Casebook on ethical issues in epidemic health research

Call for cases: Deadline 31 January 2021

Lead editors: Susan Bull and Michael Parker

Introduction

There is a complex, dynamic, and at times contested, landscape of academic literature and policy on research ethics in the context of epidemics and pandemics. However this literature, whilst rich, is not always informed by an in-depth understanding of practical issues arising in context, nor the voices of relevant stakeholders, which limits its capacity to inform practice.

This casebook seeks to address this gap by providing contextually rich and sensitive accounts of research ethics issues encountered by health researchers and ethics reviewers during epidemics and the COVID-19 pandemic. The case studies and accompanying commentaries aim to promote understanding of relevant ethical approaches and competing considerations in a manner which promotes thoughtful evaluation of their implications for practice. As such they can support a range of preparedness and capacity strengthening activities.

We are seeking case studies (300-1000 words) addressing practical ethical issues associated with health research in epidemics and the COVID-19 pandemic. Possible themes include, but are not limited to:

- Research policy and practice in epidemics, including
    - Epidemic and pandemic research exceptionalism
    - Research prioritisation
    - Accelerated epidemic research pathways
    - Pausing, restarting and amending research activities which do not directly address the pandemic
    - Research quality and misconduct
    - Pre-publication, publication and retraction of relevant research
    - Multinational research collaborations
    - Boundaries and overlaps between research and public health responses
    - Monitored use of unregistered and investigational products
    - Novel technologies (e.g. vaccine candidates, testing kits)
- Governance and review including:
    - Adapting review processes to epidemics and pandemics including
        - Prioritised national and multi-site ethical review
        - Establishing COVID-specific ethical review processes
    - Data safety and monitoring
    - Review of novel, complex and adaptive trial designs

Cases reflecting a range of experiences, perspectives and positions are sought, including (but not limited to) those of research teams, funding agencies, ethics committees, governance bodies, policy analysts and advisors, clinical teams, community groups and research participants.

Submission guidelines

The deadline for submissions is 31 January 2021

Case study submissions must:

- Focus on the ethical conduct and review of research during epidemics or the COVID-19 pandemic
- Include a title and list of main ethical issue(s) or thematic area(s) evoked by the case
- Be 300-1000 words in length
- Describe a real-world example of which the author(s) have knowledge or experience
- Include 2-4 questions designed to prompt reflection on ethical issues arising during research in epidemics and pandemics
- Exclude all information which could identify individuals, groups, organisations or countries

Please see overleaf for two examples.

All queries and submissions should be sent to Susan Bull (susan.bull@ethox.ox.ac.uk) with the subject line 'Casebook'. Receipt of submissions will be acknowledged, and feedback will be provided by 14 February, after initial editorial review. Members of the international editorial team will liaise with contributors during the finalisation of case studies.

Casebook structure and timelines

The proposed casebook format will be similar to the WHO Casebook on Ethical Issues in International Health Research (https://www.who.int/ethics/publications/9789241547727/en/). Case studies will be organised thematically into chapters. Each chapter will additionally contain an introduction to the theme and suggested additional reading. If you are interested in co-authoring a chapter introduction during February and March 2021, please contact Susan Bull to discuss areas of specific interest and potential contributions.

The Casebook is expected to be published on an Open Access Platform at the end of March 2021. Publication details will be advised once finalised.

Acknowledgments

We are committed to appropriately recognising contributions to the casebook. To limit potential re-identification of individual cases, our proposed approach is to collectively acknowledge and list all case study authors at the beginning of the casebook. If you have an interest in being acknowledged as the author of a specific case, please contact Susan Bull to discuss the permissions required. Authors of the chapter introductions and members of the editorial team will be specifically acknowledged.

Funding

This project is funded by the World Health Organization (reference: Call on Public Health Emergency Preparedness and Response Ethics).

Draft case study 1: Research or surveillance?

Coronavirus antibody testing initiatives in a European country

Throughout 2020, a number of different programmes involving testing for coronavirus antibodies were established in a European country.

