

ARTICLES

Rethinking Vulnerability and Research: Defining the Need for a Post-Research Ethics Audit

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Abstract

Vulnerability of research populations is a fundamental area of interest and debate in bioethics. Based on mental health research in a humanitarian setting context, I explore vulnerability-related issues and developing enhanced protective practices. Motivated by experience from mental health research among forced migrants, and faced with a lack of guidance in the sharing of ethical lessons, I explore the concept of post-research ethics audit as a mechanism for reflection that researchers working with vulnerable populations can use. Presently, a coherent post-research strategy to critically examine the quality of ethical frameworks, debrief researcher experience and explore ethical challenges in research implementation is unavailable. The more established clinical audit process can be a model for the post-research ethics audit due to conceptual similarities in improving current practices by comparing the ideal versus the real scenario and measuring the effect of implementing changes. The proposed strategy presents a feasible way of identifying discrepancies between existing guidance and actual on-field implementation of research. Such a concept, if supported by empirical evidence based on its applicability, adaptability and feasibility, can become a platform to identify participant community needs, perceive community-specific ethical challenges,

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identify gaps in ethical oversight, and examine researcher integrity and potential misconduct. However, such activity needs to be researcher- and ethics committee-friendly, easily adaptable and implementable within existing ethical oversight frameworks, to enhance researcher-driven ethical practices and promote participant involvement.

Keywords: Vulnerable populations; post-research ethics audit; ethics review; mental health research; humanitarian settings

Background

Vulnerability is considered a fundamental issue in research ethics since the inception of bioethics, and forms a central part of all of the principle ethical guidelines today.¹⁻³ Vulnerability and vulnerable populations have been defined in various ways, oriented around the theme of inequality in exposure to harm and subsequent protection against the risk of harm or exploitation.^{4,5} However, the many attempts to define vulnerability and the vulnerable seem to have created wide-ranging debates among ethicists and researchers, often neglecting an all-important point: identifying practical and realistic ways to minimise harm and exploitation of at-risk, susceptible research populations. In this article, using mental health research in humanitarian settings as a contextual platform, I explore the idea of a post-research ethics audit and the ways it could be used as a practical tool in increasing protection and reducing harm and exploitation of vulnerable populations.

Vulnerability, Vulnerable Populations and Research

The broad definition of vulnerability is based on the principle of increased risk of harm for those who are liable to bear an unequal burden, and the ability to make an informed decision based on autonomy.⁵⁻⁷ From the Nuremberg code to more contemporary codes of ethical practice in clinical or research settings, vulnerability and vulnerable populations have been regarded as a special area of concern.^{1-3,8-10} Various attempts at exploring vulnerability in conceptual, contextual and needs-based approaches can be found in the literature.^{4,5,11,12} Grouping or “labelling” populations deemed vulnerable has become an accepted ethical practice, although some researchers and ethicists argue against such practice, as it may promote stereotyping, paternalistic attitudes, reinforcement of stigma and hindrance of research.⁶ Power-relationship issues are central to ethical conduct and particularly salient in research among some vulnerable

populations (e.g. conflict-affected people, disaster victims and the mentally ill), as clinician-patient or researcher-participant power dynamics can become disproportionately imbalanced by the inherent lack of power and autonomy among such groups.¹³ However, vulnerability of other groups (e.g. pregnant women) are often not linked to a lack of power.

Despite these different views, both ethicists and researchers tend to agree that the vulnerability of certain populations requires increased protection, and that informed consent should ensure maximum autonomy of participants and minimise harm and exploitation. Ethical issues arising from research among vulnerable populations has been a topic of extensive debate, especially in the context of mental health research in humanitarian settings (e.g. conflict-affected, disaster victims).^{5,8,14–18}

Mental health research among traumatised populations in humanitarian settings involves complex ethical dilemmas.^{18–21} While all research projects must adhere to ethical principles, mental health research conducted in humanitarian settings is open to particular concerns of autonomy, informed consent, justice, and differing cultural understandings of illness, health and behaviour.^{22–24} Further compounding these ethical issues are concerns of possible language barriers, ongoing conflict, disrupted health systems and challenges of methods and measurement validity.^{21,22,24} Populations in humanitarian settings present opportunities for unscrupulous researchers to conduct unethical and exploitative research, in the guise of humanitarian aid.^{25,26} As research is often conducted in chaotic environments, the risk of participant exploitation, coercion or inducement can be high.^{21–26}

