

THEME EDITORIAL

Public health research ethics – Indian case studies

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Public Health research and practice exposes individual researchers and practitioners to dilemmas that are slightly different from those of clinical research. This is because in public health, the focus of research is not an individual patient, but the population. The nature of dilemmas confronted in public health research impinges upon community identities, individual vs collective risks and benefits, and power relations between gate keepers and actual participants. Ethics in public health and its practice call for a shift in focus from individual rights and autonomy to the interests and health of groups, equity and justice in access and distribution, and the human rights of individuals (1). In addition, any discussion on fairness in the distribution of health and healthcare, needs to be informed by the distribution of healthcare infrastructure and human resources. When public health research is contextualised in terms of the healthcare resources available, it focuses on health systems as an axis of analysis. Health systems research, which is distinguishable from clinical or even population-based public health research gives rise to ethical challenges which are unique in themselves (2).

We can explain this more clearly using a specific public health research study and the ethical discourse it generated. In 1993, a study on home-based neonatal care (HBNC) was conducted in Gadchiroli, India, by the Society for Education, Action and Research in Community Health (SEARCH) team with Dr Abhay Bang as the Principal Investigator. This research was reported in the *Lancet* in 1999 (3). The study comprised of testing an intervention in 39 villages in which SEARCH was working, and the control group consisted of 47 other villages where demographic surveillance was being undertaken by SEARCH. The intervention involved neonatal care in the 39 intervention villages through trained female health workers selected from the villages. In the first year, the female health workers listed the pregnant women in the village, collected data through home visits in the third trimester, observed labour and neonates at birth, visited the home on days 1, 2, 3, 5, 7, 14, 21 and 28, and on any other day if the family called them, to examine and document the mother and child. They also weighed the child on a weekly basis, treated minor ailments and pneumonia in the neonates. In the second year of the study, a survey of 280 parents (who choose to seek care from a trained female village health worker if the neonate was sick) was carried out. The trained village health workers (VHW) offered home-based management of neonatal illnesses from April 1996 and managed neonatal sepsis from September 1996 in addition to the tasks mentioned earlier. In the third year, health education of mothers and grandmothers about care of pregnant women and neonates was included. The results indicate a difference in case fatality rate from 16.6%, before treatment by female village health workers was initiated, to 2.8% among those treated by the VHW. No treatment was offered in the control area where the SEARCH team documented the neonatal deaths during the study period (3).

Subsequently, this study was presented as a case study for bioethics where it was criticised for not using an appropriate study design and also not providing appropriate standard of care to the control group (4). Reacting to this criticism, Dr Bang said that, in her critique of this research strategy, Marcia Angell had recommended a research process which would have necessitated the introduction of state of the art (the US Standard) neonatal care in the control area to compare the efficacy of HBNC against it. However, given the fact that it was health service research that was being carried out in real life settings, it was not possible to control situations as was possible in a clinic-based experimental situation. He asked "...what makes her think that it would have been possible to create an island of state-of-the-art medical care in the control area in remote Gadchiroli, 1000 km from Mumbai, where no doctor wants to go and live?" (5). Without going into the relative merits of the ethics of the standards of care debate which are still controversial (6), applying a health systems approach would have offered guidance on both standards of care and context of research (7).

This in essence, captures the context specificity of public health interventions which depend on the available healthcare systems that operate in the sites of research. It is in these settings that public health research in low- and middle-income countries

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(LMICs) is also carried out. Situating the ethical dilemma merely in a moral relativism vs universalism misses the context in which people live in LMICs.

Healthcare access is limited in most parts of India, even twenty years after the publication of the paper on HMNC in the *Lancet* (3). Does this mean we should wait until state-of-the-art care is available in these settings to undertake testing for less efficacious but likely-to-be -available interventions? The availability of the state-of-the-art option merely for research purposes, when it is not otherwise available in the setting, renders the intervention being tested egregious and provides invalid results. As shown in the National Health Profile, 2018 (8), access to government healthcare facilities varies substantially across the states of India, with the ratio of population per government hospital bed ranging from 899 in Tamil Nadu for 2017 to 8645 persons per bed in Bihar for 2016, considering only the major states of India during 2015-17 (8: p 260). The availability of allopathic doctors indicated by the average population served by government allopathic doctors also shows a similar variation with an average of 28,391 persons served per government allopathic doctor in Bihar for 2015, to 6810 being served per government allopathic doctor in Kerala for 2017 (8: p 221). While these figures do not reflect access to private sector facilities, the variation in access to healthcare across the country is well represented.

Public health research needs to test the efficacy not only of a drug, but also its delivery mechanisms through a functional health system, which is not a constant across the country. For this reason, the varying health system contexts form a backdrop to many interventions in public health and therefore interventions need to be tested in their contexts. The argument with regard to the ethical challenges arising in such research tends to get mired in the relativist vs universalist ethics conundrum, assuming constancy of contexts and of the research ethics situated in a clinical research ethics frame of reference. However, public health research happens in these contexts with varying access to healthcare which calls for varying care delivery mechanisms. This is exactly what the Gadchiroli trial sought to do, and was successful in those contexts where no alternative healthcare was available. The ethics of testing the intervention will be clear to those who include health system contexts within the framework of ethical analysis.

While training health researchers, ethics committee members and other stakeholders in India on the ethics of health research in general, and public health research in particular, we have been confronted with a paucity of training materials that are specific to the Indian context. The tendency has been to use international case studies and these experiences do not resonate with the local contexts that researchers face in their everyday practice. The efforts to translate the local terms to suit international audiences tend to obfuscate the levels of care, or any other subject being discussed. For example, when one mentions an Auxiliary Nurse Midwife (ANM) who, in theory, is supposed to be available for every 5000 population in the Indian context, it would easily be understood by an Indian audience. The translation to "Trained nurse-midwife" would not indicate the difference between an ANM and a nurse practitioner, who has about four years of health training as opposed to the 24 months that an ANM receives (9). Similarly, translating the Accredited Social Health Activist (ASHA) to Community Health Worker would miss the relatively fewer skills imparted to ASHAs when compared with other trained health workers in the Indian context.

