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COMMENTARY

The WHO Guidance on Clinical Ethics: Some concerns from the Indian context

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Abstract

The World Health Organization (WHO) released a draft guidance on clinical ethics in May 2025. This document covers education and capacity building in clinical ethics, the setting up of clinical ethics services in institutions, and the development of policies to implement clinical ethics review at institutional, national and international levels. The guidance is promising, but there are important contextual issues in India, raising concerns about its adoption and effective implementation. From the experience with research ethics committees, we know that despite more than a decade of mandating ethics committee review of medical research, we still face a number of challenges. The same practical issues will likely plague the operations of clinical ethics committees. We need to learn from and adapt learnings from these experiences. Clinical ethics rounds could offer an important model to be considered in the hospital setting. However, a large part of primary healthcare is delivered in the community. Clinical ethics considerations also arise at the intersection of a pluralistic medical practice milieu in India, and in diagnostic laboratory and imaging services and allied healthcare services like physiotherapy and occupational therapy. Clinical ethics review must include all of these. Patient advocacy groups, and civil society organisations act as watchdogs against medical malpractice and are important stakeholders in the clinical ethics review process. Media reports also play a crucial role. The role of these stakeholders must be given due importance in the guidance for it to realise its full potential to initiate discourse and strengthen clinical practice regulation in India.

Keywords: *WHO clinical ethics guidance, clinical ethics, clinical practice regulation in India*

The World Health Organization (WHO) released a draft guidance on clinical ethics and has called for public opinion, in May 2025. Clinical ethics refers to ethical considerations that arise while providing healthcare for patients [1]. Patient care is provided in diverse settings including the clinic, hospital, or community levels. It involves several stakeholders including healthcare providers, community members, patients, their families and administrative staff in hospitals. This clinical ethics guidance has the potential to mainstream ethics review into clinical care in India. The document focuses on the "why, who, and how" of the practice of clinical ethics. The introductory section outlines what clinical ethics is, and why it is important. Chapter 2 covers the education and capacity strengthening of stakeholders in clinical ethics. Chapter 3 categorises various types of clinical ethics services and discusses their functioning, advantages and disadvantages. The other three chapters pertain to establishing policies at the institutional, national and global levels to conduct clinical ethics reviews and consultations. The document is enriched with several examples of clinical ethics services in member countries. I read this document with keen interest from the perspective of a clinician practising primary care in a rural community in India. In this commentary, drafted and submitted on June 8, 2025, I present a narrative review of the guidance and some of the concerns that arose in my mind as I read this document.

Institutional clinical ethics

I served as member secretary of a research ethics committee of a medical institution for five years, and as a member of several other institutional research ethics committees. This experience has given me an insider perspective of the functioning of a research ethics committee. Getting the committee members together for a meeting is a daunting task due to the conflicting schedules and availability of members. After accomplishing this, ensuring the fair participation of all members in the discussion is another major challenge. Often the ethics committee meetings are hosted by the institution and the members are even paid a "sitting fee", thus introducing a conflict of interest. The meetings tend to be dominated by the clinicians present, usually an "old boys club". The social scientists, religious leader, ethicist and community representative are not given a fair chance to express their opinions. The ethics committee itself is seen by the medical researchers as "a hurdle that needs to be crossed" to proceed with research, rather than a useful space to brainstorm on participant safety and ethics. Many ethics committee members have limited ethics review capacity, and hence, ethics committee review meetings usually focus largely on scientific and technical issues with limited consideration of ethical issues. This is not unique to the ethics committees on which I served. There are reports about such practices in ethics committees from different parts of India and other low- and middle-income countries (LMICs) [2–5].

There is a reasonable understanding that all research involving human participants must be reviewed by ethics committees. There are also clinical trial regulations and laws in many countries that mandate ethics review of clinical trial protocols. It is possible to regulate the research process and ethics review process using standard criteria. Though the

ethics review process is time consuming, it is planned, and time is specifically allotted for this process [6].

Now, turning to clinical ethics guidelines, if India and other LMICs were to adopt the clinical ethics committee model, we may face issues like those before research ethics committees. For instance, all important patient care scenarios with ethical issues may not come up for review to the committee. If we mandate ethics review of all patients, the committees will not be able to handle the burden. Given the existing challenges of organising an ethics committee meeting and the time taken to achieve a good quality review, the clinical ethics review committee may not be able to function in a timely manner. Achieving reasonable research ethics review has been made possible by legislation and by regulation. Mandating a universal clinical ethical review process may not be feasible as it may hamper timely clinical decision making. The clinical ethics committee model, the consultation team model or the individual consultant model proposed in the guidance document may not be feasible or practical in the Indian context. One model that does not find mention in the document is that of "clinical ethics rounds", which may be useful.