Protective Mechanisms: Current Practices in Research Ethics

In contemporary bioethics, protecting vulnerable populations from harm has generated special interest. Key guidance statements have dedicated sections to discussing research among the vulnerable, emphasising the requirement of minimising harm and exploitation.¹⁴ The latest amended version of the Declaration of Helsinki states that “all vulnerable groups and individuals should receive specifically considered protection”, highlighting that research among vulnerable groups is justified only if it is meeting health needs of the population and that the groups should benefit from resulting research outputs.²⁷ Research ethics committees and researchers are governed by these guiding statements, along with an implicit need to implement ethically sensitive strategies in the design of mental health research protocols and in the ethical approval process.

As highlighted by Hurst (2008), approaches to vulnerability and related research ethics practices are largely based on consent and harm or a combination of the two. Such approaches are aimed at safeguarding participant rights in a balanced nexus of power between them and the researchers, with the ethical oversight provided by REC.⁵ However, valid questions arise over excessive protection deemed necessary for the vulnerable, often misguided by “grouping” or “labelling” tendencies shown by REC, which hinder research progression and may itself be unethical by denying access to new treatments and research modalities.^{4,6} Despite and regardless of different perspectives on the definition of vulnerability, I argue that increased attention should be paid to the adequacy of safeguards against potential harm and exploitation, and to the evident lack of guidance on protective mechanisms.^{11,28} I propose that the process of identifying the risks of harm or exploitation and inter-linked protection strategies requires a dynamic approach, which should not be limited only to a pre-research assessment, but should also include a feedback mechanism by way of a post-research ethics evaluation.

Post-Research Ethics Audit: Revisiting the Ethics Process

The concept of post-research ethics evaluation as a tool for enhancing ethics practices was first discussed through a publication outlining ethical challenges encountered during an epidemiological study among a group of internally displaced people (IDP) in Sri Lanka.²⁹ This publication explored theoretical aspects of ethics considered during the design, funding and ethics approval stages of the study, while highlighting numerous challenges encountered during the conduct of research in the actual field setting. Although ethical challenges with informed consent, confidentiality, minimising harm and cultural issues were perceived and addressed by the research team and ethics committees, a number of hitherto unperceived challenges were identified during research implementation.²⁹

Three decades of civil conflict, which concluded in 2009, was the main cause of forced internal migration involving populations living in Sri Lanka’s northern and eastern provinces. Different groups of these conflict-affected, forced internal migrants (or IDP) have endured prolonged (over 20 years) or short-term (2–3 years) displacement episodes, and have been the subject of various mental health research, ranging from epidemiological surveys to interventional studies.^{29,30} Inherently, these IDPs can be considered as “vulnerable” based on a number of reasons: experiencing conflict-related physical and psychological trauma; going through conflict-enforced displacement; living in camp-like resettlement

facilities during displacement (in some cases for prolonged periods of over several years); living under the power of various authorities; and dependence on financial, material or other forms of aid. Due to their vulnerability and the humanitarian context, they face an increased risk of exploitation for research in various ways, as discussed earlier.

Currently, these populations are, to a degree, protected from exploitation for research by the ethical approval requirements in place for biomedical research. However, sociological and other types of research among forced migrant populations in Sri Lanka are not covered by similar stringent ethical guidelines, leaving substantial gaps in protection. Sri Lanka has a number of RECs, mostly linked to medical faculties of major universities and some have received international accreditation. Mental health research conducted among vulnerable populations, including IDPs, are usually subjected to thorough scrutiny by these RECs. However, ethical oversight provided by most of these RECs ends with the provision of ethical approval before study commencement. Although an end of study report is a mandatory requirement by a few RECs in Sri Lanka, no information is available on the assessment outcomes of such reports.

