

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *The linking and use of biological and health data* between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.

The linking and use of biological and health data
Open consultation by the Nuffield Council on Bioethics
Submission from the World Medical Association

1) Do biomedical data have special significance?

Yes. This is the most personal and confidential type of data that currently exists. Every person has an interest in safeguarding this data for inherent reasons of personal privacy but also for more practical reasons, for example being able to obtain insurance and for reasons of employability. There was a recent troubling example in Toronto where a young woman was denied entry to the United States because she suffered from a mental health condition and had attempted suicide several years earlier. Somehow, the border services agent was able to access this private information and deemed her a risk to entering the US. Biomedical data is inherently more personal and sensitive, regardless of the context or circumstances, and must consistently be treated as such.

There are subsets of biomedical data that do present particular ethical challenges. The example of genomic data sets is a good one, as these will be of concern not just to the individuals concerned but to their family members as well. When it comes to genomics in particular, the information that is provided is rarely absolute – that is to say, it usually represents risks and possibilities rather than diseases and conditions. In some cases, there is no treatment available for the condition under consideration. In others, the environment plays a significant role in the development of an illness.

Genomic data sets must be regarded as belonging to one individual first and to family members only secondarily. Consent to the collection and use of such data must be formally sought and obtained from the individual involved and disclosure of information involved in the consent process must include all relevant considerations, including potential familial implications and considerations.

2) What are the new privacy issues?

The advent of electronic data storage and interpretation, together with electronic health and medical records, has raised several important new privacy considerations. In linking data across large numbers of data bases, anonymity can still be protected but this will be more challenging as more data bases are linked and as control over the data is potentially relinquished at each step.

There is clearly a public interest in biomedical data and in using this information for a wide variety of purposes. However, this legitimate interest cannot be allowed to supersede individual privacy rights and considerations. There are very few circumstances where the public interest should take precedence over individual and minority group interests – perhaps, for example, when the lives and safety of large numbers of people are at immediate risk.

There are real harms we need to seek to avoid. Some of these include discrimination in terms of work and insurance, social discrimination and stigmatization and other unforeseen consequences. An example of the latter occurred in Ottawa, where an ex-husband of a hospital patient, who was himself a hospital employee, accessed her private medical information and used it against her in court in order to try and obtain custody of their child on the basis that she was too ill to provide care.

Using a patient's medical data without their knowledge or consent is inherently wrong and should not be done. A deontological versus a teleological approach must be used in this circumstance – the ends do not justify the means. Even though people may be more willing to share personal information through social networking platforms, we should not make the assumption that this consequently extends to sharing biomedical data and information. Vacation photos are not the same as genetic profiles.

3) What is the impact of developments in data science and information technology?

The availability of biomedical data and new techniques for analyzing them has led to an enhanced focus on the use of secondary data for research and other purposes. Research priorities may be more likely to align with population versus individual needs and may also be more likely to focus on income generating opportunities. In addition, priority may be given to pursuing studies that would generate data that could subsequently be used for other (secondary) means, commercial or otherwise, rather than as an endpoint in and of themselves.

4) What are the opportunities for, and the impacts of, the use of linked biomedical data in research?

There are clearly significant hopes related to data use for ongoing research, including the possibility of “personalized medicine” and genetic therapies. The main concerns are similar to those outlined previously – a loss of privacy protection, the potential for the abuse of personal health information and the stigmatization of individuals and populations.

The collaborations required for data-driven research will require new and different legal and regulatory structures and models. This will require a combination of public and private involvement and oversight, with differing interests and priorities.

Researchers should not be required to allow others access to data they have collected.

When research is carried out by a commercial firm, it raises special concerns that there will be too much focus on the potential for profit from the results of the research, and that research with a high social but low financial value will not be pursued. This has clear implications for scientific advancement and for the integrity of the scientific process.

5) What are the opportunities for, and the impacts of, data linking in medical practice?

