethical challenges?

Notes of workshop held on 9 December 2016: 10:00–13:30
28 Bedford Square, London WC1B 3JS

Chair: Jonathan Montgomery, Chair of the Nuffield Council on Bioethics.

Guest list: see Annex B

Introduction

The Nuffield Council on Bioethics hosted this workshop of invited guests to explore the ethical challenges for research and innovation that arise in the context of global health emergencies; to consider, in light of recent and ongoing work by a number of agencies, what 'ethical gaps' remain; and to identify what further work (by the Council or others) might be valuable.

The meeting was held in accordance with the Chatham House rule, under which what was said may be freely reported but not ascribed to named individuals, and this summary takes the same approach. Each session was introduced by one or more delegates, followed by open discussion; key points made by participants are summarised below under the session headings, organised by theme rather than chronologically. **It should not be assumed that all present agreed with all points made, or that the opinions expressed represent the view of the Nuffield Council**.

A Nuffield Council briefing note, drawing both on the discussions on the day and on the background paper circulated in advance, will be published in due course.

Session one: tensions between response (to emergencies of various kinds) and research

'Therapeutic misconception' and its limits

- Tensions between experimental practice of many kinds and routine or public health measures are endemic, particularly in low-income environments, and in circumstances where populations are less likely to be familiar with research concepts. Many people take part in research for the benefits they perceive to be associated with it – whether in terms of access to healthcare, or to transport, or because of the compensation offered.

- Traditionally research ethicists respond to this issue by attempting to create hard and fast distinctions between what is 'research' and what is '(health)care', but pragmatically this distinction does not always speak to those on the ground. There is a role for further

empirical research here, to find out how the potential tensions between the provision of healthcare, public health measures and research interventions are really perceived.

- Rather than using binary distinctions between 'research' and 'healthcare', it would be more helpful to break down the activities in question and look at what is actually being done. It would be very useful to map which activities can clearly be classed as belonging to just one of these categories, and which relate to both (or indeed to additional categories: there are important overlaps with and between research / healthcare and routine public health activity too).

- Even where the same activity (for example consent, or what happens when research ends) is significant from both a research and healthcare perspective, *how* it is significant may differ. By mapping in this way, it should be possible to identify both 'pinch-points', where obligations relating to research and healthcare may conflict, and responsibilities. This could lead to a new way of thinking about activities that are both research and treatment: for example considering whether it might be possible to consent to treatment and research in one conversation.[1]

- Similarly, why is it thought that you need to seek consent for research data but not for public health data, when they might be seen as doing fundamentally the same things? Whether a project is 'public health' or 'research' is a recurring theme, and some progress has been made in finding an integrated 'public health evidence' approach – this appears to be the way to go.

- Greater capacity strengthening of researchers *and* care providers / public health practitioners is important, to enable them to understand how they feed into, and relate to, each other. Forward planning to avoid breaches of trust, for example in relation to use of data, is essential: in the Ebola crisis the situation arose that researchers had better data than those working in public health, but felt they could not share it because of research confidentiality.

- The Ebola crisis brought out how the duties of researchers with respect to beneficence are not understood well enough: the focus in research ethics is primarily on not causing harm, minimising risks etc., rather than on the good that researchers might be able to do.

- In learning lessons from Ebola, it should be remembered that it is/was not the only example: there are many other outbreaks and emergencies from which important lessons could be drawn.

When emergencies end

- Particular tensions arise when the experimental practice comes to an end, and hence potential benefits end too: this is a particular source of vulnerability, recognised, for example, in research ethics in the debate around post-trial access. In global health emergencies this mismatch between contribution / burden and potential for benefit is potentially amplified.

- The *timeliness* of the research question may help resolve some of these dilemmas: if research is carried out quickly enough it may directly help the populations taking part; and the very process of contributing to research may be perceived to be of direct

[1] For example, building on existing good practice in 'pragmatic trials'. See: Kim SYH, and Miller FG (2014) Informed consent for pragmatic trials: the integrated consent model *New England Journal of Medicine* **370(8)**: 769-72.

benefit. In the convalescent plasma trials in the Ebola pandemic, participants benefited in terms of access to services for 'post-Ebola care' and through support for survivors' groups; but they also talked of the joy of contributing to the solution for an 'African problem'.