Despite the protective mechanisms described above, the specific internally displaced community chosen for our study has been seen as an easy target for exploitation by various groups of researchers, and we became aware of previous attempts at coercion and inducement. Thus, we had to prove our credibility prior to approaching the community. The IDP community we worked with had a strong religious and civic leadership through state appointed “camp officers”. In order to recruit individual participants, we first had to approach these religious and civic leaders. However, due to the nature of their social power dynamics, our introduction to the community by these leaders had presented the possibility of undue influence. As a preventive measure, we had to develop unique ways to minimise the role of power hierarchy in the recruitment process, while keeping our relationships with the leadership and community intact. We used gender-matched research assistants to counter sensitivities within the community. During the ethical review process, we also encountered problems due to the inadequate expertise in ethical oversight of mental health research within the REC.²⁹

It was observed that the particular internally displaced community lacked ways to voice their health research needs and also did not possess a platform to voice their concerns or opinions about research conducted among them. Although our research team managed to obtain insight into the community health research needs through interactions during the study, there was no known helpful strategy to share our knowledge with the wider research community,

particularly among those with potential research interests in a similar participant community. Although one can argue that the publication of academic papers or dissemination activities through other media would be a way to address this, we found it difficult to tailor some of the sensitive information (e.g. inter-communal issues, politically sensitive declarations, inter-ethnic issues, etc.) to match journal or other media requirements for publication, without breaching existing ethical guidelines and boundaries.^{31,32} Although public engagement has been promoted as a solution to disseminate research findings to participant communities,³³ it appears to lack the necessary means to provoke reflection on specific ethical dilemmas that concern both participants and researchers.

We also encountered a common problem faced by researchers in any setting: the important factor of researcher integrity. Contemporary research processes are complicated and extremely demanding due to the interplay of funding regulations, deliverables, ethical approval and career issues, to name a few, thus increasing the chances of unsound ethical practices and damaging researcher integrity.^{34,35} Although consciously uncompromised in ethical aspects, our study stands to benefit from a re-examination of the ethics process, and such an exercise would identify potential gaps in practice.

Vexing Retrospection or Helpful Hindsight?

Withholding important research findings (e.g. clinical trial findings) from participants can be considered as unethical practice, especially in the contexts of developing countries, humanitarian settings and vulnerable groups.³⁶ Similarly, withholding information about participant community needs (expressed by those communities) and lessons learnt during research processes can also be considered as unethical practice. Research findings are usually shared through academic publications, and are sometimes also made accessible to the general public through the mass media. However, experiences of researchers gained in specific contexts, especially while conducting research among vulnerable populations in cross-cultural settings, are rarely shared. A key characteristic in this lack of knowledge-sharing in process pathways is the absence of a coherent post-research strategy to debrief the researcher experience, especially the ethical aspects of research implementation.

Although the Declaration of Helsinki states that researchers have to submit a final report containing study findings and conclusions to the REC that is responsible for the ethical approval and subsequent oversight,²⁷ this is not practised by many RECs, whose responsibility of ethical oversight usually ends with the final ethical approval prior to study commencement. Where post-study reports are required, clear guidance in how to discuss ethical challenges is lacking.

Benatar (2002) argues that RECs have a responsibility to monitor and audit research processes in order to enhance accountability.³⁶ However, the responsibility of ethical oversight, especially post-research evaluation, cannot entirely centre around the REC and should involve multiple stakeholders in the research process: researchers, participants, funding agencies and advocacy groups.

The lack of a participant community voice to communicate its research needs and the absence of a platform to share insights with other researchers are two important ethical issues that can be addressed through a retrospective ethical analysis. The issue of post-clinical trial benefits to participants has been much debated, but an agreement has been reached, in that efforts should be made to diversify post-trial benefits to both participants and the associated extended communities. Through a post-research ethics audit, a similar conceptual framework can be developed for studies which are non-randomised controlled trials, encouraging the distribution of benefits to the wider public.

