*Establishing a global ethics response network for Public Health Emergencies: meeting report*

Stellenbosch, South Africa, 15 November 2018

**Background**

The UK Department for International Development has provided funding to explore the possibility of establishing an ethics response network to provide real-time, contextual ethics support and advice for researchers working in public health emergencies (PHEs). An initial scoping meeting took place at Wellcome in January 2018 to discuss: what the network could look like; what its aims should be; what is required to make it a success and what the barriers and challenges may be. The group agreed that development of the network should be informed by a robust evidence base with respect to:
- What the demand is for this network
- What models work
- Where people currently go for advice, at what time and when
- Who is it that needs and seeks the advice – researchers? Ministries? Research Ethics Committees (RECs)? Who should be seeking advice?

To explore these questions further, a second meeting took place in November 2018 with a different set of stakeholders[1]. The meeting was a satellite to the annual Global Forum on Bioethics in Research.

**Introduction**

There is a significant demand for research in PHE given the many gaps in our knowledge – both logistical and fundamental. Often, the only opportunity to acquire this knowledge is during the PHE itself. PHEs are challenging contexts to operate in; they can be unpredictable and uncertain in location/scope and seriousness. Research in these situations involves multiple institutions, countries and agencies with (often) competing interests, concerns and priorities.

There is broad agreement that the initiation, conduct, and conclusion of research in emergency contexts presents important ethical issues. These issues are currently addressed through:
- Guidelines and regulations: international, regional, national
- Formal ethics review
- Institutional/organisational ethics requirements
- Ethics advice and support

However, there are challenges:
- Interpretation of guidelines and rules in particular contexts can be difficult especially in a time-pressured, emergency situation. Conflict exist between the applicable guidelines and there are gaps and a lack of conceptual clarity.
- Formal ethics review processes may: be poorly resourced and lack training; lack experience of reviewing emergency research; lack a rapid review mechanism; be fragmented with no national focal point or lack effective communication and collaboration between local RECs; in some setting there is no established ethics committee and there can be conflicted relationships with institutions involved in the research.

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[1] The 24 participants were from 12 countries: Pakistan, Bangladesh, India, South Africa, Zimbabwe, Chile, Dominican Republic, Singapore, UK, Switzerland, USA and Canada.

- It can be difficult to distinguish between research and the response effort. Arguably, research has always been part of the response effort i.e. as part of the 'investigation' into how to respond (better). These blurred boundaries create uncertainties about what form of ethics oversight and/or review is appropriate or required.

## Key points from the discussion

### Proposed aims of the network

- To provide real-time contextual advice for researchers on the ground, through a mechanism that is flexible, distributed (but co-ordinated) and has a learning approach (i.e. the network doesn't only 'respond' but is part of a cycle, working before, during and after the emergency).
- To promote inter-epidemic learning by supporting empirically-informed ethics research based on the real needs that emerged in past outbreaks.
- To facilitate and perform training to capacity build in the Global South (including RECs and researchers).
- To build on existing mechanisms and good practice.

### Scope of the network

- Discussion focused on 'what is research?' and 'what is an emergency?' and the blurred line between research and response. Should the scope include responders (e.g. to humanitarian disasters) who would benefit from ethics support? Should the scope include research undertaken in chronic, rather than only time sensitive and suddenly emerging epidemics emergencies? If the network focuses on research in epidemic emergencies the rationale for the scope needs to be explicit – what's unique or morally different about research in time sensitive emergencies?
- The network could initially focus on research in epidemics as a proof of concept before considering a wider scope.
- The network would be advisory only – it is not an appeals body or approval mechanism.

### What is required to make the network a success?

- The network will require a cadre of well-trained bioethicists across the globe who are pragmatic and expert with emergency documents (protocols, consent materials etc). Fogarty/NIH perform bioethics training to develop ethics expertise in low- and middle-income countries (LMICs). The Institute's database of alumni could be a good way of reaching people for the network. Bioethics capacity in some regions – for example South East Asia – is limited. The network should take account of existing limitations and not 'spread itself too thinly'. Expertise at the moment is weighted unevenly between the Global North and Global South. Mentorship could play a role – but encouraging a diverse first-line with access to support that may be less diverse.
- The network will need people sufficiently knowledgeable about science, rather than ethicists working in silos, and should draw on other disciplines such as social sciences.
- Being responsive may not be enough. Ethical problem may not have been spotted by those in the field, especially when the problems are found on the uncertain margins between research, care and public health. Case-studies can be used as a prompt to enable researchers to recognise that the challenges they faced are 'ethical' and to encourage them to ask for advice.

- The goal is to develop the network over time to be a trusted resource and neutral partner.
- The network needs to be 'mainstreamed' and internationally credible. Credibility could be enhanced by embedding the network in regional hubs (e.g. WHO regional collaborating centres). 'Branding' will be important as a form of certification for the hubs and to show others that the network is an organised, international collaboration.
- High quality standards will be required to build the network's reputation ('brand') and to give it legitimacy. How can the capacity to meet those standards be developed? Should there be a gatekeeper to make sure standards are high?
- The network needs to be reliable and available (24hours a day, 7 days a week) and requires linguistic plurality.

**Format and funding**

- The network will require leadership but not ownership in order to be truly global.
- A range of formats were discussed: it could be a virtual network, or hosted by one organisation on behalf of others. Some networks have a secretariat that is not necessarily a 'lead' but ensures co-ordination and momentum. Similarly, a Steering Committee could promote continuity and help with strategic direction. Rotating leadership can also work well. A consortium approach could also be considered – e.g. engaging existing research centres, with other kinds of centres, and with national bodies.
- The network will struggle to be sustainable if it is dependent on short-term external funding. On the other hand, if based in an organisation and linked inextricably with normative mission statements, it will be more sustainable, but this raises ownership issues.
- The network would not have to run everything – for example, pre-existing training programmes will play an essential role without being 'owned' by the network.
- Funders could require applications for PHE research to include collaboration with the network – and potentially provide funding to contribute to the network's activities.
- The network could be established in a phased approach, with an initial 'proof of concept' phase involving a core group from which the network builds over time.

**Key partners, good practice and related activities**

- The network should learn from, complement, and build on existing good practice and networks e.g. AVAREF[2], TEPHINET[3], the WHO - ALERRT[4], WWARN[5], IDDO[6] and REECAO[7].
- Key partners could include: WHO, Pan American Health Organisation, WHO collaborating centres, Fogarty International Centre, MSF ethics board, Ministries of Health.
- Related activities: The Nuffield Council on Bioethics project on 'research in global health emergencies'.

**Next steps**

- Seed funding is available to support further scoping work.
- Establish a pilot/'proof of concept' phase.

[2] African Vaccine Regulatory Forum https://afro.who.int/publications/african-vaccine-regulatory-forum-avaref-strategic-plan-2018-2020-new-plan-accelerate
[3] Training Programs in Epidemiology and Public Health Interventions Network https://www.tephinet.org/about
[4] African coaLition for Epidemic Research, Response and Training network https://www.alerrt.global/
[5] The WorldWide Antimalarial Resistance Network
[6] The Infectious Diseases Data Observatory assembles clinical, laboratory and epidemiological data on a collaborative platform to be shared with the research and humanitarian communities. https://www.iddo.org/
[7] Renforcement de l'Ethique des Essais Cliniques en Afrique de l'Ouest http://reecaoafrica.org/