- However, even where such benefits accrue, the question of what happens when the emergency ends remains acute. During a crisis, multiple agencies accept a responsibility to work towards a coordinated response, but how does this responsibility play out when the population is no longer in crisis? What legacy do, or should, international organisations leave – for example in terms of improved infrastructure or lab facilities? This is a critical ethical question for researchers to consider in any context where local health systems are inadequate to deal with the pressures placed on them.[2]

- There *are* clear existing research guidelines (such as the Council for International Organizations of Medical Sciences (CIOMS) guidelines) on post-trial access, and questions of legacy services: the important question to ask is why they are not being followed. This is partly a question of capacity and mechanisms for enforcement (for example, the difficulty in relying on research ethics committees (RECs) to do so, when they are under-resourced or non-existent); but also whether it should really be seen as the problem of researchers, rather than others. And this is exacerbated where research is short-term and in response to a specific emergency, rather than as part of a long-term programme: short-term responders/researchers may simply not have the wherewithal or focus to take legacy questions into account.[3] There are two different sets of actors here.

Problems of translation

- Many of the tensions described are indeed not new, and are familiar to those carrying out long-term health-related research in low-income environments with potentially vulnerable populations. What is new in emergencies is that there are many players who may be collaborating for the first time: the populations themselves; local providers; international agencies such as Médecins Sans Frontières (MSF) whose primary expertise is not in research; and then the researchers. One of the problems is the need to translate experience from other areas – and to do so quickly (as in the Ebola crisis, where so many groups were trying to solve many problems at once).

- Humanitarian organisations such as MSF may be well placed to carry out research, but they need support and training for their staff to do so, as formal research is not their core activity. (They have in fact always engaged in research activity on the ground, in terms both of getting politically sensitive information into the public area, and understanding the terrain in which they are working – but this is not necessarily understood as research or made available academically in the manner of 'formal' research.)

- Other experiences of working with 'delivery-focussed' NGOs highlight tensions linked not only with ideology and experience, but also with respect to processes: the requirements of ethics review, etc, may simply not be on their radar. A significant legacy of joint working with researchers in such cases is that those NGOs will be alert to research requirements in future, in a way that they were not before.

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2 It was noted after the meeting that the timeliness of such negotiations is also important: they can be lengthy, and this may either delay the research, or make it impossible.

3 It was noted after the meeting that there are other ways of contributing to 'fair benefits': for example by contributing to the humanitarian response, or by committing to reconstruction efforts later.

- Similar problems of translation arise between responses to outbreaks that are not seen as emergencies (for example rabies, which kills more people every year than the Ebola crisis did), and those that are. The question was asked, why plasma was being used to treat Ebola, when it should have been possible to use monoclonal antibodies without all the 'nasties' associated with plasma?[4] The view was expressed that there is a failure to learn even from one virus to another. What of 'hidden' emergencies such as lack of access to HIV drugs?[5]

Stakeholders and influence

- The question of *who* the stakeholders are in any situation is critical. What funders, for example, want and expect (and exact, through their performance management agendas) is hugely influential with respect to what happens on the ground. The actual beneficiaries may be 'bottom of the heap' in terms of influence.

- Distracting agendas from different stakeholders can place those working in emergencies (whether as responders or researchers) in considerable tension: potentially putting them at more risk than the situation itself.

- The role of politics also needs to be taken into account: the point was made that the international response to Ebola, for example, was delivered on colonial lines, with little cooperation or understanding between the various parties. Similarly, researchers need to take account of local politics such as highly negative attitudes to HIV research or pre-existing political tensions. International politics also plays a part in determining response: was so much attention paid to Ebola, in contrast to other health threats in Africa, because it was perceived as being a threat to Europe and North America?

- How 'soft' funding is classified is important and can significantly limit flexibility in how it can be spent: for example, UN High Commissioner for Refugees (UNHCR) cannot accept development money.

