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Research primer

Principles of research ethics: A research primer for low- and middle-income countries

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ABSTRACT

Ethical oversight in the form of review boards and research ethics committees provide protection for research subjects as well as guidance for safe conduct of studies. As the number of collaborative emergency care research studies carried out in low- and middle-income countries increases, it is crucial to have a shared understanding of how ethics should inform choice of study topic, study design, methods of obtaining consent, data management, and access to treatment after closure of the study. This paper describes the basic principles of Western research ethics – respect for persons, beneficence, and justice - and how the principles may be contextualized in different settings, by researchers of various backgrounds with different funding streams. Examples of lapses in ethical practice of research are used to highlight best practices.

African relevance

- Low and middle income countries (LMICs) have a high burden of acute illness, but insufficient research on emergency care
- Ethical barriers and lack of oversight impede emergency care research in LMICs
- Ethical clinical research in LMICs builds capacity and contributes to the evidence base for emergency care

The International Federation for Emergency Medicine global health research primer

This paper forms part 7 of a series of how to papers, commissioned by the International Federation for Emergency Medicine. This primer discusses ways to ensure that research is carried out ethically. It discusses principles for researchers from the global north involved in emergency care research projects in LMICs and provides guidance for LMIC researchers who may not have experience for navigating ethical issues in research. We have also included additional tips and pitfalls that are relevant to emergency medicine researchers.

Background

Despite a disproportionally high burden of acute illnesses in low- and middle-income countries (LMICs), there is insufficient emergency care research. In a survey carried out through the African Federation for Emergency Medicine (AFEM), 67.3% of respondents agreed with this statement [1]. Research that targets local health challenges, such as context-specific health service delivery and drug development for diseases prevalent in LMIC, has the potential to improve population health in host countries [2–4].

Ethical barriers and oversight have been cited as an important barrier to research in LMIC [5]. Emanuel et al. provided a framework for conducting ethical research that stressed collaborative partnerships, social value, scientific validity, fair selection of study populations, favourable risk-benefit ratio, independent review, informed consent, and respect for recruited participants and study communities [6]. In their review of the framework, Tsoka-Gwegweni and colleagues concluded that most recurring ethical issues relating to research in LMICs were informed consent, scientific validity, fair participant selection and ongoing respect for participants [7]. Research priorities are often determined outside the host country, raising concerns of outsourcing risk

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and exploitation of uninformed populations [8].

The value of building ethical clinical research in LMICs goes beyond the specific information collected in a study. Conducting research has substantial positive impact in a community by raising local scholarly standards and encouraging independent thinking and creativity as many LMICs work towards building evidence-based emergency care systems. Each project builds confidence and skills which allows local researchers to participate fully in the scientific process which impacts the care of their local community. This may lead to intellectual and financial resources for the community which in turn encourages local empowerment and self-sufficiency for additional research.

Bioethical principles

Review of research protocols by experts not involved with the study is one way of ensuring protection for human research subjects. In the United States of America (US), such review committees are called Institutional Review Boards (IRBs). In other countries, these committees may be called Human Research Ethics Committees (HREC) or have other titles. Several articles discuss the evolution of HRECs in sub Saharan Africa [9,10].

Most Western scholars agree on the main principles of autonomy, beneficence, and justice for clinical ethics, with some adjustments in how these principles are applied in the research setting. However, these principles are not universally acknowledged. Some authors argue that these principles are less relevant in populations where community rather than individual values are stressed. Others argue that local development of research ethics is crucial to ensuring buy-in and avoiding bioethical imperialism [11,12]. Acknowledging the past abuses that took place under the guise of research, Western ethical thought now insists on voluntary consent, with special protections for traditionally vulnerable populations such as children, women, and ethnic minorities. Emergency care research, however, introduces a unique type of vulnerability in unconscious or other otherwise mentally altered patients who do not meet criteria for giving informed consent. In some Western countries like the US and the United Kingdom (UK), such patients may still be enrolled in studies through a different process called an exemption from informed consent or waiver of consent [13–15]. The same principle may be applied in LMICs, however, a detailed assessment of the research components necessary to guide HRECs in order to reach decisions that protect this vulnerable group from harm or unnecessary risk.

