COMMENTARY

Ethical obstacles in health systems research in India: Need for focused guidelines

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Abstract

This paper focuses on the ethical tensions seen in health systems research by researchers owing to their scientific obligations to their research, ethical obligations to study participants, and social obligations to the community. Health systems research differs from other public health research fields in terms of the participants selected, power relations within health systems and the socio-political environment. The study seeks to answer the following questions through experiences in health system research. 1. What are the ethical tensions experienced by researchers in field work? 2. How are the existing guidelines used in resolving tensions arising in field work in India? To understand these ethical tensions, the World Health Organization's Ethical Considerations for Health Policy and Systems Research were applied to research conducted in the health system settings. These tensions faced by researchers are explained through four emerging themes: the researcher's position in the health system; voluntariness of participation: participation; and social justice.

Keywords: *ethics, reflexivity, positionality, health systems research, anganwadi workers*

Introduction

Prior to conducting research, the researcher has predetermined notions about what the target community is and how it functions leading to a bias while gaining access to the community. Besides this pre-existing bias, the researcher has the power to determine a topic of interest and to focus on a community that will provide answers to the research questions. It is in this context that I describe the ethical challenges that emerged during a public health research exercise undertaken to fulfil the requirements of a master's degree in public health. The study required access to *anganwad*i workers (AWWs) who form the base level of frontline workers within the Integrated Child Development Scheme (ICDS) that aims to provide nutrition and pre-school education to children under six years, particularly those from vulnerable socio-economic groups.

The original research aimed to identify the barriers to implementing the ICDS program in a tribal district of Maharashtra. Data collection for this research was undertaken during the period December 2020 to February 2021, when the pandemic-imposed restrictions on the ICDS programme were in place. Therefore, this situation positioned itself as an additional barrier to the programme and to the research. When a research exercise requires information from grassroots level workers within a public system, it is incumbent upon the researcher to ensure that the information is collected in a manner which will not cause any additional harm and to obtain information that enables the fulfilment of the research objectives.

In any such health system, to gain access, it becomes necessary to negotiate with various gatekeepers within the system at the district level, such as district programme officers and administrative heads. These gatekeepers are themselves potential key informants for the research process. Even as they provide the required permissions to access grassroots level workers (who will not respond without express written permissions accorded to the researcher), they also have a vested interest in ensuring that their writ prevails in the discourses emerging out of their subordinates' responses. Should the grassroots level workers not comply with the writ of their supervisors, they could face a range of adverse consequences. *Anganwadi* workers could, and did, present a different narrative with respect to the programme from the one posited by the higher-level stakeholders within the system. It was incumbent upon the researcher to provide these vulnerable AWWs with the opportunity to narrate their perspectives and ensure utmost confidentiality for the responses. However, negotiating this privacy rested with the discretionary authority of the higher-level functionaries and could be jeopardised should they disagree. This poses a serious ethical dilemma for any researcher, regardless of the power they may wield within their own sphere of influence.

I describe the ethical challenges faced in obtaining valid informed consent and responses from *anganwadi* workers when access to them was controlled by their supervisors,

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who wanted to control and structure the exact responses that were to be proffered to the researcher. I will also report on the struggle to maintain confidentiality as well as disseminate the collected data, by describing the structures and intrinsic hierarchies within health systems and the politics of power that obtains from these hierarchies. I will refer to the existing guidelines for research in health systems, which helped to resolve the ethical dilemmas in data collection.

Context of data collection

The study was carried out in a tribal district of Maharashtra that is infamous for its child undernutrition. The original study aimed to identify the barriers to implementation of ICDS programmes that help in improving the overall child wellbeing through nutrition and pre-school activities. The programmes are implemented by AWWs at the frontline and they were my primary source of information on the barriers faced in programme implementation at *anganwadis*. Barriers were studied through AWW interviews of well-performing and not so well-performing *anganwadis* to compare the infrastructure, and routine activities of AWWs, including problems faced on a daily basis. In order to get access to the district, I had to convince the Chief Executive Officer (CEO) of the district administration of my trustworthiness and intentions. After written permission was obtained from the CEO, the ICDS district officer's (DO) permission was essential. A level of suspicion was observed, with remarks and warning not to publish anything untoward regarding district practices. Identification of specific *anganwadis* was determined by the Child Development Project Officers (CDPOs) and district level officers who also acted as key informants. Consent forms were provided in the local language and read to the participants to ensure clarity. Ethical guidelines followed and prescribed by the Indian Council of Medical Research (ICMR) *National Ethical Guidelines for Biomedical and Health Research involving Human Participants*, 2017, (hereafter ICMR Ethical Guidelines), were followed for data collection [1].

