Guidance for research in response to humanitarian emergencies

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Introduction

A humanitarian emergency is defined as a natural or human-made phenomenon of a scale that it overwhelms local resources and severely disrupts the functioning of a community or society. Conducting research during or in the immediate aftermath of an emergency poses increased practical and ethical challenges, not least because the need to rapidly generate valuable knowledge must be constantly balanced with the principles of humanitarian assistance. The purpose of this guidance is to outline the ethical principles that should guide research during emergency responses. They are established principles of research ethics, yet their application will depend on the unique set of circumstances in which activities take place. Emergency research is unavoidably context and time sensitive, making generalized guidance difficult. This document does not provide a checklist for decision making but aims to assist researchers discern what constitutes ethical practice during these exceptional times. It is intended as an aid to ethical decisions.

Social Value

Ethical research should maximise the potential benefits of the knowledge generated and ensure that these outweigh any harm to participants, communities and society. Emergencies involve multiple urgent needs and time pressure to act swiftly, alongside stretched material and human resources. For this reason, research during emergencies should only be conducted if it has high social value: it provides support to the immediate response, either through evidence that assists decision making or direct interventions aimed at minimizing the magnitude of the harm suffered by a population.

In deciding whether a particular research study can be justified as socially valuable during an emergency, the following criteria should be considered:

- *The study has realistic prospects to answer the most pressing questions and provide critical evidence to assist decision making and/or meet the immediate needs of those most affected.*
- *The study will help build preparedness for future emergencies.*
- *The study design is appropriate and sensitive to the challenging contexts in which research is taking place, and respectful of people's attitudes and emotions.*
- *The study directly contributes to the humanitarian response through adequate coordination with governments and relevant non-governmental organisations.*

Fair participant selection

Decisions regarding who to include in a research study should always be based on principles of fairness and justice. Participants should be chosen on the basis of the study aims and not because of ease of access, vulnerability, privilege, etc. During emergencies, pre-existing vulnerabilities are amplified, and new ones emerge, whilst otherwise resilient individuals may find themselves in highly precarious conditions. Individuals experience susceptibility to harm in various degrees and at different stages of the emergency. *It is therefore important for researchers to take an intersectional, nuanced approach and consider the varying levels and types of vulnerability experienced by research participants during emergencies and avoid using the vulnerability label indiscriminately.*
Researchers must avoid exploiting individuals' needs and vulnerabilities to advance the research aims; they should be equally weary of excluding potential participants simply because of their vulnerability and consider the risks of not including them. Rather than automatic characterisations of vulnerability, *inclusion and exclusion criteria should be based on a consistent assessment of the risk/benefit ratio for a particular group(s) and in the particular context in which they find themselves during an emergency.*

Benefit sharing

Individuals and communities who participate in research should benefit from their participation. During emergencies participants and communities should have access as soon as possible to the direct benefits of the research. In particular, *participants should benefit from any treatments resulting from the study, including unregistered and investigational interventions, provided they are considered safe and effective.*

Researchers have a duty to maximise access to interventions for research participants but must also consider equitable distribution of research benefits for those most in need. Individuals enrolled in research studies may be those already accessing the essential services that facilitate participant recruitment in the first place. When thinking about fair allocation of resources and prioritisation of research benefits, it is therefore important to consider the ethical issues arising from research not in isolation but as part of the ethical complexity of the humanitarian response as a whole. *Research benefits should be made available to participants as soon as possible but care must be taken that this does not prevent those most in need from accessing essential help.*

Consent

During emergencies, many factors can challenge researchers' ability to obtain genuinely informed consent to research, from dealing with uncertainty, disruption, fear and family separation to language barriers and unequal power relationships. Challenges to voluntary and informed decision-making may be exacerbated where potential participants are unclear about the distinctions between humanitarian assistance and research or where no effective treatment is available.

These challenges do not suggest that informed consent can simply be waived during emergencies and *researchers must always ensure that the interests of prospective participants are properly considered.* In some situations, it may be necessary to develop rapid mechanisms for obtaining consent. *Researchers should also identify appropriate ways of seeking consent from those who are most marginalised and disempowered*.