A major biobank invited existing participants to provide blood samples in order to provide data about the extent of previous infection in different parts of the country. This research study was subject to standard ethical review processes. No feedback of results was available to participants, on the basis that this was a research programme, set up to study results at population and not individual level. As such it was not intending to offer a clinical or public health service.

At the same time, health authorities in the country established an antibody testing programme. This programme had the similar aim of providing information on the prevalence of COVID-19 in different parts of the country and of helping improve understanding of how the disease was spreading. This was not badged as research, and did not undergo ethical review. Antibody testing was offered initially to healthcare workers, and then to patients who were having a blood test for other purposes. Results were shared with participants.

Running alongside these two initiatives, a nationwide study of levels of both current and past infection was considered to be research, and was subject to ethical review. Participants were sent their results around a week after testing.

Questions

1. What are the differences between the initiatives identified as research, and the initiative identified as public health surveillance?

2. How relevant are these differences from the perspective of the participants who are being invited to take part?

3. Could these differences in approach be justified by technical reasons, for example relating to the likely accuracy of individual results? If so, how could this be handled so that participants feel informed and respected?

4. Does the fact that the public health initiative did not require ethical review mean that it raised no ethical issues?

Draft case study 2: Restarting research

A community-based intervention for indigenous older persons with mild/moderate dementia

Cognitive Stimulation therapy (CST) has been shown to improve cognition, mood and quality of life in adults with mild to moderate dementia. Delivered in twice-weekly group sessions over a seven-week period, it is considered safe and is delivered therapeutically internationally and in some regions of the country where a CST trial was being conducted.

In the trial gerontology researchers partnered with an indigenous community in a relatively remote area where CST was not available. Working together over time to develop trust and mutual understanding, the researchers and community adapted the programme for culturally appropriate delivery, in the indigenous language. The researchers and community commenced a trial to determine its effectiveness, with several rounds of recruitment planned. The indigenous community was instrumental in recruitment and facilitating the trial.

The first round of the study intervention, involving ten participants, was completed before COVID-19 emerged. It demonstrated significant improvements over baseline measurements for both cognitive function and mood and was well received by the participants and their wider family networks. The second group of participants had been recruited and baseline measurements completed when the first COVID-19 cases in the country were reported. Shortly thereafter the country was placed under prolonged lockdown restrictions. In line with public health directions, the trial was put on hold. COVID-19 spread in several aged care facilities during the first wave in the country, resulting in deaths and highlighting COVID-19's increased morbidity and mortality rates in older people, which had been reported internationally.

After several months, lockdown restrictions were eased and some normal activities were able to resume. Several of the recruited participants had been placed in care in the intervening period and were no longer able to participate in the study. Baseline measurements would have to be completed again for the remaining participants and new participants identified. It was possible that participants and their families would be more cautious about the intervention's group setting given the effects of COVID-19. A decision was made not to proceed with the recruited participants but to re-attempt recruitment at a later date when the outlook regarding COVID-19 rates in the community and public health responses was more certain.

During the months following that decision, localised lockdowns outside the study area occurred, highlighting the ongoing risk of COVID-19 transmission. Community workers who would be involved in recruitment and delivering the intervention were managing increased demands for their services. The researchers had time-limited funding to develop relationships with indigenous health providers in five more sites, with a view to rolling out the adapted programme more widely. However, those efforts hinged on completion of the trial.

Once COVID-19 was well-contained nationally there were no government restrictions preventing the trial, and there appeared to be no COVID-19 circulating in the community. In the absence of nationally-licensed COVID-19 vaccines and curative treatments, researchers remained reluctant to recommence recruitment due to the ongoing risk of a possible COVID-19 outbreak with attendant risks to older people. They, and their community partners, were unclear about how to determine when recommencement of the trial would be justified.

QUESTIONS:

1. What factors should determine when, and whether, this trial is recommenced?

2. Should a higher level of caution regarding participant risk apply in a research context than that which is embedded in national and local public health measures?

3. How should the potential benefit of participation in this trial figure in reasoning about when recommencement is justified?