

The WMA Declaration of Taipei: Human databases and biobanks for the common good



Ames Dhai

Editor

amaboo.dhai@wits.ac.za

On 22 October 2016, the World Medical Association (WMA) announced that it had approved new ethical guidelines for physicians involved in the collection and use of identifiable health data and biological material in health databases and biobanks, and that these guidelines would help people control the use of their health data. The WMA believed this would be achieved by respecting the rights to autonomy, privacy and confidentiality which individuals should be entitled to and as set out in the guidelines. In this way they would be able to exercise control over the secondary use of their personal data and biological material, both in and beyond research.^[1] The guidelines, named *The Declaration of Taipei*,^[2] were approved by delegates at the WMA's annual assembly in Taiwan.

The process

With rapidly increasing advances in science and technology, health databases and biobanks, in biomedical research and healthcare, are being used extensively. However, the open and evolving nature of these storage facilities have resulted in ethical, legal and social complexities of a nature and magnitude not seen in the past, and international policy guidance on the subject has been long anticipated. But what goes into the development of such policy and how does it attain the status of being truly global? Having been appointed to the Working Groups as a representative of the South African Medical Association (SAMA) for the most recent revisions to the Declaration of Helsinki, and the recently adopted Declaration of Taipei, I was privileged to experience first-hand the complex processes together with the trials and tribulations that are inherent in the progression towards reaching consensus in a milieu of over 100 different countries with differing socioeconomic conditions and diverse multicultural contexts. Of note, the WMA is an independent confederation of national medical associations from 112 countries and represents more than 9 million physicians. The process of developing the Declaration of Taipei took several years and included extensive consultations globally. In addition there were two rounds of consultations, which solicited advice from outside expert organisations. There were 87 commentators in the first round and 29 in the second round of consultations – a total of

116 in all. There were eight workgroup meetings, one in Reykjavik, two in Copenhagen, two in Berlin, one in Seoul, one in Argentina and one in Taipei. In addition, there were six expert meetings, which were held just prior to the Working Group meetings in Reykjavik, Copenhagen, Berlin and Seoul.

Historical perspective

Historically, it is clear that the WMA had been concerned with this issue for decades and in 1973, at its 27th General Assembly in Munich, passed a 'Resolution on Medical Secrecy', which addressed computers and confidentiality in medicine. A short statement on the subject followed at its General Assembly in Venice in 1983 and an extensive Declaration in 2002 at its General Assembly in Washington entitled 'The WMA Declaration on Ethical Consideration regarding Health Databases'. This Declaration was strongly aligned to the Declaration of Helsinki and its core ethical principles focused on access to information by patients, confidentiality, consent and the de-identifying of data. With the focus being on revisions to the Declaration of Helsinki during the decade that followed, there was only a minor revision in 2008 to the document on health databases. However, an in-depth revision process started in 2011, and a Working Group was established to take the processes forward in 2012. This ended in a new policy in 2013 where the scope was increased to include materials and data in biobanks as well. The membership of the Working Group was revised at this stage with South Africa (SA) being included in the membership of the Working Group. It is worth mentioning at this juncture that paragraph 32 of the Declaration of Helsinki had evoked considerable discussion and debate and reads as follows: 'For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.'^[3]

Definitions

The Declaration defines a health database as 'a system for collecting, organizing and storing health information', and a biobank as 'a collection of biological materials and associated data'. It describes biological materials as samples obtained from living or deceased individuals which can provide biological, including genetic information, about that individual. The collections in the health databases and biobanks are described as being from individuals and populations with both giving rise to similar concerns regarding dignity, autonomy, privacy, confidentiality and discrimination.

Sections

There are three sections to the Declaration: Preamble, Ethical Principles and Governance.

The preamble underscores that the Declaration is intended to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. It is in concordance with the Declaration of Helsinki and also provides additional ethical principles for research. It highlights the importance of research using health databases and biobanks, the impact of which is often significant acceleration and improvement in the understanding of health, diseases, the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions. It appeals to the social contract by stressing that health research represents a common good in the interests of individual patients, as well as populations and society. Physicians are cautioned that while their country level ethical, legal and regulatory norms and standards should be considered, no national or international requirements should reduce or eliminate any of the protections in the Declaration.

The ethical principles emphasise that database- and biobank-related activities and research should be of benefit to society and in particular, public health. Protecting privacy and confidentiality is essential for maintaining trust and integrity and physicians have both ethical and legal obligations as stewards with regard to protecting information provided by their patients. While detailed stipulations on information to be shared with individuals is listed where data and materials are stored for multiple and indefinite uses, the type of consent that should be obtained is not specified and neither is any specific type of consent censured. However, based on the detailed stipulations, blanket consent will not be a feasible option. In the event of a clearly identified, serious and immediate threat where the health of the population needs to be protected, and anonymous data will not be practicable, the requirement for consent may be waived conditional to ethics committee clearance. In terms of justice, the Declaration specifies that the interests and rights of communities, in particular when vulnerable, will need to be protected, especially with regard to benefit sharing. Exploitation of intellectual property must be safeguarded against by invoking protections for ownership of materials whereby rights and privileges must be considered and contractually defined. A policy addressing intellectual property issues and covering the rights of all stakeholders needs to be communicated transparently. Health databases and biobanks will require ethics approval by independent ethics committees.

Robust governance mechanisms are necessary to foster trustworthiness and should be designed such that the rights of individuals prevail over the interests of other stakeholders and science; relevant information is made available to the public; there is consultation and engagement with individuals and their communities; and custodians of health databases and biobanks are accessible and responsive to all stakeholders. Several elements regarding governance are laid down, including criteria and procedures for the access to and the sharing of health data or biological material including the systematic use of Material Transfer Agreements when necessary and the procedures for re-contacting participants where relevant.

Significance

While not perfect, the Declaration is a laudable attempt at achieving a balance between protecting individual rights over their tissues or data and scientific progress in biomedical research towards the common good. It is the first concrete set of international policy guidelines providing ethical direction for the complex issues that arise with activities associated with human databanks and biobanks. The WMA must be commended for once again providing strong leadership and endeavouring to address the policy guideline gap. It has provided a substantive set of benchmarks for ethical, legal and societal issues (ELSI) associated with human databases and biobanks.

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References

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