Indian J Med Ethics Vol X (Cumulative Vol XXXIII) No 4 Oct-Dec 2025

COMMENTARY

Challenges in obtaining informed consent for health research from dependent older persons in the Indian socio-cultural context

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Abstract

In this brief commentary, we share our experience of obtaining informed consent from older persons living in the community, dependent on their sons, daughters or in-laws. We present a scenario in which for our community-based cluster randomised controlled trial on diabetes peer support groups for diabetes self-management, we attempted to obtain informed consent from an older person living in a dependent state with her daughter. While the older woman herself was interested in participating in the study initially, later she declined to consent, probably influenced by her daughter and son-in-law with whom she was living. In this article, we reflect on this unique social dynamic in India where many older persons are in a dependent relationship with their primary caregivers; and what this relationship means to autonomy in research participation. We propose that engaging with primary care givers of older persons before approaching them for research participation may be a crucial step in this social context.

Keywords: *informed consent, older participants in biomedical research, autonomy, dependent older persons*

Introduction

A demographic transition is taking place in India, with a rise in the country's older population [1]. The number of older persons in India is predicted to exceed the number of children, by 2050 [2]. Simultaneously, an epidemiological transition is taking place with a rise in the numbers of non-communicable diseases (NCD) such as diabetes [3]. Consequently, much research on NCDs in India is going to be focused on older persons, and we need to closely examine the ethics of conducting biomedical and health research among older participants. There has been some discourse on ethical issues while conducting research among older persons; for instance, on the aspect of cognitive impairment, common among the elderly, which may compromise their capacity to provide informed consent [4]. The ethical debates on conducting research on older participants date back to the early 1970's, when several issues such as biomedical vulnerability of the elderly, cognitive impairment associated with ageing, legal authority of surrogates and next of kin, and issue of legal authority of the institutionalised elderly were debated. But not all older persons can be classified into these vulnerable categories. They are a heterogenous group and hence considering all of them as vulnerable research participants was not acceptable to some [5].

Most of the ethical discourse on conducting research on the elderly is in the western socio-cultural context. The unique social dynamics of caring for older persons in many Indian households has been discussed in the context of health research; and how it is important to consider its unique aspects from an ethical perspective [6]. The Indian Council of Medical Research (ICMR) National Ethics Guidelines for Biomedical and Health Research, 2017, for conducting research involving human participants, does not have a section on research involving older persons. While classifying participants who are considered vulnerable, the Guidelines do not specifically mention the elderly [7].

Here, we present our experiences in obtaining informed consent in a study involving older persons in an area in rural Tamil Nadu. We highlight the need for developing specific ethical guidelines while conducting biomedical and health research among older participants in the Indian socio-cultural context.

About the study

We are currently conducting a study to assess the effectiveness of peer support group interventions and mHealth intervention in helping persons with Type 2 diabetes adopt self-management behaviours in a rural area in Tamil Nadu. We enumerated all persons with Type 2 diabetes in the 26 villages served by our organisation and generated a database. We trained our field investigators to approach these individuals, explain the details of the study, and obtain informed consent from them. Here, we share an incident that occurred while obtaining informed consent from an older participant in this study.

The incident

A field investigator, henceforth referred to as JL, was assigned the job of visiting an older lady with Type 2 diabetes to obtain informed consent. JL went to the lady's house, but her neighbours informed her that the lady had moved into her daughter's home recently, due to multiple illnesses. So, JL went to her daughter's home. She met the elder and explained the details of the study. She indicated that she is interested in the study, but asked JL to give the information sheet and the consent form to her daughter, who would make the decision regarding her participating in the study.

The challenge

This older lady had multiple medical problems including diabetes, hypertension, and heart disease. She could not read or write and had limited health literacy. Her health condition had made her adopt a dependent living arrangement, where she was dependent on her daughter and son-in-law socially and economically. Though initially, the lady expressed some interest in participating in the trial, eventually she did not consent. It is not clear whether she made a well-informed decision to decline. Even if we assume that she did, she was in a dependent relationship with her daughter and son-in-law, who are likely to have influenced her decision.

