

Comments on WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks (Draft 2015-03-18)

The [Nuffield Council on Bioethics](http://www.nuffieldbioethics.org) is an independent body that examines and reports on ethical issues in biology and medicine. We have recently published the report [The collection, linking and use of data in biomedical research and health care: ethical issues](#), which is relevant to the proposed WMA Declaration on ethical considerations regarding health databases and biobanks and on which we draw in the comments provided below.

We welcome the proposal of this declaration to address the prospects and challenges for database and biobank-based research, and share the assessment – as outlined in more detail in our report – that “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” (request for comments, p. 1).

We also agree that the drivers of increased use of data initiatives derive from big data technologies in general and do not pertain exclusively to the biomedical sciences, but must be considered against a background of these technologies as impacting on all areas of life (see in particular chapter 2 of our report).

Specific comments (by paragraph) on the draft declaration

▪ 8.

“Health Databases and Biobanks that exclusively contain fully anonymised and non-identifiable data and biological material are not the subject of this declaration.”

As noted above, the stipulation of “fully anonymised and non-identifiable data” suggests that re-identification of individuals in data sets can be made impossible, which we question in our recently published report. Furthermore, this stipulation might exclude relevant kinds of databases, such as GWAS databases. In our view any

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database with individual-level data or rich aggregate (e.g. genomic) data would raise ethical concerns continuous with the ones addressed in the draft Declaration.

- 9.

“Anonymous or pseudo anonymous data are always preferable to identifiable data, whenever satisfactory for the purpose of a Health Database.”

References to different forms of anonymisation should be clarified as these are by no means standardised, and their limitations should be made explicit. Putting paragraphs 8 and 9 together it is not clear whether databases containing ‘anonymous’ and ‘pseudo anonymous’ data are preferred because they are outwith the scope of the declaration or whether databases within scope should prefer to include such data in any case. We would argue that databases containing individual-level data and rich aggregate data should come within scope.

- 13.

“The right to privacy, confidentiality and self-determination entitles people to exercise control over the use of and disclosure of information about them as individuals.”

When read in isolation and without qualification this principle might appear to be too broad (covering all data, even data for which there is a legal basis other than consent to process) and too strong (mandating interference in the details of data use rather than a simple option to withdraw). This might be helped by connecting it explicitly to qualifications on the reach, and limitations, of such control powers, for example as set out in paragraph 21.

- 15.

“Individuals must be given the opportunity to decide whether their identifiable information will, or will not be included in a Health Database or their biological material in a Biobank. As part of the consent process, individuals must be informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected and about who will have access to the Health Database or Biobank. They must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information.”

While we understand the significance of consent, purposes, the nature of data/material and who will have access can be specified narrowly or broadly. In our report we draw attention to the importance of the correspondence between the underlying norms of privacy and disclosure, the choice available to participants, and the form of governance. In order to find an alignment – to determine a set of morally reasonable expectations – we recommend participation of those with morally relevant interests, in both the design and

governance of data initiatives (see chapter 5 of our report). This will not always be possible, especially with existing holdings, but we believe that participation can help to optimise the use of data for public good.

Participants in any initiative should also be given information about provisions made for changes in ownership or transfer of the data should the database or biobank cease to operate, or be taken over or subsumed.

- 17.

“Individuals must have the right to, at any time and without reprisal, withdraw their consent for their identifiable information to remain included in a Health Database and their biological material to remain in a Biobank.”

We suggest including a reference to the necessity for a process enabling of participants to receive clear information concerning any potential implications of withdrawing their consent, such as for clinical care if, for example, the database is relied on by their health care provider, either directly or indirectly, in the provision of care (notwithstanding paragraph 4 of the draft declaration).

- 18.

“If Health Databases and Biobanks are established to allow for multiple studies and if, during the consent process, all principle information about future use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, and if all use is explicitly approved by a dedicated, independent ethics committee, then conditional broad consent is acceptable. In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable.”

We argue that a morally appropriate ethics and governance process is not limited to, and cannot be based exclusively on, any form of consent since consent is not in itself sufficient to abrogate our moral responsibility to others. We agree that broad consent is acceptable in well-governed research and that research that does not have adequate governance arrangements, regardless of the consent given, is not morally acceptable.

- 19.

“In the event of a clearly identified and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect public health. An independent, dedicated ethics committee should confirm that each exceptional case is justifiable.”

We suggest considering adding a more general reference to an

“appropriate authority” that could fulfil the functions assigned to the ethics committee here.

- 21.

“The ethics committee must approve all use of data and human material and decide on the type of consent necessary, taking into consideration risks and benefits of the activity. The committee must have the right to monitor ongoing activities”.

The stipulations in paragraphs 19-21 reiterate the reliance on specific forms of consent and specific committees. We would like to see a positive statement that these processes should involve people with a broad range of interests in the data use (see chapter 5 of our report and especially principle 3 relating to participation). It would be useful to distinguish more clearly between the roles of an ethics committee and of a data access committee or similar authority (for approving specific requests for access and operating within an approved ethical framework).

- 25.

“An appropriately qualified physician should be appointed to safeguard Health Databases or Biobanks with responsibility for ensuring compliance with this declaration.”

Professional or legal accountability within this role is important, although in our view it need not necessarily be fulfilled by a physician, as opposed to another person and subject to appropriate forms of accountability.

- 26.

“Governance arrangements must include:

- *26.1 The purpose of the Health Database or Biobank;*
- *26.2 The health data and biological material that will be contained in the Health Databases or Biobank;*
- *26.3 Arrangements for the length of time for which the data or material will be stored;*
- *26.4 Arrangement for obtaining appropriate consent or other legal basis for data collection;*
- *26.5 Arrangements for protecting privacy, confidentiality and autonomy;*
- *26.6 How the health data or human material will be accessed;*
- *26.7 The person or persons who are responsible for the governance;*
- *26.8 The procedures for receiving and addressing enquiries and complaints;*

- *26.9 The security measures to prevent inappropriate or unauthorized access.”*

We suggest including in this list a reference to arrangements for the disposal or transfer of data/samples in the event of the database/biobank ceasing to operate, particularly as some of the data initiatives covered will be commercial or have links to commercial enterprises.

If you have any questions or require any further information in relation to this response or our report, please contact Bettina Schmietow via bschmietow@nuffieldbioethics.org.

Yours sincerely,

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