International standards

In 1964, the World Medical Association adopted the Declaration of Helsinki. This document and subsequent revisions lay out the principles of minimizing risks, informed consent, privacy, special protections for vulnerable groups, access to beneficial treatment after trial, and dissemination [16]. The first Declaration was adopted largely in response to the unethical experiments carried out by Nazi researchers during the Holocaust, in which prisoners were exposed to infectious disease, extremes of temperature, and experimental drugs without their consent, often resulting in death [17].

The Declaration is a guideline of research ethics but is not legally binding. Individual countries are responsible for implementing legislation that reflects the principles. In the United States, discovery of ongoing research abuses such as the Tuskegee syphilis study in the 1970's led to adoption of the Belmont Report [18]. The Belmont Report requires that researchers uphold three basic principles: respect for persons, beneficence, and justice. Researchers in the US must have the protocol approved by an IRB prior to enrolling subjects. IRBs are charged with operationalizing the principles outlined in the Belmont Report and subsequent regulations specified in the Common Rule [19]. Certain research may be exempted from IRB review and these typically include surveys, interviews, and research using existing specimens, records or data. The concept of “minimal risk to participants” plays a key role in allowing this exemption and should be considered when conducting research in LMIC's. “Minimal risk” is defined as that “ordinarily encountered in daily life or the performance of routine physical and psychological testing.”

These previous regulations, however, were written without consideration for Emergency Care research. Therefore in 1996, the US' Food and Drug Administration recommended procedures for enrolling patients in emergency situations into research studies through exemption of informed consent [20]. Similar procedures were adopted by the United Kingdom in 2006 [21]. This concept of “waiver of consent” in emergency care research should be considered in LMICs where contextualized processes are critical for development of sustainable emergency care systems.

Guidelines intended for global adoption often lack details required for context-specific implementation and can be slow to respond to emerging realities. Barugahare uses an analogy to jurisprudence to discuss how local HRECs can guide implementation of global ethical principles within their own contexts [22]. With that in mind, we will go through the guiding principles and discuss pitfalls in implementation.

Respect for persons

Respect for persons requires that research subjects freely participate in research after informed consent. Subjects should be counselled on the known risks of the drug or treatment being examined, the expected course of illness without intervention, and any compensation or benefit they may receive from participating. This must occur in the subjects' native language. If documents require translation from the researchers' language to the local language, the documents should be translated back to the original language and reviewed to ensure consistency with the originals. Only after the subject has shown comprehension and has had any questions answered can they be considered to have given informed consent. There is some disagreement about the need for a signature on a consent form, but researchers must treat consent as an ongoing process rather than a piece of paper. Subjects must also understand they are free to withdraw from the study at any time.

Research in the global context highlights challenges to the notion of consent. In the global north, the concept of respect for persons is often supplanted by the principle of autonomy. But many cultures outside the global north stress the importance of the family unit and communitarian values over individual decisions [23]. Community leaders and heads-of-household should be involved in the process, often before approaching individual subjects [24]. This is especially critical in emergency situations where “waiver of consent” protocols require involvement of family or communities of unconscious or otherwise incapacitated patients. Consent processes may also be challenging when approaching female subjects, who may require approval of a male head of household in addition to their own consent [25–27]. While 18 years is considered the age of adulthood in many Western countries, other cultures may consider younger persons to have reached maturity [28,29]. In one qualitative study of 15–19 year old participants in HIV research in Kenya, 50% thought parental consent should be sought, 25% felt this was not necessary, and 25% had mixed feelings [30].