While reflecting on this challenge during a research team meeting, many of the field investigators mentioned that when approaching older persons to participate in the trial, their sons or daughters interrupted and screened the consent document. There were several instances where the older persons wanted to participate, but their sons and daughters did not permit them to, and where they did not want to participate but their sons and daughters forced them to. This is a major challenge and is more common in the Indian social context, where dependent older parents are treated in a paternalistic manner by their caregiver sons and daughters.

Discussion

One of the unique social situations that older persons living in India face is their dependent relationship with their offspring. When they have multiple medical problems and debility associated with it, they are frequently pushed into poverty and a dependent social status. A situational analysis of older persons in India revealed that more than 65% of rural seniors are economically dependent on others for their daily maintenance. A major part of this dependency is due to lower participation in the workforce and physical disabilities that accompany ageing [8]. Such a dependent older person often lacks the freedom to make day to day decisions about their own life. They often live in a space provided to them, eat food that is served to them and live a restricted life without much autonomy. With a lack of robust social security schemes for older persons, their independence and agency is often seriously compromised. Under these circumstances, they do not have the freedom to volunteer to participate in research studies. Their primary care givers may not be willing to support them during the process of participating in the trials or may be wary of any potential adverse events related to the trial participation, which would be an additional burden to them. In some situations, they may not be involved in the decision making regarding participating in trials, and so the older person may not fully understand the implications without having a responsible family member with whom to discuss it. It is also challenging for elderly persons with diminished visual and auditory capabilities to either read the consent form or listen to it being read. They may require the presence of a younger family member to help them process the information. However, the younger member may not be able to provide the time to go through the consent process with them. The elderly may suffer from cognitive impairment, which may sometimes be so mild as to be non-recognisable. The presence of a caregiver may be to protect the rights of the elderly in such cases. The elderly person may want to talk to the researcher and provide consent just for the sake of the attention that they may get by participating in the trial. They may not have the capacity to analyse the pros and cons of participating in the study due to their minor cognitive impairment. Sometimes caregivers may withhold some sensitive health related information regarding the elderly. So, they may avoid cooperating with the study. However, this may come across as the care giver preventing potential research participation by the elderly. Besides this, the social norms related to caregiving for the elderly may prevent caregivers from enabling the parent to participate in research, as it may be misconstrued by the researchers and the larger society as abuse and exploitation of the elderly for some ulterior motives.

Therefore, it is important for researchers designing studies involving community dwelling older participants to carefully think through this social dynamic while planning their study. We propose a stage-wise consent process. In the first stage, the older person must be approached and the details of the research explained to them. In the second stage, with the permission of the older person, the researcher must have a dialogue with the primary care givers of the dependent older persons. Open communication and engagement with the older person as well as their caregivers will help earn trust and ensure accountability. If the older potential participant and the caregiver have conflicting opinions regarding participation in the trial, a combined meeting and discussion with the older person and the caregiver can be attempted. We believe that in the Indian socio-cultural context, it is important to engage with the primary care givers of dependent older participants in all research-related decisions, especially when there are no other forms of support available for older persons.

Ethics committees that review research studies on older participants must be aware of and sensitive to this social dynamic. They must scrutinise the informed consent process and ensure that the autonomy and agency of the older person is protected and at the same time, the socio-cultural dynamics of care giving for a dependent older person is also considered.

Conclusion

Obtaining informed consent to participate in research from dependent, community-dwelling older persons can be a challenge, as their dependent status compromises their autonomy and agency. Researchers and ethics committees must be sensitive to the socio-cultural dynamics of dependency of older persons in India while conducting research involving them. We propose a two-stage consent process involving older persons and their family caregivers.

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Conflict of Interest: None **Funding:** None

Acknowledgments: The authors would like to acknowledge the contributions of Venkatesan M and Louis Chrysolite, Research Assistants at RUWSEC for identifying this ethical challenge and participating in investigating it in the field. The authors would like to acknowledge Azim Premji Foundation for the Health Research Grant 2024 awarded to Dr Sudharshini Subramaniam, Principal Investigator for the research project on diabetes peer support groups for self-management in the rural community.