'Humanitarian' response and links with security

- Reference to 'humanitarian' responses to emergencies bring in further complexities, alongside international humanitarian law. Humanitarian 'assistance'[6] typically implies the neutrality of those offering aid, while humanitarian 'intervention' could involve armed force in order, for example, to stop atrocities (cf Chapter VII of the UN Charter[7] and Security Resolution 688[8]). In the context of healthcare emergencies, the language of 'containment' and the use of the military as part of the response demonstrates how these distinctions can be blurred (just as the Red Cross was born in war zones). Thus epidemics may be seen to present a threat to international peace and security, justifying 'containment action' in the same way as in response to genocidal slaughter.

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4 It was noted after the meeting that monoclonals were simply not available in sufficient supply at the time.

5 Attention was drawn after the meeting to the related concepts of 'hidden' disasters (not seen beyond the communities directly affected) or 'silent' disasters that have little fanfare or publicity but may be linked with the worst impacts (see http://www.ifrc.org/silentdisasters).

6 See: UN General Assembly Resolution 43/131: www.un.org/documents/ga/res/43/a43r131.htm.

7 http://www.un.org/en/sections/un-charter/chapter-vii/.

8 https://documents-dds-ny.un.org/doc/RESOLUTION/GEN/NR0/596/24/IMG/NR059624.pdf?OpenElement.

- The response to emergencies such as Ebola has brought together researchers working in previously quite distinct areas: research linked with security concerns (such as bioterrorism) and global health research based on concern for inequalities and social justice. Even the language used in these different research domains is different, and highlights some of the tensions within the research community. Ways of bridging this gap need to be identified.

Session two: research conduct and governance in global health emergencies: specific challenges

What is different in emergencies?

- Crossing the Rubicon from being a clinician helping a patient to being a researcher asking a question for which you need publishable answers is always difficult (taking into account, for example, protocols, REC approval, and consent processes). However, it is even more challenging in emergencies when you want all the answers straight away, where you don't have time to build community engagement and trust in advance, and so forth. So while many of the identified difficulties arise in non-emergency research (whether in improving treatment for malaria or worms), it is an even 'bigger ask' in emergencies, and in contexts where 'research' is not widely understood.

- There is a lot of good practice in community engagement (cf the MESH platform[9]) and in consent practice (understanding consent as a process and not as a 20-page form) – but emergencies often seem to start at the beginning again. The example was cited of the difficulties of being expected to go through ten fixed questions on a consent form with respect to future use of blood, regardless of whether patients could read or write, had any understanding of viruses, or believed witchcraft was the source of the disease – exacerbated by the need for the practitioner to be wrapped in plastic protective equipment.

Research governance

- It is not a question of a lower standard of conduct or governance in emergencies, but of an appropriate standard. This could include broadening models of REC review: expedited review, registration and retrospective review, and so forth. It is also about proportionate regulation and oversight: this can be facilitated through achieving substantive ethical agreement in advance through anticipatory review, so that what needs to be reviewed at the time is narrowly focused.

- We need to recognise that there is a trade-off between effective and efficient governance of research, and in determining where to make compromises, perceptions of legitimacy are very important. There is also a trade-off between what is best for the individual, and what is best for the wider community / future generations.

- Pragmatism is important in responding to the situation on the ground: for example, while the gold standard of care for the Defence Medical Services (DMS) might be something akin to the UK NHS, in practice you aim to achieve what you can within the constraints of the operation. Could one have a similarly pragmatic approach to dealing with ethics in difficult situations? In thinking what such a 'pragmatic' approach

9 https://mesh.tghn.org/.

might be, it is important to distinguish between taking the context seriously (being culturally sensitive, responding to the facts on the ground and the resources available, etc) while still recognising the need to justify one's action on ethical grounds, versus the dangers of 'normative creep' (the attitude of what works is what is right). Being pragmatic is not an excuse for being less serious about ethics.

- There were felt to have been some real failings of ethical governance in relation to Ebola: one trial received approval from five different RECs, and yet those conducting the trial were criticised both by chairs of other RECs and in a *Lancet* article of acting in a way that was "profoundly unethical".[10] The point was made that this was simply unfair to researchers. 'Research ethics' and 'humanitarian response ethics' use the same language to mean different things: before the review process can work, there has to be agreement on the principles under which it is being conducted.