Within this context, I will expand on the conflict that exists when a researcher conducts a study within a health system by answering the following questions:

- What are the ethical tensions experienced by researchers in field work?
- How are the existing guidelines used in resolving these tensions during field work in India?

The practical challenges in ethical field work

Any research includes mainly three stakeholders — the researcher, the participant, and the community. Ethical tensions occur between the researcher's scientific obligation to the research work, social responsibility to the community, and ethical obligation to research participants. In health systems, such as ICDS, AWWs provide information that could potentially expose the shortcomings of the *anganwadi* center (AWC) and higher officials; but also expose the AWW to the possible loss of her job, and therefore of livelihood. This ground reality of the system must be disseminated as part of the scientific obligation towards improvement in implementation of nutrition programmes in the AWC. Here, the researcher faces the ethical tension of whether to prioritise the collective social good and hence their scientific obligation, or to safeguard the AWW who provided the information. As described in the Belmont report, in cases where participants belong to vulnerable populations, the dangers of participation are so high it sometimes becomes imperative to even remove them from the study [2].

An overview of ethical guidelines for health systems research

In the global context, a scoping review on health policy and systems research (HPSR) suggests that the planning, conduct, and review of HPSR must specifically address a number of ethical issues, such as the responsiveness of the research to local needs, the nature of equipoise, the implications of study design, the operationalisation of informed consent, the possibility of exacerbating inequalities, anticipating risks and benefits in all groups, the levels of accountability of all stakeholders for post-study obligations, sustainability, and ancillary care, among others [3,4]. In low- and middle-income countries, the ethical guidelines must identify local values, balance them with public health policies through valid research; and provide guidance for the promotion of social justice and accountability [5].

In India, the widely followed guidelines for public health are ICMR Ethical Guidelines. Section eight of the guidelines describes ethics in public health research and recognises seven ethical principles that overlap with public health service and research. It recognises that different areas of public health require separate sets of ethical guidelines, but does not distinguish health systems research from public health and biomedical research [1]. Health systems research differs from other types of research in many aspects, such as the study population, the method of data collection and the contexts within the health systems. Many collective economic, social, and political risks are also unique to health systems research [6].

In 2019, the Alliance for Health Policy and Systems Research , with the Global Health Ethics Unit [both hosted at the World Health Organization (WHO)] published *Ethical Considerations for Health Policy and Systems Research* [7]. These guidelines were used to identify and describe ethical tensions such as those arising in the context of my study [Annexure 1, available online only]. Some themes that emerged are described below.

The researcher's position in the health system

Reflexivity in research shapes the questions, themes and approach which the researcher takes up and how they present their findings. Ethics requires researchers to reflect

on what they believe, why, what they value, and on what basis they do so [8]. It is important for the researcher to be straightforward about acknowledging the power they possess and their relationship with the determinants of change in the community — in this context, the health officers, peers in the research community — and their access to publishing research that drives change [9]. Researchers should also acknowledge how they are perceived in the community and analyse the role and position of each actor playing a part in the research and whether it is for the greater good of the community [10]. By virtue of being a post graduate student with an introduction from my educational institution, permission was granted by the district level officials to visit AWCs. Permission was sought from the gatekeepers of AWCs, ie, key informants. The Institutional Ethics Committee (IEC) suggested using an objective criterion to select well-functioning and not-so-well-functioning AWCs; but granted permission for the method of *anganwadi* selection put forward, due to a lack of publicly available *anganwadi* level data sources [Annexure 2 , available online only]. During data collection, when the researcher pursuing higher education visits AWCs, and she is dressed in attire different from that of the rural community, it establishes a sense of hierarchy. This is evident in the way participants tell their stories to showcase either their qualities or troubles with the expectation or fear of the consequences of their participation, despite the consent forms explicitly stating that no personal benefits would be provided by the research, except the collective good of reduction in child undernutrition. This entry route puts the researcher in a position where they might have to comply with the guidance provided by these health officials, exposing the researcher to the risk of moulding the study through the lens of the system.