Furthermore, an ethical framework report commissioned by the Research for Health in Humanitarian Crises in 2014 revealed issues, such as the failure to obtain ethical approval for programme evaluations or follow-ups, and a lack of continuous ethical oversight from REC approval up to the end of the research process.³⁷ Overlapping concerns of consent, confidentiality, power and risks to participants and researchers are crucial issues in mental health research in humanitarian settings.¹⁸ However, there is a dearth of practical resources to support researchers and RECs to tackle these concerns, with current bioethical models lacking the ability to address complex issues present in these settings.¹⁸

The post-research ethics audit or evaluation is proposed here as a tentative solution to address these gaps. Although not a completely new concept, it has yet to see wider (if any) implementation. It can be considered an important tool in developing adequate protection to vulnerable populations.^{11,14} The role of an “ethical ombudsman” has been suggested and researched as a tool to ensure the autonomy, voluntariness and confidentiality of the informed consent process.³⁸ Similarly, the proposed strategy can provide mutually useful information on ethical issues in research from concluded studies to both RECs and researchers.

Declaration of Helsinki requirements, Benatar’s (2002) concerns and gaps in continuous ethical oversight^{27,36} can be addressed by incorporating the post-research ethics audit into a final report submitted to the REC by researchers, by way of a section dedicated to discussing ethical challenges encountered during the study process, how they were addressed, lessons learnt and a set of recommendations for other researchers planning to work with the same participant community.

However, it must be reiterated that the process does not have to be embedded within REC regulations. While that is an option to be considered, a more viable option is to create an open forum where researchers and the REC can discuss, reflect and engage on ethical challenges encountered during research implementation.

The proposed audit method can be drawn from the more established clinical audit process, based on its similarities in improving current practices. It will explore the ideal setting versus real setting, and find ways of implementing change.³⁹ Clinical audits are considered an effective and systematic way of improving patient care.³⁹ The same principle can be applied in improving the ethical aspects of recruiting research participants and subsequent research process management, using the classical audit stages of: i) setting standards; ii) measuring current performance; iii) comparison of practice and standards; and iv) implementing change.³⁴ Existing ethical guidelines in research ethics can be considered as the standards mentioned in stage 1. Current performance (stage 2) equivalent refers to the ethical practices of researchers during the research process. By retrospective comparison of practice against the standards (guidelines), gaps and lapses can be identified.

In addition, the post-research ethics audit presents a feasible opportunity to recognise discrepancies between existing guidelines and their actual field implementation, along with gaps in existing guidance provision itself. For example, instances of protocol deviations due to logistical or methodological obstacles during the research process require rapid responses from researchers and the REC in amending protocols which more often than not are hampered by a lack of guidance. Previous records of responses in similar situations, gathered through a process such as the post-research ethics audit, would be an ideal reference point for guidance to researchers and RECs, when faced with such dilemmas. Identifying such discrepancies also creates a unique opportunity of information flow between guidance and practice, enabling dynamic changes at both ends.

The post-research ethics audit can be used to give voice to participant community needs, by enabling representatives of the participant community to provide feedback on research projects. Such feedback can be gathered on the suitability and necessity of research projects—whether sufficient justification was provided; whether participant needs were met during research; and whether participants were made aware of potential short- and long-term risks and benefits at the individual and community levels. It must be noted that if participant feedback is gathered through researchers, however, there is a possible risk of misinterpretation. To avoid this, a third party such as the REC, advocacy or

activist groups could contact participant community representatives during the post-research period. Else, a central public forum can be established (country-wise, region-wise, or globally), where research participants can provide such feedback without compromising their anonymity or confidentiality. However, the feasibility of this aspect of the post-research ethics audit requires empirical exploration.

Thus, the post-research ethics audit has the potential to become a multi-pronged framework that can: identify participant community needs via the feedback of its members; recognise community-specific ethical challenges; identify gaps in ethical evaluation and guidance; and provide an in-depth examination of researcher integrity and potential misconduct. However, without a doubt, a reflective activity framework such as the post-research ethics audit needs to be researcher- and REC-friendly, and easily adaptable and implementable within the existing ethical evaluation frameworks. For such a concept to take root, a culture of trust needs to be developed between various stakeholders, including researchers, RECs and research participants. Furthermore, any process of discussing ethical issues arising from a study has to be sufficiently rigorous, credible and comprehensive so as to draw and sustain the interest of other researchers.