Clinical ethics rounds

The clinical ethics rounds model could work well in a hospital setting [7–10]. Just as a hospital infection control committee does a round of various wards to evaluate potential infections and implements actions on infection control, the clinical ethics committee or an equivalent body can do clinical ethics rounds. This could be a service as well as a teaching opportunity for undergraduates and postgraduates. Rather than having specialists in clinical ethics doing these rounds, clinicians, nurses or other trained healthcare providers who are not directly involved in the care of patients in that ward may lead the rounds. This is because clinical decision making involves substantial subject matter expertise and a nuanced understanding of the care of the patient, it is best dealt with by the treating team or by someone who has experience in the field. In some settings, even undergraduate and postgraduate students do take up patient care scenarios with ethical dilemmas for discussion. This model has several potential advantages. It ensures that ethical issues are identified by the treating team and presented in the rounds. These rounds can either be part of clinical rounds or be a separate clinical ethics round. Since they would occur at the patient's bedside, the relevant issues of every patient can be covered during the round. Potential disadvantages could be that the discussions tend to be focused on medical aspects, as there are limited non-medical voices and perspectives present during the rounds. Moreover, this model works only in an in-hospital setting, hence clinical ethics pertaining to out-patient services and community-based settings cannot be covered by this model.

Community health and clinical ethics

A large part of primary healthcare is delivered in out-patient settings and in communities. Clinical care for pregnant women, women who have delivered their babies, breastfeeding mothers, couples who seek contraceptive services and children who seek treatment for common minor ailments is provided by the community health workers at patients' homes. Our team has documented several important ethical issues that arise in the interactions between community health workers and their clients [11–13]. We encountered young women in the rural communities for whom intrauterine contraceptive devices were inserted, many times without their permission and even without their knowledge. There were several instances where community members reported that they felt discriminated against by community health workers, based on their socio-economic class and caste. Such ethical issues arise in clinical care delivered in communities. The guidance document does mention, in passing, that all outreach and community-based services come under the purview of the parent organisation's institutional clinical ethics review mechanism. However, how this would be organised and operationalised remains to be explored. Institutions, usually tertiary care medical college teaching hospitals, remain ivory towers of healthcare. They are distanced from the field realities in communities. For such institutional review mechanisms to understand and engage with field realities might be challenging.

Medical pluralism, allied health services and clinical ethics

India has a pluralistic healthcare system with various streams, including modern medicine, Ayurveda, Siddha, Homoeopathy, Yoga, Naturopathy, Unani, Acupuncture, etc, coexisting and thriving. Traditional healing practices and faith-based healing also exist within this complex and diverse system [14]. It is not uncommon to find patients taking treatment from multiple such systems of medicine for different illnesses. When patients take treatments from multiple systems, clinical ethics issues emerge at their intersection. For example, when the treatment approach for a condition in modern medicine is the opposite of the approach in an alternative system, and both these treatments are taken by the patient, how does one reconcile the conflict? Institutional clinical ethics review cannot effectively cover these inter-system ethics challenges as the ethics process may not have the tools and capacity to understand the nuances of intersection of pluralistic practices.

A large part of clinical care also depends on the interactions between people and medical laboratories, diagnostic and imaging centres. Extensive and indiscriminate testing and screening packages of investigations that are not

customised to patients, can lead to incidental findings of harm to patients. There is also the all-pervasive "cut practice", where the diagnostic or imaging laboratory gives a cut or commission to the prescribing physician for referring patients for tests. Clinical ethics issues such as these arise in the process of diagnostic testing. Clinical ethics should also include services such as physical therapy, rehabilitation, occupational therapy, speech and language therapy. These, too, are frequently outside the healthcare institutions and hence fall beyond the institutional review process. Even in the diagnostic, imaging and allied health services that are situated within the institutional setting, these services are often not covered by the ethics review process. Therefore, comprehensive ethics review rounds including all these services are necessary. The WHO guidance document focuses largely on institutional mechanisms of clinical ethics review and on setting policies at the institutional, national and international levels for such mechanisms. One of the key stakeholders in clinical ethics is the people, and people's voices are often neglected in clinical ethics review.

People's voices and clinical ethics

Many ethical and human rights violations in healthcare are brought to public notice by civil society organisations, patient advocacy groups and health activists [15–18]. Many examples of negligence, and medical malpractice have been identified and reported by these groups. There are media reports of deaths due to the wrong medications and procedures, ill-treatment of patients in hospitals and even after death. Institutional clinical ethics review committees and groups usually have representatives from the community [19]. But as mentioned above, these representatives often do not have a voice within the committee. Strong independent patient advocacy groups and activists serving as watchdogs and raising alerts when there are ethical violations would further strengthen the clinical ethics review process, at the state and national levels. Social media, television, and print media play a crucial role in maintaining surveillance over ethical breaches in clinical care. They must be included as key stakeholders in the clinical ethics review mechanism.