Lack of education, limited health literacy, poor access to medical care, and the sense of urgency that accompanies disease outbreaks also call into question the notion of voluntary, informed consent. The Pfizer meningitis trial in Nigeria reported that 100% of patients approached were enrolled in the protocol, suggesting patients were desperate to access care [31]. All participants in a clinical trial for malaria believed procedures followed solely to meet research objectives were a required part of their individual curative treatment [32]. Some participants in an Ebola vaccine trial enrolled in hopes of accessing free healthcare for other conditions [33].

Beneficence

Beneficence requires that researchers obtain scientifically valid data with useful applications, while minimizing risks within the study protocol and protecting subjects during the trial.

Although several guidelines recommend research in LMIC focus on health conditions that contribute substantially to the local burden of disease, research objectives are set by funders and do not always meet this guideline. Research on cancer therapeutics focuses on lung and breast cancer, even when trials are performed in LMIC which have a large burden of cervical, liver and gastric cancers [34]. While some risk is unavoidable when testing new drugs, research subjects should expect benefits to accrue for their population.

Use of rigorous methodology with adequate power and appropriate control groups is essential to ethical research. Underpowered research, poorly designed studies, and falsified data will not yield valid results and are inherently unethical. The use of placebo controls has been an area of contention since early studies of maternal-fetal transmission of HIV [35]. While placebo-controlled trials are optimal from a methodological standpoint, patients should be treated with their standard local regimen if effective treatment is available. Cheah et al. provide a compelling rationale for a placebo arm in their malaria trial, as use of the placebo is equivalent to current clinical practice, thus the subjects do not incur additional risk [36]. Researchers should ensure that interventions proven successful will be sustainable in their study population [37].

Unproven interventions may be utilized during emergency and disaster situations. The World Health Organization convened a panel to help guide use of novel therapies during epidemics [38]. They stress the importance rigorous data collection to assess effectiveness and safety of such interventions, and transparency and fairness in decisions regarding access to investigational treatments.

Minimizing risk means building safety into the protocol and monitoring for adverse events throughout the trial. Adverse events may require unblinding, a report to the HREC, or cessation of the trial. Dissemination of all results, regardless of the success of the trial, is crucial to ensure future study participants are not exposed to risks of unsuccessful interventions and funding can be distributed to projects more likely to result in improved health [39].

Protection of privacy is another important principle of beneficence. Data should only be accessible to the research team. Surveys and other paper documents must be kept in a locked cabinet or drawer in a secure room. Files should be password protected. Study ID numbers should be substituted for individual identifiers. Master lists that could be used to link data back to participants should be destroyed after data is cleaned. Data must be de-identified before sharing data with anyone outside the original study team. Data-sharing is important for verification of results and avoidance of duplicate efforts, but regulations and guidelines have not kept pace with emerging technologies [40,41]. Privacy laws vary widely between countries, with the European Union having some of the strictest protections. Although it would seem that outside researchers would adhere to the standards they must uphold to in their own settings, this is not always the case. Medical students from the US are more likely to violate patients' privacy online during international electives than during rotations at home [42].

Justice

Justice requires that the costs and benefits of research are distributed fairly within the population. Even this statement is open to interpretation, as there are no global norms of fairness [43]. Justice is a key consideration in the research framework proposed by Pratt and Loff [44].

The global distribution of harms and benefits in research is particularly problematic in the setting of clinical trials. The cost of research is significantly lower in LMIC but there is concern that pharmaceutical companies are also benefitting from lax regulatory oversight to conduct high-risk research that would not be tolerated in the global north [45]. Millions of persons participate in clinical research each year, but the number of adverse events is difficult to determine and likely underreported [46,47]. Deaths in clinical trials are not distributed evenly across nations, with higher rates of morbidity and mortality in LMIC. While deaths in the global north tend to be rare and highly publicized, India had 2644 deaths during clinical trials in the years 2005–12 [48]. Laws regarding compensation for injuries sustained during research are markedly different between nations, adding another layer of disparities [49].