- Research governance can only go so far: researchers need authorisation to go ahead but the ethical questions do not stop there. A better way of embedding ethics in science is not through 'more review' but by integrating ethical thinking into the day-to-day thinking of those conducting research. Compliance and ethics are different things, and there is no substitute for a moral compass guiding one in what is right to do in an awful situation. At the same time, mechanisms by which people can be held to account for the decisions they make in those situations are needed: a research mechanism analogous to the way in which the General Medical Council (GMC) regulates doctors. This is a challenge for regulators and for ethicists: not just guidelines or tick boxes that 'let people off the hook' from using their judgment.

- What happens when there is no REC or other form of ethical scrutiny, and no priority is given to developing one? This will often be the case, especially in unstable settings. Implementing agencies and researchers need to work together – they have the same questions, and also the same interests in resisting the 'securitisation' agenda.

- 'Medical ethics' can also be (mis)used in a socially repressive way, to control information about governance and entrenched interests, including academic competitive interests. 'Ethics' should be about ensuring that people actually participating in research or accessing services have a voice (for example in public health or research programmes designed primarily to promote uptake of medication).

Trial design

- The practical requirements relating to contracts, material transfer agreements etc need to be sorted out in advance of emergencies: what is critical at the time of research are the 'errors that matter': the aspects of research that might pose a risk to the safety of people, to communities more broadly (e.g. fears and rumours), or to the quality of the data produced (hence the value of the research).

- There are complex methodological questions around trial design, and there needs to be a better framework of risk and benefit with respect to unproven therapeutic interventions: existing clinical ethics frameworks assume benefit is proven, and are unhelpful in dealing with interventions of uncertain but hoped-for benefit; while current research ethics frameworks evaluate risk and pay insufficient attention to

[10] 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, *Lancet Infectious Diseases* **15**:738-45.

scope for benefit. While these are 'old' questions, resolving them becomes even more important in emergencies.

- Identifying which kind of trial design is ethical should be seen as a technical question – and one that should be resolved in advance. Is it, or is it not, acceptable to randomise access to unproven therapies where mortality is 70 per cent? Has a precedent been set by ZMapp [an experimental drug used in Ebola]? (At the height of the Ebola crisis, community representatives said randomisation at this level of mortality was not acceptable, but this now appears to have changed.)

- However, politics and context also play an important part: ethics is contextual and it is necessary to apply ethical guidelines in context. It could be possible that the same trial design might be ethical in some circumstances and not in others – and this points to the need for more ethical competence / confidence on the ground, linked with accountability ('showing workings' and being transparent about the basis of decision-making rather than simply applying rules). This is not about 'different ethics' but about different situations: for example options may be constrained if researchers are surrounded by the military.

- Even recognising all these constraints, ethical guidelines still have an important role: they set out areas of agreement, and ways in which actions may be justified.

Capacity in low-income countries

- As in other areas of research, low-income countries (LICs) need to be supported in their capacity building so that they are able to be generators of their own response in the future.[11]

- If / when there is another Ebola outbreak: what would be different? There might be progress in vaccines, better personal protection equipment and more known about infrastructure – but would there be better local capacity to respond? And how can research help with this?

Session three: setting priorities and challenges of collaboration

Priority setting and anticipation

- Anticipation is crucial in responding rapidly, effectively and ethically to a global epidemic: once an epidemic has started, it is too late to set priorities at a global level. The World Health Organization's (WHO) R&D Blueprint12 is the WHO's response to this challenge: it aims to encourage effective collaboration by funders and to accelerate R&D once an outbreak occurs through effective anticipatory means, such as the identification of between six and eight 'priority pathogens', mapping gaps in research and identifying who is best placed to fill those, and setting out a R&D roadmap to support stronger ethical and regulatory pathways.

- These priority pathogens were determined by scientific input, sought from academics from different regions: this was seen as primarily as a scientific question, rather than

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11 As emphasised, for example, in the 2013 *WHO Guidance note on capacity building in malaria entomology and vector contro*l: available at: http://www.who.int/malaria/publications/atoz/who_guidance_capacity_building_entomology.pdf.

