

NUFFIELD COUNCIL ON BIOETHICS

Rethinking ethical research in emergencies

Consultative meeting in Colombo, Sri Lanka, 5-6 March 2020

The UK-based Nuffield Council on Bioethics published the findings of its two-year-long inquiry into the [ethical conduct of research in global health emergencies](#) in January 2020 – just as a new global health emergency in the form of the novel coronavirus causing COVID-19 was emerging. The [international working group](#) established by the Council drew on input from researchers, practitioners, research participants, and policymakers in more than 30 countries worldwide to explore the dilemmas at the heart of such research.



Katharine Wright, presenting on behalf of the Nuffield Council

In response to these challenges, the Nuffield Council's working group developed an '[ethical compass](#)' to guide not only the conduct of researchers on the ground, but also the actions of policymakers – recognising that the decisions taken (often far from the scene) by bodies such as

research funders, employing institutions, governments and others, can influence and constrain scope for ethical conduct in the midst of the emergency. The compass is made up of three core values: helping reduce suffering; demonstrating respect for others as moral equals; and fairness. Drawing on these values, it asks policymakers and researchers to think about:

- Whose needs are being met by the research – and who is involved in defining those needs? Whose voices are being heard in deciding what research gets done?
- How are affected communities involved in planning the research, and how are research designs sensitive to local values and traditions?
- How are participants being treated respectfully throughout the whole research process, including receiving feedback on study findings?
- How can the benefits and burdens of the research be distributed equitably, without excluding people unfairly?
- How can working relationships between researchers in different countries be made fair for all?

Alongside its detailed report, the Nuffield Council published a '[Call for Action](#)' highlighting key recommendations for research funders, governments, and others – and this has already been publicly supported by a number of leading research bodies and humanitarian organisations. In order to share findings around the world, and explore how different national contexts might influence culturally-appropriate application and implementation, the Nuffield Council is now aiming to hold roundtable consultative meetings in each of the World Health Organization Regions, with a particular focus on the remit of national governments and WHO Regional Offices.

The first of these consultative meetings was held in Sri Lanka on 5 March, attended by Additional Secretary Dr Lakshmi Somatunga and senior officials from the Ministry of Health; Dr Kumara Wickramasinghe, Deputy Director General, National Hospital of Sri Lanka, and hospital directors; a representative from WHO Country Office, Sri Lanka; and leading medical administrators, public health specialists, health professionals and academics. Presenting the report, Katharine Wright from the Nuffield Council focused on the recommendations made to national health and research leaders, and to regional bodies such as WHO Regional Offices. These included:

- National governments and research institutions taking the lead in setting research priorities, collaborating with, and supported by, regional and global actors;
- National governments collaborating with researchers to ensure that research participants' basic health needs are being addressed through the response effort;
- Long-term investment by governments and research funders in structures that facilitate community engagement;
- Long-term investment by governments in domestic research capacity, including stable financing for academic departments, and provision for research infrastructure such as effective research governance and support for research ethics committees;
- Regional support to develop collaborative approaches between ethics committees across the region to facilitate rapid and responsive multi-country ethics review in emergencies; and
- Shared responsibility among all stakeholders for prioritising emergency preparedness, emphasising the fundamental importance of resilient health systems.

The wide-ranging discussion in response to the presentation of the report was led by Dr Suranga Dolamulla, Senior Research Fellow, University of York and Senior Medical Administrator, Ministry of Health. It encompassed ethical challenges arising both specifically in research, and in emergency response – illustrating how closely interwoven these activities are. Key themes included:

- How issues that arise particularly starkly during an emergency are often highly relevant in 'normal' times. The importance of infection control in hospitals, and of effective and regular handwashing among the general public, for example, need to be taken seriously

at all times. The extreme nature of emergencies can prompt us also to challenge our normal practices. Good practices developed during emergencies, such as clear messaging over hand hygiene in infectious disease outbreaks, need to be maintained once the emergency is over.