Compensation for participation in research is another potential pitfall. Western research ethics considers whether compensation for participation is enough to exert undue influence or coercion. Paradoxically, using this standard in LMIC research would decrease the value of compensation as smaller amounts would likely constitute a larger proportion of subjects' income [50]. Participation “gifts” of nominal value, such as soap or sugar, may carry hidden meanings in the local context and should be discussed with community leaders [51]. One proposed solution would be to consider participation as work, to be compensated according to local custom [52].

A final area of justice concerns authorship of manuscripts. There is an inherent imbalance of power when outsiders approach a community to do research. Researchers should strive to build capacity in local communities and ensure all members of the study team receive appropriate credit. The International Committee of Medical Journal Editors requires the following criteria be met to be listed as an author: contributions to study design, data acquisition, or data analysis, drafting or substantial revisions to the manuscript, final approval of submission, and agreement to be accountable for integrity of the work [53]. All persons who meet these criteria should be listed. Guest authorship has been reported as common and usually involves including superiors or subject experts that did not contribute substantially to the manuscript [54]. Some authors fear that the criteria to draft/substantially revise and approve the final document discriminates against researchers from LMIC whose native language is not commonly used for international publications [55]. Determination of authorship and order of authors may cause great angst, particularly if not done early in the process.

Emerging challenges

Data security

Collection of genetic material, even blood samples, may jeopardize anonymity. Consensus is lacking on how best to use “big data” to improve public health while protecting individual privacy concerns.

Tips on this topic

- Research in LMICs, contextualized to their local health systems, is necessary to ensure patients receive the most appropriate care.
- Researchers should ensure sound methodology and data management practices in their studies.
- Community engagement is one way of ensuring patients' values are incorporated into setting research priorities, the consent process, risk assessment, and dissemination of results.
- HRECs have a responsibility to protect human subjects but also serve to protect researchers from allegations of improper behaviour. Ethical approval for a protocol is required before researchers approach participants and is required for publication by most journals.

Pitfalls to avoid

- Failure to consider local norms in obtaining informed consent
- Failure to execute the study in exact accordance with the approved

study protocol and other documentation may undermine the ethical integrity of the project and violate the ethical principles of research. Any changes to approved study protocols must be reviewed and approved by the local HREC prior to adoption.
- Inadequate procedures for confidentiality and data security

Annotated bibliography

- Biruk [51] uses the example of soap as a gift for participation in surveys to discuss ethical compensation for participants and duties of researchers.
- Das et al. [32] discuss participants' limited understanding of the overlap of clinical care and research in malaria studies.
- Emanuel et al. [6] established benchmarks for ethical research in the global setting.
- The WHO advisory panel report [38] and Ezeome and Simon [31] discuss ways of minimizing ethical pitfalls when performing research during epidemics – these articles are applicable to the discussion of experimental treatments for the ongoing COVID-19 pandemic.
- Groves et al. [30] used qualitative methods to explore adolescents' views on research requirements for parental involvement in studies of HIV in youth.
- Ochieng et al. [10] describe the development of research ethics within Uganda, starting with early regulations on protection of human subjects, through revisions to applicable statues, and training of local experts.
- Tangwa [8] critiques the lack of inclusion of African researchers in the efforts surrounding HIV vaccine trials and the response to the Ebola outbreak of 2013–16.
- World Medical Association Declaration of Helsinki [16] describes the principles that should guide research. Most recent version available at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

Podcasts

Academic Life in Emergency Medicine: Society for Academic Emergency Medicine Research Learning Series provides helpful guidance for junior researchers in many stages of starting a research project. In particular, episode 3 deals with IRB pitfalls and episode 8 discusses waivers from informed consent.

University of Oxford Global Health podcast has an interview with Dr. Phaik Yeong Cheah on the ethics of research in vulnerable populations (Oct 5, 2015).

Authors' contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: CB contributed 50%; AAN contributed 30%; and ES and DMT contributed 10% each. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of competing interest

The authors declared no conflicts of interest.

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