Request for Comments on WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks (Draft)

The World Medical Association's Declaration of Helsinki provides guidelines for medical research on human beings. It aims to promote the ethical conduct of research and to protect human subjects from associated risks.

The Declaration of Helsinki was the first international research guideline that required research participants to provide informed consent. This concept was not invented by WMA, but it was the WMA that successfully promoted it for the first time in a global policy. Informed consent, although not perfect, is the strongest instrument for protecting personal autonomy, and with it selfdetermination and dignity. It is the primary means for all potential research subjects to express their will and/or preferences. We consider it a crucial instrument for protection and respect.

Research is changing. Large collections of data and human specimens allow for the development of new research strategies and models, as well as new predictive types of research and analysis. The combination of large amounts of data, the possibility of combining large databases and the application of information technology is already changing all aspects of our lives. Research is no exception.

The potential of such databases is vast, but so are the dangers. While there is a strong possibility of finding solutions, cures and remedies for a multitude of medical problems, illnesses and suffering, the challenge lies in the high potential for the abuse and misuse of health databases and biobanks. We are convinced that the answer to this dilemma is to be found in an ethically correct process which takes into account the willingness and trust of those donating and sharing their data (or specimens) as well as acknowledging the obligation to apply high standards of protection.

It is clear that the "one-by-one" approach, which has so far been taken in obtaining informed consent for any physical experiment, must be retained because of the immediate impact upon subjects. However, we also acknowledge that the use of personal health data and specimens can lead to similar or comparable damage and likewise requires the protection of donors. While physical experiments allow and

require direct contact with the subject, the use of databases and biobanks allows for the frequent use of data sets. Therefore, if gaining consent from donors of the data or specimens were to be a “conditio sine qua non” for their use it could entail multiple problems or even be prohibitive as it may no longer be possible to contact the donors, or the high frequency of requests for use could become a burden upon them.

One solution could be the use of anonymised, pseudonomised and potentially aggregated data which protects personal integrity and eliminates the risk of harm to the donor. At this point it is helpful to note that, in contrast to physical experimentation scenarios, with databases or biobanks the holder of the data will often be separate from the researcher using the data. This separation allows for stronger protections against the reidentification of individuals than in the classical setting of physical experiments where identification is crucial for protection. However, even anonymisation and pseudonomisation will not always be possible or feasible, and the possibility of consent that accepts the use of data or specimens on more than one occasion should be considered (broad consent).

Furthermore, it must be acknowledged that the potential for harm will often be minimal or even non-existent when using only data or specimens as compared to physical experimentation. Prohibiting research simply out of respect for a non-relevant principle would not be desirable. But giving up the principle would not be an option either. Finally, we know that harm and discomfort can also occur as a consequence of the abuse or the mishandling of health information. This is one of the reasons for patient confidentiality and medical secrecy in general.

A WMA work group chaired by the Icelandic Medical Association has developed a draft guideline in the form of a “DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS”, which advises a balanced approach by requesting broad consent from the donors of data or specimens indicating their preparedness to share or donate their data or material for later use, which at the time of donation or sharing cannot be definitely described. However, this broad consent will be conditional upon a governance process, which can partly substitute individual informed consent or ensure that informed consent will be obtained at a later date if it is deemed necessary by an independent ethics committee.

In analysing the already existing scenarios for the use (and abuse) of health data and biobanks, the work group came to the conclusion that the major risk scenarios do not result from science, but from the commercial, administrative or political use of such data. Limiting our guidelines to research only would have left us blind to the imminent risk of abuse from outside the field of medicine: commercialisation, cost-cutting and

potential political abuse.

Therefore, in contrast to the Declaration of Helsinki, this policy aims to address any use of health databases and biobanks and is not restricted to research. As physicians are the primary custodians of confidential health information, they feel an obligation towards their patients and other persons who entrust them with their data and specimens.

How to participate in the open consultation

The WMA kindly invites all experts and stakeholders to submit comments on this draft version via email to the WMA secretariat at hdbb@wma.net no later than **5 June 2015**. The workgroup will thoroughly review all comments and consider all input; however please note that it may not be possible to take account of all the suggestions received in the draft declaration.

The draft version of the Declaration on Ethical Considerations regarding Health Databases and Biobanks from the work group may be downloaded here.

Although desirable, due to time considerations it will not be possible to provide documentation or consider comments submitted in languages other than English. The finished version of the document will be translated into Spanish and French by the WMA.

All submissions will be kept on file and may be made available to members of the public upon request to the WMA following completion of the revision process.