Declaration of Helsinki 2024: Too much too late?

It has been 60 years since the World Medical Association's (WMA) Declaration of Helsinki (DoH) was first adopted in 1964 and has been revised seven times after that. The most recent revision was done by the WMA in October 2024 at the General Assembly. This declaration, although legally not binding, is one of the important ethical guidelines for medical research.[1,2]

The new amendment has expanded the scope of the document to make it applicable to all the stakeholders-physician, researchers, teams and organizations, for example, industry, who are equally responsible for the ethical conduct of any clinical study.[3] The current revision reiterates the significance of participants as an important stakeholder in a clinical study and has replaced subjects with participants in this amendment. Furthermore, the DoH now recommends deep engagement with potential and enrolled participants and their communities prior to, during and after the clinical research.[3] This was something Indian Council of Medical Research (ICMR) Guideline[4] propounded since the first revision of that guideline affirming the importance of taking the community's consent, especially for research falling under the public health umbrella.

DOH 2024 has a special focus on the diversity of vulnerable populations, and impact of exclusion of women, children, and racial and ethnic minority groups on wider usefulness of outcomes of research. This guidance does emphasize greater risk and harm of including such vulnerable populations in research. However, it recommends fair and responsible inclusion of vulnerable population in research after critical review of risks and benefits. Of course, the declaration does highlight the responsibility of the research team to be sensitive to the vulnerable participants' health needs and priorities and to ensure that they benefit from the results of medical research. The guidance also expects the researchers to consider a participant's previously expressed preferences and values when a legally authorized representative may consent on his/her behalf.[3] This has some unresolved questions as to what the quality of the documentation of the preferences that participant should have been expressed before the participation in this special scenario.

The WMA has a new recommendation on informed consent for biobanking. Considering the lack of satisfactory reference for informed consent requirements and risk to protection of privacy of participant's personal data, this revision recommends for free and informed consent for the collection, processing, storage, and foreseeable secondary research use of biological material and data. The ethics committee should approve and monitor such databases and biobanks. DoH 2024 also acknowledges that consent for unforeseen secondary research on stored data is not only difficult but also unrealistic to obtain. This should require ethics committee consideration and approval.[3]

The DoH 2024, reflecting on learnings of COVID-19 pandemic, urges that the researchers should ensure adherence to the ethical principles of the DoH during research in public health emergencies even when pandemics require innovation and urgency in clinical research.[3,5]

The revision also focuses on environmental sustainability, avoidance of waste during research through rigorous design, and the need to always ensure scientific integrity of the study. The amendment reinforces the independence of ethics committees and stresses the need to provide adequate resources for their functioning and their independence.[3] However, there are some gaps in the revision, for example, it does not address newer challenges such as data privacy and security, oversight of clinical investigator during a clinical trial, using ghost authors and true meaning of conflicts of interest.

We need to consider what impact DOH 2024 would have on conduct of clinical research in India. We wonder whether we need to follow it since the principles and practices outlined by the declaration are already covered in New Drugs and Clinical Trial (NDCT) Rules (2019), ICMR National Ethical Guidelines for Biomedical and Health Research 2017, and in National guidelines for Ethics committees reviewing Biomedical and Health Research during COVID-19 epidemic, 2020.[6,7] In addition, the National Digital Health Mission: Health Data Management Policy (2020) and the Digital Personal Data Protection Act (2023) describe very well the data privacy and security requirements for India.[8,9] Indian and foreign multinational pharma companies and academic clinical investigators follow local regulations and guidelines and the International Council on Harmonization (ICH) E6 in conduct of clinical trials.[10] The revamped ICH E6

(R3) version of GCP is also linked to all the trial conduct processes – planning, initiating, performing, recording, oversight, evaluation, analysis, and reporting activities.[11] Although DoH has been around for six decades, it seems that the influence and relevance of DoH24 would be diluted by the availability of Regulations and Guidelines on ethical guidelines and codes of practice (both Indian and international).[2] Is DOH 2024, arriving in the leap year, a case of too much too late?

DISCLOSURE

The insights stated in this article are author's personal opinion and does not reflect those of the current and previous employers.

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