There are significant hopes and expectations for medical practice associated with the increased use of linked electronic data. As noted above, these include, but are not limited to, the field of personalized medicine, whereby interventions are tailored to a person's genetic profile, and genetic therapies which might allow for manipulation and correction of faulty genetic sequences, etc... This raises several concerns and fears, including the selection of genetic traits that are more highly valued (and the implications this has for discrimination and the appearance of eugenics), access to emerging therapies and technologies (which will be very expensive) and privacy and confidentiality concerns.

The public should expect that health care data will not be shared without individual consent and without a clear understanding of what the data will be used for. There is clearly the potential for privacy controls to disadvantage people in unintended ways, but individual privacy rights outweigh these possibilities and must be prioritized.

Yes, there are issues raised by risk-profiling. In Saskatchewan recently, several women were contacted by their regional health authority and reminded to see their general practitioner for their annual Pap smear examination. There was a huge public outcry that health officials were able to access such sensitive health information without the consent of patients and several of those contacted indicated that the process would make it less likely for them to see a physician in the future, or to share sensitive health information were they to do so. This has clear implications for individual and population health.

When episodes of treatment across different health care providers are used as research data without the express consent of the patient, there will clearly be a high potential for damage to the patient-physician relationship. This relationship is based first and foremost on trust. When this trust is lost – when physicians share patient information for uses other than direct health care provision without their consent – the relationship is irreparably damaged. Research has shown that such patients are less likely to subsequently share important information with their physicians, and that this can have detrimental impacts on health outcomes.

The possibility that biomedical data can contribute to a research base to advance the effective treatment of others creates no moral obligation to allow them to be used in this way. Those who refuse to allow their data to be used have this right and must be allowed to do so with no detrimental impact on their health care, even when it means that research cannot be done. Paragraph 26 of the WMA's Declaration of Helsinki (2013 Revision) states that "The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal."

6) What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

There will continue to be concerns of privacy and confidentiality, and when biomedical data is used in areas outside of research and clinical practice, of misuse and deceit. It is very difficult, without knowing specifics, to determine what “compatible purposes” and “public interests” might entail in this context. It is also difficult to outline specific restrictions but in general one would say that data obtained in this way should be used to serve the public interest and not to line the pockets of individuals or organizations.

Using predictive analytic tools outside health care has numerous important implications. Many of those tools are imprecise and will result in undue discrimination when used in a population context. The greater the control of the individual over the use of data, the greater the range of further uses might be allowed – assuming that the control is real and that consent for use is truly fully informed.

With respect to individuals profiting from the use of their medical data, such as selling access for commercial purposes, the ethics community is divided on this issue. Some feel that such data should not be commoditized regardless of the circumstances, while others feel that if it truly belongs to the individual, they can do with it as they wish. The WMA does not have a specific position on this complex issue.

7) What legal and governance mechanisms might support the ethical linking of biomedical data?

The key ethical principles to be considered involve autonomy and confidentiality. Yes, primacy must be given to respect for autonomy and the right of individuals to determine what will be done with their health data, whether generated from clinical encounters or for research purposes.

In general, the current principles required for patient consent, including the fact that it can be withdrawn, apply in these circumstances. Specific consent is preferred over broad consent, with limited exceptions. As stated in Paragraph 32 of the Declaration of Helsinki:

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.

Individuals should have continuing involvement in how their data are used to the extent required to ensure that their consent and privacy are respected. There should be an opt-in system for people to decide whether to allow their personal medical data to be used for public benefit; opt-out systems are too prone to abuse.

There are very limited conditions where individuals should be expected to delegate authorization for the use of their data – like opt-out systems of consent, this process is prone to misuse.

Public engagement and democratic processes have critical roles to play in the determination of governance measures. Many governments have an inherent conflict of interest in this area as they intent to use the data generated for their own planning purposes, and private companies seek to use it to generate profit. However, the outcome of such a process must not be used to override individual rights and interests.