12 http://www.who.int/csr/research-and-development/r_d_blueprint_plan_of_action.pdf?ua=1.

one in which a more inclusive approach to priority setting was required (and it was expected that academics from different regions would have similar approaches).[13]

- Had the list been in existence earlier, it is likely it would have included Ebola, but not Zika: responding to the unexpected will always remain a challenge. Algorithms to identify priorities, like all mathematical algorithms, are useful but do not give concrete answers: if you take too systematic an approach to research and innovation, you risk making things worse.

- However, work such as the WHO's recently-launched guidelines on responding to epidemics[14] highlights how having a framework to tweak is much better than starting from scratch (cf a virtue ethics approach vs a systems approach: knowing the questions to ask, rather than a set of tick boxes).

- How do these WHO priorities on pathogens relate to other areas of research? Research on methods of emergency response, and frameworks for data-sharing between researchers and responders, for example, are both urgently needed.

Community / local population involvement

- The WHO blueprint is very 'top down': it recognises that the ethical questions that arise in the context of a particular research microcosm cannot be anticipated in advance as they are too specific. It is for communities / populations at local level to set priorities at this level: how relevant stakeholders are involved in that, and how choices are made, is a different (and pressing) problem, especially as they are likely to be competing for the same resources from the same funders. To what extent should likely impact be a key criterion for priority-setting at this local level, for example when associated with higher risk?

- What does 'community' mean in this context? It is often a feature of humanitarian crises that people do not feel that they are part of a 'community': they may hate each other; they may be forcefully relocated; they may speak entirely different languages. It can be dangerous to refer generically to 'communities' without being more specific.

- It may be more helpful to phrase these issues in terms of 'how populations have a voice' – and to recognise that within populations there will be diverse voices, and that how they are understood or translated by those to whom they are speaking will also be important. There is a strong onus on those going in from outside to inform themselves in advance through ethnographies or other sources.

- It is particularly important that local voices are heard in this way in capacity building: for example with respect to priorities for the development of health infrastructure.

Collaboration

- Some of the collaborative and logistical challenges inherent in responding to emergencies are exemplified in the involvement of the DMS in coordinating the UK response to Ebola. Liaising with Department for International Development, the Department of Health, Public Health England (PHE) and NGOs involved a significant

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13 It was noted after the meeting that there are many implicit ethical choices in what are seen primarily as scientific decisions, and that ethical input into such prioritisation exercises is very desirable.

14 WHO (2016) *Guidance for managing ethical issues in infectious disease outbreaks*, available at http://www.who.int/csr/research-and-development/guidance_for_managing_ethical_issues.pdf.

amount of expectation management, including with respect to priorities and information exchange. Military personnel, NHS staff, and foreign national military and clinical personnel all had different customs and expectations with respect to kit, and whatever was used needed to be robust enough to survive use in Africa and transportation en route. Questions of cooperation and responsibility were highlighted by the loss by one agency of the anticipatory equipment list, leaving two weeks to identify, procure and deliver the equipment needed to set up hospital services in Sierra Leone.

- In determining levels of protecting and training processes, military planners had to consider not only how to provide safe care for patients, but also how to ensure the safety of personnel, and how to provide reassurance with respect to those safety concerns (for example confidence that the protective clothing worked).

- Ethical challenges with respect to the DMS' role in Sierra Leone itself included concerns that the hospital facilities provided in Kerrytown (which included 20 beds staffed by UK medical personnel and 80 by Save the Children) might be perceived as a two-tier response; whether defence personnel on the casualty ship RFA Argus could be asked to be platelet donors to obviate the need for expensive twice-weekly flights to provide platelets from the UK; if so whether this should be for the 20 DMS beds or also for other treatment centres; and the acceptability of the collection and return of medical samples to PHE.

- Looking more broadly at collaborative challenges (cf earlier comments on colonial links with the focus of intergovernmental response, and the dangers of academic competition), ethics of collaboration itself needs further thoughts.

Capturing lessons learnt

- An ongoing ethical challenge is the failure to create any kind of single repository or 'corporate memory' for the lessons learned: not so much of the practical arrangements but of the required mindset. As in the NHS, there is always the risk that one is 'fighting the last war' because of a failure to learn from history.