In some emergency contexts it may be necessary to waiver consent. Examples when individual informed consent cannot be sought include research with unconscious patients and research that would otherwise not be feasible or practicable – for example when using data from population databases. In these unusual circumstances, *waiver of consent should be accompanied by measures to ensure community acceptability and earlier publicity within communities.* Where prospective participants are too unwell to give full consent, an attempt should be made to involve them in the decision making, e.g. by establishing an emergency assent process.

Tensions between research and duty of care

In humanitarian emergency research, it is often inevitable that there is a conflict between the duty to provide assistance and the aims of research. In the medical field, that conflict has been conventionally resolved by the concept of "clinical equipoise": that duty of care can only be reconciled by the impersonal constructs of research when, all things considered, there is reasonable and genuine disagreement about the best approach to a clinical problem, because there is value generated in resource allocation and in making better clinical decisions.

Even in the absence of this clinician-patient relationship, researchers should ground their commitments in treating each person as a free and equal agent whose basic interests should not be sacrificed for public welfare.

Therefore, *interventions in response to humanitarian needs should take priority – people who do not have their basic health needs met should not be asked to take part in research*. The emergency response should also pay close attention to other essential services and *researchers should not undermine or threaten such provision.*

In determining the balance between the interests of individuals and the wider interests of communities, further consideration should be given to the following:

- Is respect demonstrated for others as moral equals?
    - Is appropriate respect for dignity, humanity and human rights (including basic food, shelter, health and security needs) provided to research participants?
    - Are communities being involved in decision making? (see community engagement)
    - Is appropriate feedback and follow-up being provided?
- Whose needs are being met by this research and are these the most important needs?
    - Could this research be achieved through other non-emergency means?
    - Is there a direct or indirect benefit to research participants and/or to the effectiveness of the emergency response?
    - Is there a reasonable expectation of benefit?
- How can fairness be achieved?
    - Are the benefits and burdens equitably distributed?

    o   Are the primary goals of crisis response threatened or undermined?

    o   Is the study designed fairly (such as inclusion criteria, recruitment, treatment)?

Trust, respect, accountability and transparency

The development of trust-building relationships between researchers and participants and local communities, can be undermined by fear, stress, panic and time constraints. In order to establish trust in research in emergency situations researchers should:

- *Take into account participants' vulnerability in order to build respectful relationships and avoid 'empty choice', where research participation becomes the only possibility for participants to address basic needs.* Strategies to address the basic needs of participants could include collaborations with recognised humanitarian organisations or, if trusted by the local populations, governmental organisations. Addressing basic needs of participants avoids false expectations, which could lead to misunderstandings and distrust.
- *Build trusted/trustworthy relationships through community engagement*. Engaging with local communities will enable researchers to better understand the acceptability of the proposed intervention and respond to the needs of the community, and avoid additional burden the research might involve (see community engagement).
- *Develop clear and transparent research goals that serve the interests of the community and minimise harm.* Trust can be built only in a system that is not exploitative and non-discriminatory, therefore, it is important to be transparent about your research's aims and goals.
- *Communicate clearly*. Giving participants clear information about the nature of research, its aims and risks and the development of transparent governance frameworks (e.g. data sharing policies) can promote trust and accountability. This involves widespread information and consultation prior to recruitment, and throughout the research. It is important for researchers to be clear about limitations, benefits and potential harms of emergency research to manage unrealistic expectations during a crisis. A clear governance framework detailing data protection strategies allows participants to hold researchers and institutions accountable in case of misconduct.

Data sharing

Rapid data sharing in times of emergencies is crucial to improve the effectiveness of the response, reduce risks, save lives and rebuild livelihoods after the crisis. Despite the urgency and benefit of data sharing, humanitarian action must remain compatible with data protection:

- *Continue to follow current guidelines for data protection during the crisis, and recognise that pre-existing standards for data sharing have not changed.* Data protection principles should **not** be abandoned because there is a crisis.
- *Establish clear boundaries for future data sharing.* History tells us that it is difficult to discontinue practices (e.g. surveillance) started in an emergency. In the absence of clear systemic rules, it must be made clear that "emergency" practices are not continued after

the crisis is passed, and data should not be kept forever or used for other purposes; clear rules help maintain and build public trust.