Challenges of regulating clinical practice in India

Regulating clinical practice in India has been a serious challenge. The National Medical Council (NMC) is the regulatory authority for medical practice in India [20]. It has been severely criticised for its lack of transparency and accountability. When ethical violations are reported to the council, rarely is any action taken against the doctor. There are robust appeal mechanisms for doctors and such appeals are not available for aggrieved patients. In 2023, the NMC attempted to amend the Code of Medical Ethics of 2002 [21]. An amendment was released, but there was strong opposition to these amendments and the NMC repealed them, and the entire process of amendment has been put on hold. The Nursing Council and Pharmacy Council of India are also regulatory bodies of the respective professions. They have their code of ethical conduct, but the ethical regulatory function is scarcely exercised. In 2021, the National Commission for Allied and Healthcare Professions Act was established, and this is the common regulatory body for all allied healthcare professions, including physiotherapy, occupational therapy and others [22]. This Commission is relatively new and not yet functioning as an ethics regulatory body. Professional associations like the Indian Medical Association act as a strong lobby and oppose effective regulation of clinical practice. The Consumer Protection Act of 1986 amended in 2019, covers doctors and clinical care [23]. The Central Consumer Protection Authority (CCPA) has powers to investigate, of its own accord, matters related to products and services available in hospitals and clinics. For a long time, doctors have been arguing that the CPA should not cover doctors, as the doctor-patient relationship is not like the manufacturer-consumer relationship. Several powerful medical associations lobbied strongly to remove doctors from the CPA. But the amendment of the Act in 2019 still includes doctors. The Clinical Establishments Act of 2010 aims to regulate health facilities in the country and set minimum standards for the facilities and services provided in them [24]. However, healthcare being a state subject, there is a gross disparity in adoption and implementation of this Act in various states. Professional associations of doctors oppose the implementation of this Act. All measures taken to regulate clinical practice have been faced with opposition from the country's professional associations and bodies. The regulatory Acts and legislations are either not adopted or are poorly implemented. This is the current plight of the regulation of clinical practice in the country. It is in this context that the WHO guidance document must be read, interpreted, and adopted.

Concerns about the clinical ethics guidance and the way forward

I am unsure what impact the WHO clinical ethics guidance document will have on clinical ethics practice and policy in India, given our history of regulation and the current situation. It will remain one more among the numerous regulatory documents, that is downloaded, read, discussed and shelved without actual implementation, if it does not specifically consider the contextual complexities of clinical practice in India. In settings like India where multiple systems of medicine coexist — private, public, facility-based, community based, modern medicine, and complementary and alternative systems, clinical ethics must be far more nuanced than the way it is currently conceptualised in the guidance document. Institutional ethics review committees may not adequately address clinical ethics review. Clinical ethics rounds in hospitals and health facilities may help to an extent by making the clinical ethics review process systematic and integrate it into the general work schedule of the facility and staff. However, there is a need to conceptualise block level, district level and state level clinical

ethics review committees. These committees must be granted the powers to take up cases for ethics review on their own accord. These clinical ethics committees must also be open to the common people, civil society organisations, and patient advocacy groups, who can bring in cases for review. Opening up the clinical ethics review process to the people and patients democratises the process. The process of institutionalising and integrating clinical ethics review into the routine medical practice of each level of hospital depends on whether the facility belongs to the primary, secondary or tertiary level. It may also depend on the purpose of review, whether to help a family take treatment decisions or end-of-life decisions, or to address the family's care experience, or to address social or economic marginalisation in care-giving. The resources of skills, time, and human resources available for clinical ethics review will also determine its practice. Social, television and print media must closely work with these district and state level clinical ethics committees to maintain a level of community accountability. The medical education curriculum has been recently revised by the NMC in 2019. In this revision the Attitude, Ethics, and Communication (AETCOM) module has been introduced, aimed at building ethical analysis skills among doctors [25]. There is a fair amount of published work on the perceptions and attitudes of medical students and clinicians on the ethical practice of medicine [26]. There are also critical commentaries on ethics education in India and the scope and effectiveness of the AETCOM module of ethics education in the medical curriculum [27].

This commentary focuses on the clinical practice aspect of this document from the perspective of a practising clinician and therefore does not include much on clinical ethics education. There is a need to conceptualise clinical ethics more broadly and include ethical analysis and reasoning in the curriculum of nursing, and all allied health professional courses. Recently, efforts have been made to understand ethical awareness, attitudes and practices among community health workers and a curriculum for their training in ethical reasoning has also been developed [28]. Similar courses on capacity building in clinical ethics must be developed for all healthcare professionals. The clinical practice regulatory environment in India is disorganised and ineffective. While self-regulation of the profession is the ideal, it remains inefficient and inadequate. There is a need to legislate rigorous laws to regulate clinical practice. These laws must be adopted and implemented uniformly throughout the country. It would be good if this guidance document could initiate discussions and action on clinical practice regulations, the code of medical ethics, and clinical ethics review in the country.

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