From the system's perspective, in areas where health issues are a matter of political sensitivity, inability to maintain confidentiality in research could harm the health authorities who participate in the research. As the CDPO of a block known for a high undernutrition rate put it:

> *"This is a difficult place and I am getting to learn also. But this can be very tricky. One time one person came like you and recorded our data. Then they leaked our recordings. We were answerable to the district officer and higher reporting when it was all over the news. So, I didn't let you record. It is only that you showed me the permission I let you see the anganwadi."*
>
> - CDPO 7

The fear of the health authorities is apparent in actions like their trying to control the flow of information by being present during the interviews in half the AWCs, despite explicitly stating my need to speak to the AWWs in private, and even some outright refusals when such requests for privacy were made.

After data collection is completed, the researcher has control over the presentation and dissemination of data. In such a situation the researcher must make a decision if they want to keep the data confidential, concealing important data that could possibly benefit the society, or to reveal the data to include uncomfortable truths and cause harm to the study participants. What level of data must be presented in order to fulfil their research obligations, and ethical obligations to participants, and contribute to the collective good poses a challenge.

Voluntariness in participation

When a supervisor asks subordinates to participate in research, it puts them in a position where they may feel obliged to give answers favourable to their supervisor's perspective. Generally, the CDPOs would instruct the AWW to participate prior to my arrival. In such a situation, the researcher must gauge the situation and interpret the voluntariness of the consent provided. When the AWWs participated in the study, and their rights were explained to them while taking consent, their ability to refuse could not be assessed. Instructions from a supervisor, and insistence on the researcher's part could intimidate the participants into providing consent even if they did not want to participate.

Participation

Consent forms were designed in such a way that the participants knew their rights, were read to them in the local language if need be, and explained so that they understood their rights of participation. Even though it was a priority to provide privacy during the interviews, the CDPOs accompanied me to the AWC. The AWWs interviewed in the presence of the CDPOs replied in shorter opaque sentences, with the latter using verbal or nonverbal means to influence the information being provided, and sometimes even answering for the AWWs. The AWWs interviewed in complete privacy elaborately described the functioning of the AWCs, the problems faced and stories of children's improved health, and even cases where children were rushed to the hospitals for prompt medical attention

Difficulty in maintaining confidentiality of information provided by the participant from the CDPO because of lack of privacy could lead to a distorted view of reality in the AWC. This can either harm the participants if they reveal something that their overseer might not approve of, resulting in a range of issues including hostile work environment, loss of job, or social isolation. Conversely, the participant might use this opportunity to provide information to please their overseer to gain promotion at work. This information may not be reflective of the ground reality the researcher seeks through their research and could also deprive the community of the benefits of authentic research.

Social justice

It becomes imperative to understand that protecting AWWs in areas with high political sensitivity is important, while the

core aim of the research is to bring about positive societal change which can only be achieved through accurate data dissemination. In such a case, the ability to recognise that AWWs are a part of the population being studied and the oppression of AWWs by either their supervisors or the researchers is revealed in their helplessness when presented with an opportunity to participate in research. From a rights perspective, the dilemma gets another layer, further complicating the situation.

Guidelines not specific to health systems research miss the power relations in the study setting. Apart from the various socio-cultural and political influences at work in rural communities in India, hierarchies in health systems also need to be considered before designing a study. The reality that the researcher seeks through the study exists within these structures and awareness of these is therefore essential for the researcher. It becomes the researcher's responsibility to anticipate potential tensions/conflicts arising in this context and make complex decisions. However, even when decisions are made after immense consideration, there is still a possibility of harm that the researcher could not have anticipated as an outsider to the community.

The way forward

It is important to recognise the need for a separate set of ethical guidelines or a practical handbook on ethics with a primary focus on health systems research that recognises the power hierarchies in health systems and is specific to the Indian context.

Such guidelines could help the researcher to anticipate the ethical challenges that they may face in the field, for example, the lack of privacy, an understanding of the different stakeholders, decision making at various stages in research and their own role in the study. It would help even novice researchers to communicate freely and to ensure the voluntariness of participation, conduct risk benefit analyses, and understand their power and position in hierarchical health systems, specifically in low- and middle-income countries. This would support the researchers in designing their study methodology in such a way that the ethical tensions are minimised.

Such guidelines would help the researcher determine the extent to which the participants' confidentiality has to be safeguarded, when to exclude a participant from a study, and which information is to be altered/excluded; or in cases where the confidentiality cannot be maintained, and risk to participant is too grave, considering the health system setting where the participants are under constant supervision of their overseers during the course of the study, to even consider whether any of the findings should be disseminated at all.

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