Declaration of Helsinki: What Does the Future Hold?

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As medical students, we are mainly exposed to the rules and regulations that are set out in front of us; always wear your name tag, never be late, no whispering during tests, do not talk unless spoken to during your surgery rotation (just kidding on the last one). However, that is just the beginning of the ubiquitous rules that are present in medicine, with medical research being no exception.

Within the world of medical research, the Declaration of Helsinki (DoH) has long been considered the cornerstone document explaining the 'rules' of ethical human research. Developed in 1964 by the World Medical Association to protect the rights of research subjects, it originally contained a set of 11 articles explaining the basic ethical duties of physicians in regards to research. The original version took aspects of the Nuremburg Code and Declaration of Geneva to incorporate human experimentation with the physician's ethical role in the process and delineated a patient's rights regarding informed consent, privacy, and safety.[1,2] Since then, it has undergone seven revisions and has grown from 11 to now 37 articles, with categories ranging from General Principles to Risks to Informed Consent (http://www.wma.net/en/30publications/10policies/b3/index.html).[3] Though considered comprehensive and accurate in some aspects, it has not been without controversy over the years. Therefore, this year, which commemorates the 50th anniversary of the document, we must ask, how has the relevance of DoH changed, and will it change further in the future?

IMPORTANT CHANGES

The DoH has always been important as a regulatory tool for researchers. Though a researcher cannot be implicated under law for violating its terms, many countries have adopted legislation that has been guided by the declaration.[4] Over the years, many revisions and additions have been made, including the 1975 suggestion of research oversight by an 'independent committee' (Article 13), which would become the basis of institutional review boards (IRB) in the United States. Subsequent revisions sought consent for minors (Articles 24, 25) in 1989 and a set of standards for the use of placebos as treatment (Article 29) in 2000. The most recent revision in 2013 contains additional clauses including the importance of disseminating research results regardless of whether they are positive, negative or inconclusive (Articles 23, 35, 36), compensation and treatment for research subjects (Article 15), protection of vulnerable groups (Article 19), and database registration for all ongoing studies (Article 35).[5] In many regards, this document has been at the forefront in the evolution of ethical standards and has helped guide research in a manner that is beneficial for both the research participant and the field.

CONTROVERSY

However, this document is not without discrepancies. The DoH states that it is a set of rules for physicians, but nowadays medical research is conducted by a team, including investigators, coordinators, assistants, and others who are not necessarily physicians.[1] This inaccurate focus may deter the appropriate population from using this document to its fullest. Also, the DoH states that the 'rights and interests' of subjects are most important (Article 8), but 'research ... may only be conducted if the importance of the objective outweighs the risks and burdens' (Article 16). This discrepancy makes it unclear as to when a subject's interests can be compromised in favor of an objective, which unfortunately blurs the lines between ethical and unethical treatment of patients. Most recently, the addition of special protection for vulnerable populations is ad-

dressed (Articles 19, 20), but there is no explanation as to what the 'special protection' entails.[1] It is fair to want to protect vulnerable populations, but a vague statement does not help a researcher implement this goal in a real-world setting. It seems that as time goes on, more articles are being added with good intentions, but without thorough explanations. The committee has historically brought up important points for protecting research participants and making sure they are not put at risk, but sometimes it is impossible to remove all risk to research subjects. It also appears that as articles are constantly being revised and added, it is inevitable that they begin to contradict each other, making it more difficult to know which principles are the most important to focus on. It may be beneficial to pare down the document so that it includes the essentials most prominently, with minimized contradictions.

CHANGING TIMES

As we move further into the 21st century, the field of medical research continues to change, which brings about new problems and novel ethical dilemmas. Due to the numerous revisions that it has undergone, the DoH has received mixed feedback, with some saying that multiple revisions undermines its authority while others say that multiple revisions deem it an active document that is evolving. Others say that the DoH should focus more on basic principles rather than clinical practice guidelines which can cause controversy.[1] Another hurdle that the DoH has faced is the development of other documents outlining the ethical treatment principles, which in some cases have replaced the DoH.[2] The International Conference on Harmonisation of Technology Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Council for International Organizations of Medical Sciences (CIOMS) are two examples that have gained popularity in recent years. The ICH is a group of regulators and pharmaceutical experts that discuss the scientific and technical aspects of drug registration. This group publishes the Good Clinical Practice (GCP) guidelines, which includes standards on how clinical trials should be conducted by defining the roles and responsibilities of sponsors, investigators, and monitors and is used by various government institutions worldwide.[2] CIOMS is an organization established by the WHO and United Nations Educational, Scientific and Cultural Organization (UNESCO) that also publishes guidelines for ethical research. Their document focuses more on the implementation of clinical studies in resource-poor countries and is more often used by groups conducting research outside of their home country.

In April 2008, the United States Food and Drug Agency (FDA) stopped using the DoH as their standard for ethical practice and began using the GCP instead due to controversy over the use of placebos.[5] The DoH had added the phrase 'this does not exclude the use of inert placebo in studies of where no proven diagnostic or therapeutic method exists', which seemed to rule out the use of placebo in any study where a proven therapy already exists, making it more difficult to assess the safety and efficacy of new drugs.[3] Therefore, as the field keeps changing and more resources become available, it is no surprise that the DoH has lost some of its hold as the sole regulator of ethical behavior for human research subjects.

CONCLUSIONS

The DoH has provided a set of ethical guidelines for medical researchers to follow and has been essential for regulation within this field. However, as time has passed, with the addition of controversial articles and the development of other human subjects' research guidelines, attention to and use of the DoH has been compromised. The document is comprehensive and puts the subjects' well-being at the forefront of the research study, which is essential for protecting the patient, but it is not without faults. Some articles are unclear while others are contradictory to each other. With the 50th anniversary of this historical document, we visited its evolution and saw that it is still relevant to today's changing world of medical ethics and it has its place in the complicated world of medical ethics despite its flaws.

As we set out on the road toward residency and beyond, there will be plenty more rules to learn and follow. To accommodate an easier transition for new researchers, it would be beneficial to simplify the guidelines of medical research ethics. It would be most relevant for students and new researchers to have a central document to learn from and understand in order to know the ethical standards that are needed to conduct research. It is great that there are esteemed members of the medical field that are continuously revising this document, but the excessive revision and addition of unclear and contradictory articles does not help its evolution. To continue to be a revered document in the international health community, it is important that the nebulous articles are revised, the contradictions are taken out and the most important

clauses are fleshed out so that they are clear and concise. Presently, it does not seem that there is a large emphasis on teaching about the DoH in medical schools. A clearer document would assist with appropriate education as it could be incorporated into medical ethics classes with greater ease when those who teach the class can understand the intricacies of the document. If students are exposed earlier, such as in their first or second year, they can incorporate these factors into their continued perception of research and effectively use this information when they conduct their own studies as residents and attending physicians. With the appropriate changes, the DoH may continue to be at the forefront of medical ethics research and be essential for everyone hoping to conduct research in the future.

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