- Academic journals provide a reliable and accessible source of past learning (although less so with respect to case reports and practical 'on the ground' experiences): a key question is whether they are accessed and by whom. How lessons are absorbed and translated within organisations (whether academic, NGO, or governmental) depends on that organisation and its mindset. While it was suggested that some organisations have systems that thrive on collective ignorance, examples were cited of progress across a range of organisations: from academic centres and NGOs to Department of Health initiatives for rapid response and changes at the WHO.

- The key lesson that should be learned is that of the importance of health infrastructure in LICs: what, after Ebola, Zika and many other emergencies, is yet being done to strengthen this? While the UK has put in resources to improve the UK's capacity to help in future, how about countries' own capacities? Until populations have the capacity to respond to outbreaks at local level, the problems associated with external capacity will persist (note, for example, how more children died from malaria during the Ebola epidemic because of the refocusing of health resources). The WHO needs funds to support such capacity-building.

Session four: ethical gaps

Ethical issues that need to be addressed

- Distinguishing between lack of clarity in ethical approaches to research in general (exacerbated when arising in emergencies), and where ethical challenges are *particular* to emergencies. Common ground on the first question (can there be agreement on what the values should be that lie behind the formulations used, and can they be articulated?) will help with the second.

- Finding a way to respond to the 'grey zone' between clinical, research and public health practice (cf earlier discussions of 'mapping' activities and their ethical significance), in order to develop a 'non-binary' ethics for this domain – how can ethics and research pathways be built from the bottom up so that it is embedded in actual practice? The current binary approach is also a real practical problem with respect to funding: research funding based on the need for a specific hypothesis is not available for integrated learning from care, while development agencies will not fund research. How can there be a switch from a focus on 'trials' to one on 'research' – or even on 'evidence'?

- Exploring the current orthodoxy in priority setting that research should never compromise response: can that really always be the case given responsibilities towards potential future victims of emergencies, as well as those now? Could this be put the other way round: that no clinical care should be delivered in the absence of research – that there is an imperative to achieve an evidence base for response?

- Looking at wider priority setting questions, and in particular the extent to which what is feasible/more straightforward/currently available 'off the shelf' may take priority over what might be ideal (another aspect of the 'pragmatism' question discussed earlier).

- The need to find a common language in relation to ethical concerns, particularly when coming from different disciplinary backgrounds.

- Further work to develop standard protocols in advance of an emergency, learning from Ebola and other recent emergencies: some variables will change but efforts can then be much more targeted.

- Looking at the 'ethics of ethics': understanding how existing ethical guidelines and review processes may, in practice, operate in ways that are not conducive to ethically-conducted research and/or constitute unjustifiable burdens. How can ethical practice become more than compliance (incorporating voice of conscience), and ethical review be constructive rather than burdensome?

- Developing more flexible REC approaches (cf the WHO Ethics Committee who took a proactive role with respect to nearly all the Ebola protocols in West Africa, including proactive contact with lead researchers and scientific review processes, and facilitating external support for local RECs with lower capacity).

- The need to include in ethical processes the importance of making an effort to understand the populations amongst whom you are conducting your research: they are not simply universal 'objects of disease'.

- Responsibilities with respect to capacity building: how could the 'next Ebola' be different?

- The ethics of collaboration, for example with respect to sharing information across domains (research/care/public health) and between actors (concerns about intellectual property/other kinds of value, confidentiality and custodianship vs scope for wider benefit in sharing early medical findings).

Practical challenges

- Need for greater flexibility in funding mechanisms, recognising the fluid nature of the demands posed by emergency response and the problems created by very specific funding requirements.

- Huge training needs, particularly with respect to understandings of law and the relevance of the law in the country in which researchers/responders are operating.

- Greater flexibility with respect to the requirements of Good Clinical Practice.

Relevance to UK

- A lot of research taking place in major academic centres in the UK, and / or funded through bodies such as the MRC, is concerned with the underpinning science and with more translational aspects of research applicable to global health emergencies: for all of this really to make a difference, it must take ethics seriously.