Training initiatives for bioethics in India have tended to use international case studies that emerge out of a clinical or health research context, as not many Indian case studies are available. These case studies are often decontextualised for both anonymising purposes and to highlight the ethical challenges in a lucid manner. While these case studies are useful, they do not resonate with the local contexts that public health researchers confront in their everyday practice. Some of us have therefore attempted to develop public health ethics case studies which retain sufficient information about the local contexts and some of these have been published, but are limited in number.

This lacuna exists, not only because public health research ethics is not yet an issue of prime focus within the research ethics discourse, but also because the distinctions between public health research and clinical research are often not delineated as clearly as they need to be. Moreover, the process of documenting research does not allow for the documenting of the nitty-gritty of moral dilemmas confronted and resolved in the process of public health research. For this reason, there is need to make a special effort to provide public health researchers with a platform for enumerating the ethical challenges in research and documenting them, to build a repository of good ethical practice in public health research.

The Achutha Menon Centre for Health Science Studies (AMCHSS) at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, a public health training institution which has trained public health practitioners and researchers since 1997, had introduced a one-credit research ethics module as part of the Masters' in Public Health programme in 2004. This curriculum included morality and ethics, history of bioethics, principles of bioethics, privacy and confidentiality, autonomy and consent, standards of care, risk benefit analysis, ethical review processes and research misconduct and integrity. This module also uses discussion on case studies as a pedagogical tool to facilitate the understanding of challenges in research ethics. In 2008, the AMCHSS faculty extended the ethics module by adding another credit to address public health ethics, and since then, it has been taught as a two-credit module on Public Health Research Ethics that includes both research ethics and ethics of public health practice. The public health practice and research ethics module also uses case studies as a means

to facilitate discussions on the relevant ethical challenges. However, if one could say that there are limited case studies that are rooted in the Indian context for discussions on research ethics, the public health area is even further deprived. At the AMCHSS, the teaching faculty have developed their own case studies to suit their training needs but these are limited in number. Efforts to encourage MPH students to develop case studies from published public health research and policy to highlight the ethical challenges has been part of the public health ethics training module in recent times.

The Theme section in this issue of *IJME* comprises of five case studies produced in a joint effort by the participants and faculty at a Workshop* organised at the AMCHSS, together with IJME, with the purpose of producing a set of case studies on public health research ethics and policy ethics relevant to the Indian public health eco-system. Each of these is followed by a commentary reflecting on the ethical questions raised in the relevant case study and exploring possible answers. We hope this is one of many such efforts across the country to fulfil the need for relevant case studies to use in training programmes for public health research ethics.

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Conflict of interest statement

The author, who is on the faculty at AMCHSS, coordinated this workshop and also participated in the training but recused herself from evaluation processes to avoid conflict of interest arising from the dual identity.

References

1. Bayer R, Gostin, LO, Jennings B and Steinbock B. Introduction: Ethical Theory and Public Health. In: Bayer R, Gostin LO, Jennings B, Steinbock B, Editors. *Public health ethics. Theory, policy and practice*. New York: Oxford University Press; 2006. pp 13-24.
2. Hyder AA, Pratt B, Ali J, Kass N, Sewankambo N. The ethics of health systems research in low and middle-income countries: A call to action. *Glob Public Health*. 2014 Oct; 9(9): 1008–22. doi:10.1080/17441692.2014.931998.
3. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal morality: field trial in rural India. *Lancet*. 1999 Dec 4 [cited 2020 Jan 31]; 354(9194):1955-61. Available from: searchforhealth.ngo/wp-content/uploads/2017/lancet-field-trial.pdf
4. Angell M. The SEARCH neonatal sepsis study: was it ethical? In: Lavery J, Grady C, Wahl E, Emanuel E, editors. *Ethical issues in international biomedical research: A casebook*. New York: Oxford University Press; 2007. pp114-5
5. Bang A. Was the Gadchiroli trial ethical? Response from the principal investigator. *Indian J Med Ethics*. 2010 Jan-Mar; 7(1): 12-14. DOI: <https://doi.org/10.20529/IJME.2010.004>
6. Council for International Organisations of Medical Sciences. International Ethical Guidelines for Health-related Research Involving Humans. 4th edition. Geneva: CIOMS; 2016 [cited 2020 Feb 3]. Available from: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>
7. World Health Organisation. Ethical considerations for health policy and systems research. Geneva: WHO, 2019 [cited 2020 Feb 4]. Available from: <https://www.who.int/alliance-hpsr/resources/publications/ethical-considerations-hpsr/en/>
8. Central Bureau of Health Intelligence, Govt of India. National Health Profile 2018. 13th. New Delhi: MoHFW, GoI; 2018 [cited 2020 Jan 31]. Available from: www.cbhidghs.nic.in/assets/common/downloads/files/NHP_2018
9. Indian Nursing Council. Types of Nursing Programs. New Delhi: INC; date unknown [cited 2020 Jan 31]. Available from: <https://www.indiannursingcouncil.org/nursing-programs.asp?show=prog-type>

*Note

A writing workshop to develop case studies on the ethics of public health research for students and practitioners was held jointly by AMCHSS and IJME in Thiruvananthapuram, in March 2018. All the received abstracts were put through a rigorous three-stage review process by the faculty, after which five case studies were selected, revised and prepared for publication.