- At the point when an emergency first emerges, research may be the last thing on people's minds – yet the need for learning is strong. Lessons learned from responding to the SARS and MERS outbreaks, for example, have been valuable in tackling COVID-19. As well as formal research, this raises issues of the responsible use of data collected as part of the response – for example data being collected at airports and other surveillance data.
- Challenges arise when it is not clear who is responsible for particular initiatives or areas of policy: for example whether responsibility falls to the Ministry of Health, to WHO national or regional offices, or to specialised professional associations. Good communication and coordination is key.
- Expert advice, such as that provided by expert committees set up by WHO headquarters and disseminated through Regional Offices, plays an important role. While scientific advice should be globally applicable, there will be political and cultural reasons why the implementation of that advice needs to be locally appropriate. (As a nice example: many of those present instinctively shook hands at the end of the meeting, despite earlier discussion of avoiding unnecessary physical contact, illustrating the deeply-embedded nature of social and cultural traditions.)
- Health and research leaders need to lead by example – and this depends on practical logistical constraints too. Wider availability of soap in toilets in public buildings, for example, would send a good signal to the wider public with respect to the key public health message of hand hygiene.
- Difficult trade-offs are inevitable. If research, for example, shows that particular practices are harmful, clearly these should be stopped – but the way in which research findings are implemented need to take account of knock-on consequences, such as the closure of wards, or even whole hospitals.
- Quarantine provides a particularly acute example of difficult trade-offs – and also illustrates how ethical challenges that arise in research also arise in emergency response. Quarantining patients, or asking those who may have the disease to 'self-isolate', is a major intrusion into personal liberties. It needs to be clearly justified both by reference to the wider public good, and through evidence demonstrating that these measures will be effective. *How* people are treated while in quarantine is crucial, highlighting the relevance of one of the core values in the Nuffield Council ethical compass: that of demonstrating respect for others as moral equals. This involves respectful communication and treatment – including ensuring that they do not suffer unnecessarily (for example through any inability to meet basic needs because of their quarantine).
- Respect for others also underpins the honesty and transparency of communication that is necessary to support trust both in emergency response and in associated research. If people cannot trust the information they are being given from official sources, they are more likely to circumvent controls designed to benefit the wider public. They are also more likely to pay attention to fake news, which in turn may feed panic and distrust.

- Preparedness is crucial. This includes sufficient permanent infrastructure, such as laboratory facilities; disaster response plans that can be readily activated, including an emergency operation centre, isolation beds, ICU beds, and quarantine centres; and confidence that systems are in place to ensure that policies instigated by the ministry of health are being effectively disseminated and implemented at hospital level.

Dr Somatunga closed the session with warm thanks to the Nuffield Council for the important work it had undertaken, and an emphasis on the importance of ongoing collaboration to ensure that the research necessary to support effective emergency response could take place.

College of Medical Administrators event: 6 March 2020

Dr Somatunga also supported a training event the following day, hosted by the College of Medical Administrators for 60 of their trainees. Those present engaged enthusiastically with the Nuffield Council report. Professor Sanjoy Bhattacharya conducted the discussion session which brought out many important issues and ideas.

There was real concern among many of those present about ‘parachute’ or ‘helicopter’ research: research conducted in low- and middle-income countries (LMICs) by international researchers without reference to national research priorities, or respect for what national researchers could offer. It would be important in future to avoid the situation where local experts ‘manage the disaster’ while outsiders gain credit for writing about it – and it was felt that the Nuffield Council report could in the future provide important support to local researchers to resist unfair collaborations. Suggestions made for strengthening the role of nation states included the appointment of a data custodian to oversee how research data were being used and shared. The value of a national research registry, and the importance of ensuring research findings directly influence policy, were also emphasised.

There was a recognition that the research culture would benefit from further strengthening. It was suggested that research is not necessarily seen by many as part of day-to-day practice, and that there can therefore be barriers to conducting research. While evidence is essential for good clinical governance, for example, it can be complicated obtaining ethical approval, and more bureaucracy doesn’t necessarily mean better ethics.



Participants take part in Nuffield Council-led session

In closing the session, important progress already being made in supporting organisational and institutional research capacity was also highlighted. This included: developing national guidance on the use of biosamples; developing pathways for cascading research findings directly to hospitals; and monitoring the take-up of such findings into day-to-day practice.