To cite: Gopichandran V, Subramaniam S, Chidambram P, Palanisamy B. Challenges in obtaining informed consent for health research from dependent older persons in the Indian socio-cultural context. *Indian J Med Ethics.* 2025 Oct-Dec; 10(4) NS: 302-304. DOI: 10.20529/IJME.2025.048

Submission received: July 22, 2024

Submission accepted: May 12, 2025

Published online first: June 12, 2025

Manuscript Editor: Sandhya Srinivasan

Peer Reviewer: An anonymous reviewer

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References

1. Halsall JP, Mei L, Siddiqui K, Snowden M, Stockton J. Demographic Changes and Ageing in China and India: A Public Policy Perspective. In: *Sustainable Neighbourhoods for Ageing in Place.* Cham: Springer Nature Switzerland; 2023. p. 197–216. https://doi.org/10.1007/978-3-031-41594-4_11
2. Lakshman A. India ageing, elderly to make up 20% of population by 2050: UNFPA report. *The Hindu.* 2023 Sep 29[Cited 2025 Jan 21]. Available from: https://www.thehindu.com/sci-tech/health/share-of-elderly-projected-to-double-to-20-by-2050-india-ageing-report/article67353547.ece
3. Habeeb S, Thankappan KR. Metabolic non-communicable diseases in India: time to act. *Lancet Diabetes Endocrinol.* 2023 Dec;11(12):897–8. https://doi.org/10.1016/s2213-8587(23)00298-x
4. Rikkert MG, van den Bercken JH, ten Have HA, Hoefnagels WH. Experienced consent in geriatrics research: a new method to optimize the capacity to consent in frail elderly subjects. *J Med Ethics.* 1997 Oct 1;23(5):271. https://doi.org/10.1136/jme.23.5.271
5. High DM, Doole MM. Ethical and legal issues in conducting research involving elderly subjects. *Behav Sci Law.* 1995 Jun 13;13(3):319–35. https://doi.org/10.1002/bsl.2370130302
6. Ramanathan M, Kochuvilayil A. Methodological challenges in studying the chronically ill elderly: Ethical need to include caregivers. *Indian J Med Ethics.* 2023 May 7;8(3)NS: 179-181. https://doi.org/10.20529/ijme.2023.031
7. Indian Council of Medical Research. National ethical guidelines for biomedical and health research involving human participants. 2017 Oct [Cited 2025 Jan 21]. Available from: http://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
8. Central Statistics Office, Union Ministry of Statistics and Programme Implementation. Situation Analysis of the Elderly in India. New Delhi; 2011 Jun [Cited 2025 Jan 21]. Available from: https://doczz.net/doc/7808535/elderly-in-india--2016---ministry-of-statistics-and-progr...#google_vignette

COMMENTARY

2024 Revision of Declaration of Helsinki: policy perspectives from India

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Abstract

The 2024 Declaration of Helsinki (DoH) marks a significant milestone in medical research ethics, addressing contemporary challenges and emphasising global ethical issues. In India, the 2017 Indian Council of Medical Research (ICMR) National Ethical Guidelines, align well with the 2024 DoH principles, particularly in safeguarding vulnerable populations and promoting ethical review processes. However, there is scope to work on further harmonisation and better implementation, such as registering all medical research, empowering ethics committees, and ensuring equitable access and inclusion. This perspective highlights the strengths and limitations of the ICMR guidelines in light of the 2024 DoH, aiming to foster a research environment that upholds ethical integrity, inclusivity, and the well-being of all participants.

Keywords: *2024 Declaration of Helsinki, ICMR National Ethical Guidelines, research ethics, bioethics*

Introduction

The 2024 revision of the Declaration of Helsinki (DoH) [1] marks a significant milestone in medical research ethics, addressing contemporary challenges while reinforcing the fundamental principles of respect for persons, beneficence, and justice in medical research involving human participants. Building on the principles established in previous versions, the updated Declaration reflects a growing appreciation of global ethical issues, emphasising the importance of fair and responsible inclusivity in research — including marginalised and underrepresented groups — as well as for research conducted in resource-limited settings. It also highlights contemporary issues such as research equity, global justice, data privacy, and the ethical implications of emerging technologies, such as artificial intelligence.

In 2017, the Indian Council of Medical Research (ICMR) published the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" (2017 ICMR guidelines) [2], which offer a thorough ethical framework for the country, and aligns considerably with the revised 2024 DoH. An analysis of the ICMR guidelines in light of the 2024 DoH would help bridge the gap between global ethical standards and national implementation. This would