As pre-research ethical approval has become a highly technical, often cumbersome and unappealing process to researchers, a post-research ethical oversight process may be unwelcome as an additional burden. However, in the context of vulnerability and prevention of exploitation, the post-research ethics audit is as important as the pre-research appraisal. To ensure that such a process can appeal to researchers and RECs, and be pragmatic without being an added burden, the post-research ethics audit process needs to be further developed through empirical research.

Potential steps that can be taken to establish a post-research ethics audit and test its feasibility include:

- i. Identifying current ethical issues, challenges and guidelines pertaining to mental health research through a systematic literature review.
- ii. Creating a series of case studies and vignettes representing identified current ethical issues and challenges.
- iii. Engaging mental health researchers, research teams, participants, community representatives, advocacy groups, REC members and other stakeholders, and gathering empirical data on ethical challenges in mental health research (current/completed) and on the need and feasibility of a sharing mechanism of lessons learnt during research. Qualitative methodologies, such as individual in-depth interviews and focus groups, can be used to collect empirical data.

- Broader areas that can be explored include: issues around vulnerability, autonomy, beneficence, risk versus benefit, informed consent, participant voices, researcher integrity and ethical oversight.
- iv. Development of a structure and the format of a post-research ethics audit mechanism, and a guidance document using both systematic review and primary data.
 - v. Conducting a pilot-test of the established mechanism with selected mental health research groups.
 - vi. Establishing a final version of the post-research ethics mechanism and guidance document which should be open to adaptation into different languages and settings.
 - vii. Establishing an open forum (e.g. web-based database) as a central repository where post-research ethics audit mechanism and guidance can be accessed, and where subsequent findings can be shared. It is envisaged that this repository can be gradually extended to link the wider global academic community, with adequate safeguards in place to protect confidentiality of information and anonymity of researchers and participants.

These steps are drawn from a proposed project that the author is involved in. It must be cautiously noted that the proposed steps require further refinement and more consideration ought to be given to the hugely diverse types, settings and methods of mental health research.

Many research studies conducted in conflict- or disaster-affected settings face the challenge of adapting to fast-changing ground realities and keeping within the ethical norms defined in pre-research ethical approval. Due to the time-consuming nature of amending study protocols, researchers are sometimes forced to abandon the projects or conduct less valid research in these contexts.^{18,37,40} However, a pre-existing knowledge repository, generated through real-life experiences of managing ethical challenges by other peers, would enable the researchers to pre-empt at least some of the potential field issues. Researchers, often daunted by the prospect of identifying and dealing with ethical issues, would find such a repository of knowledge an immensely helpful resource, and could be encouraged to contribute by conducting a post-research ethics audit of their own studies. In addition, RECs and researchers can share the ethical audit findings through conventional academic platforms such as conferences and journals, where cross-cultural research often conducted in the developing world can benefit from universally applicable knowledge. The post-research ethics audit can also be used as a capacity-building exercise for researchers and REC members, to identify vulnerability and to prevent harm and exploitation.

Conclusion

The post-research ethics audit proposed here is a way of promoting the protection of vulnerable populations and preventing exploitation in the context of mental health research in humanitarian settings. It requires more empirical evidence to support its applicability, adaptability and feasibility. Although a study in Sri Lanka is used as the contextual background, the proposed post-research ethics audit will be beneficial not only to Sri Lanka, but also to other global humanitarian settings where mental health research is being conducted. Moreover, it should not be limited to mental health research in humanitarian settings, as it has wider applicability to many other health research settings where vulnerability plays a key role.^{22,24,40} It promotes good ethical practices for researchers and presents a way of strengthening the ethical review process through a retrospective examination of existing guidance and field-related realities. While it can be seen as another way of burdening the researchers and RECs—especially in settings of already limited and stretched capacity—a post-research ethics audit can be a viable, relatively less resource-consuming way of protecting vulnerable persons while enhancing researcher-driven ethical practices and promoting participant involvement. It can strengthen the existing research ethics guidelines significantly, drawing on feedback from the real-life experiences of researchers and participant communities in dealing with the ethical challenges of mental health research among the vulnerable.

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Notes

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