- *Understand how your own datasets relate to the needs of those leading the response.* Not every dataset is useful. Sharing flawed data or focusing on only one dataset can lead decision-makers astray. Data sharing plans should help other researchers to understand both the best ways that their data can be used and the risks associated with sharing their datasets.
- *Be transparent.* To maintain public trust and confidence, it is crucial to clearly explain what data is being shared, with whom, for what purpose, how data will be anonymised (de-identified), stored and what will happen to data after the crisis is passed.

Collaboration and coordination

The purpose of a research collaboration is the pooling of expertise and resources to co-produce knowledge. This pooling is even more critical during emergencies where duplication of efforts may lead to wasting scarce resources or diverting them from response efforts and must therefore be prioritised over competition. Collaborations among researchers should generally be based on mutual respect and recognition, openness, equitable opportunities for intellectual ownership and fair authorship practices. During an emergency, however, it is likely that the challenges of establishing fair collaborations will be exacerbated by time pressure and disruption, and trade-offs between the immediate need to reduce suffering and long-term goals of building consensus and fair engagement may seem inevitable. *Researchers are nonetheless expected to behave with honesty, respect and openness towards their collaborators, and recognise and nurture the strengths and skills each partner brings as these are essential to the research efforts.*

Equally important during emergencies are effective collaborations with non-research actors, particularly those delivering the response "on the ground". Some research will be well integrated into the humanitarian response; in these cases *researchers must ensure appropriate coordination so that services are in place by the time individuals are enrolled in a study*. In some cases, however, research may not be fully aligned with the emergency response but may still require collaboration with and logistical support from individuals or organisations involved in various aspects of the response. In these cases, *effective coordination, communication and leadership is required to ensure that response services are not overstretched, and populations/groups neither overburdened nor overlooked.*

Community engagement

Meaningful community engagement involves a significant amount of interaction between stakeholders and researchers, from the conceptualisation of research to the implementation and feedback of results. Increasingly during emergencies, research has moved to a virtual space and this presents unique challenges for researchers and their stakeholders. Reduced interaction may weaken the bonds and relationships that have been already nurtured or that were developing. Researchers ought to consider the following:

- The need to consult, negotiate and involve community stakeholders to *develop a new or modified engagement strategy* that suits the current environment and context.
- *Utilising existing community networks* to reduce duplication of effort.
- *Creating virtual communities* in order to remain connected to community stakeholders and participants. Various platforms may be utilised but will need to be one that suits the majority of stakeholders. The platforms need not be complex for stakeholders to connect to.
- Ensuring that *community stakeholders are well informed of the ethical and regulatory implications* of moving to virtual community platforms. Appropriate data protection laws and regulations ought to be followed.
- Ensuring that *all stakeholders have equal access* to these virtual communities and platforms, for example by supplying devices.
- *Requesting community stakeholders' assistance in contacting participants* and ensuring that participants receive correct information. Researchers ought to make reasonable effort to create core messages to communicate risk for individual and community protection.

Some special consideration for research in low- and middle-income countries

- *Researchers ought to follow in-country guidance* released by regulators and/or research ethics committees as much as possible and where there is no direct guidance, researchers ought to adhere to the highest possible international standards.
- *Researchers should not abuse situations of emergency by using unapproved or unorthodox means*. For instance, it may be necessary to visit participants in their communities when they are not able to attend clinics or other research facilities, but doing so without prior consent and due discretion (e.g. using marked project vehicles, wearing project paraphernalia, etc) might compromise confidentiality , anonymity and privacy with far reaching consequences.

Conclusion

The ethical principles that ought to guide the conduct of research under normal circumstances should also be followed when research is conducted in emergency settings. However, the operationalisation of these principles may exacerbate certain issues and present new challenges, often compounded by the context and time sensitive nature of research activities. In seeking to follow ethical principles in the midst of the inherent uncertainty that emergencies entail, researchers will need to take interpretative stances. This may require a greater focus on researchers' internal ethical compass than on the rules and regulations that externally nudge behaviours and motivate compliance. When researchers are faced with the inevitable difficult decisions and the temptation to settle for less than the highest personal and professional standards, all they may have is their own consciences.

Resources

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