Revisions to the World Medical Association's Declaration of Helsinki: Africa Region Consultation

The World Medical Association (WMA)'s Declaration of Helsinki, which was adopted in 1964, is undergoing revisions 10 years after the previous one. Thus far, it has been revised seven times, and notes of clarification have been added twice. Globally, the declaration is recognised as one of the most authoritative statements on ethical standards for human research. It is a set of principles that is regularly updated to keep pace with ongoing and rapid advances in science and technology. The last revision was in 2013.[1]

After the end of the Second World War, evidence of lethal human experimentation, including some of the most notorious war crimes conducted by physicians and scientists, emerged during the Nuremberg Trials. Revelations of the horrors of experimentation and relentless exploitation and harms during medical studies on concentration camp inmates were publicised, with the vulnerable being considered sub-human, of inferior intelligence, lacking human dignity and of no moral status. The judges of the Nuremberg Trials tasked two of their medical advisors to develop a set of rules for them, which could serve as a standard to guide them. A 10-point memorandum entitled 'Permissible Medical Experimentation' was drafted. This later became known as the Nuremberg Code, the first international ethics guidance document for research.[1]

The WMA, established in London in 1946, initially focused on the crimes committed in the doctor-patient relationship during the war, leading to the adoption of the Declaration of Geneva and the International Code of Medical Ethics in 1948 and 1949, respectively. While these are guidance documents for physicians in the context of clinical care, they have a resounding presence in the 1964 Declaration of Helsinki and all its revisions. The 1964 declaration was adopted after 12 years of debate, and was the first formal declaration by the WMA for physicians doing research. It also served for the first time to distinguish biomedical researchers as a specific class of physicians.[1]

The South African Medical Association (SAMA) served on the WMA's Working Group for the 2013 revisions and is a member of the current revisions working group. Thus far there have been two regional consultations, the Asian and South American ones. The African regional consultation will be hosted by SAMA in Johannesburg on 18 and 19 February 2024. The overarching theme of the consultation as determined by SAMA is 'Vulnerabilities'. Engaging with communities, in particular when conducting research in resource-limited areas, and vulnerabilities during pandemics and other disasters, will also be explored. Africa is a region of vast differences in health, education and income among its populations. Africa also suffers from many of the health burdens of developing regions, and has not yet recovered from the years of oppression under colonialism. Poverty, conflict situations, civil war and gender-based violence are some examples of the lived experiences of people in Africa. For these reasons, many people on the continent are vulnerable and at risk of exploitation in research.[2] Moreover, we have been in the COVID-19 pandemic since 2020, and while the World Health Organization has declared that it is no longer a public health emergency of international concern, the pandemic has not yet been declared to be over. While vulnerabilities increased globally during, in particular, the first 2 years, certain regions, including Africa, were worse off. Pandemic-specific research needed to be conducted, and is still being conducted in this highly vulnerable context. Africa contributed to the research, but when it came to benefitting from the interventions, Africa was last in line, as has been highlighted by the 'vaccine nationalism' that we all witnessed.

African indigenous values contributing to participant protections in health research will be discussed during the consultation. The demand for practising ethics from an African perspective in Africa is growing generally, both in academic and professional circles. Since 1994, the concept of *Ubuntu* has been systematically drawn upon by the courts to arrive at judgments in South Africa. The importance of community in African indigenous systems is underscored by Mbiti when he states: 'I am because we are, we are therefore I am.'[3] This could translate to the importance of participating in health research for reasons of altruism and the greater good of all. This also requires that those participating must be protected against exploitation and other forms of harms. These issues need to be discussed and dialogued with communities. Community engagement is an age-old practice in Africa, e.g. the African tradition of *lekgotla* where all gather under a tree to examine options, opportunities and risks on a topic.[4]

For the Declaration of Helsinki to be a truly international guidance document, it would be prudent for the revisions to take into consideration African values and traditions, and vulnerabilities specific to the African context. The quest for a universal ethics document would benefit invaluably if the moral and ethical values as espoused in the principle of *Ubuntu* are taken into consideration.

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