- The kind of outbreaks under discussion could take place in the UK, and the ethics would not be that different: questions around experimental therapies and resource constraints will be central.

A particular role for the Nuffield Council?

- Independent, well-regarded and multidisciplinary: able to speak truth to power, and act as broker between research and policy worlds;
- Well placed to challenge entrenched thinking and play devil's advocate;
- Building on relevant earlier work: including on healthcare related research in developing countries; biodata; and children and research;
- Hard for others concerned in this field either to get funding to do this kind of cross-cutting thinking, or to be perceived as independent if they did.

Annex A: contributions after the meeting

- The ethical issues we confront with outbreaks are the same but more complicated than in general research on human subjects in low and middle income countries. The complexity arises from:
    - the urgency of the situation with little time to prepare community engagement and trust;
    - uncertainty in the population, among policy makers, and responders about how the epidemic is likely to unfold;
    - unfamiliarity among these same groups with the outbreak situation, which may also affect some of the responders who may be focused on a humanitarian responses and be unfamiliar with research and research ethics;
    - fear and distrust in the local population towards authority, central government, outsiders; and
    - the Siracusa Principles which may place limitations on human rights in an emergency, and also the Nagoya protocol which may place limitations on research in biological samples. More work needs to be done to clarify the implications of Nagoya on outbreak research.
- There are questions about what constitutes research. During the Ebola outbreak in Sierra Leone, anthropological studies (surveys, KABP,[15] evaluations often duplicating each other), clinical research (unproven interventions outside clinical trials), and epidemiological surveillance were all conducted without any ethics approval.
- If research is viewed as "the systematic collection of information to inform and evaluate responses to improve our performance in the future", then it can be argued that it is unethical not to do research.
- Specialised research studies usually require additional, local, staff. These should not be drawn from the limited pool of individuals providing essential services. For example Sierra Leone, after Ebola, is banning external research groups from recruiting Ministry of Health staff. So how should external research groups conduct their research in future?
- There is a need for a code of conduct for external research groups in an emergency. At the moment it is a free-for-all with groups competing over sites, over patients, and over collaborative staff.
- Finally coordination and leadership in outbreaks are crucial, but always challenging and usually suboptimal. We need to work out better ways to govern and prioritise research during outbreaks.

[15] Knowledge, attitudes, beliefs and practices

Annex B: Guest list

Tim Allen
Professor of Development Anthropology, London School of Economics

Duncan Blair *(introductory comments)*
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Karl Blanchet
Director, Health in Humanitarian Crises Centre, London School of Hygiene and Tropical Medicine

Jake Dunning
Deputy Director, High Consequence Infectious Diseases Programme, NHS England

Peter Horby
Professor of Emerging Infectious Diseases and Global Health, University of Oxford

Michael Jacobs
Consultant and Senior Lecturer in Infectious Diseases, Royal Free Hospital, London

Ann Kelly *(introductory comments)*
Senior Lecturer in Global Health, King's College London

Ilan Kelman
Reader, UCL Institute for Risk & Disaster Reduction and UCL Institute for Global Health

Trudie Lang *(introductory comments)*
Director, Global Health Network, University of Oxford

Heidi Larson
Director, The Vaccine Confidence Project, London School of Hygiene & Tropical Medicine

Andrew Mace *(apologies)*
Lead, UK Government Donor Relations, Bill and Melinda Gates Foundation

Sophie Mathewson
Policy Adviser, Wellcome Trust

Mike Parker
Director, Ethox Centre, University of Oxford

Frances Rawle
Head of Corporate Governance and Policy, Medical Research Council

Tony Redmond *(apologies)*
Professor of International Emergency Medicine, University of Manchester

Annette Rid *(introductory comments)*
Senior Lecturer, Bioethics and Society, King's College London

Abha Saxena *(introductory comments)*
Coordinator, Global Health Ethics, World Health Organization

Adrian Viens *(apologies)*
Associate Professor in Law, Southampton Law School University of Southampton

Jimmy Whitworth *(apologies)*
Professor of International Public Health, London School of Hygiene and Tropical Medicine

Richard Williams
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