

Health Databases and Biobanks
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Historical perspectives

The WMA has been concerned about health data for decades.

As early as 1973 in a “Resolution on Medical Secrecy” addressing Computers and Confidentiality in Medicine (27th GA in Munich):

GA in Venice in 1983, short statement

GA in Washington 2002, extensive declaration

GA in Washington DC in 2002

Adoption of a Declaration:

The WMA Declaration on Ethical Consideration regarding Health Databases:

- Strong association to the Declaration of Helsinki (DoH).
- Central ethical principles:
 - Access of information by patients
 - Confidentiality
 - Consent
 - De-identified data

2002 -2012

- The 2002 Declaration became a solid base for the WMA to use but otherwise, the document was not prominent outside the Association.
- During the next decade there was much debate on the DoH with new, minor revision in 2008 followed by an in depth revision process starting in 2011, ending in a new policy in 2013.

The 2013 revision on the DoH

- During the revision, an extensive external consultation was used.
- The new (and current) version was adopted in 2013 containing a revised paragraph on health data.
- The work on a renewed policy on Health Data had then already begun

Par 32 in DoH

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.

Revision process on the Health Data

- Started in 2012 at the Council meeting in Bali and a WG was established
- At GA in Fortaleza 2013, the scope was increased to cover data and material in Biobanks as well
- At GA in Durban 2014, it was decided to have an open consultation with a subsequent expert meeting in Copenhagen
- At GA in Moscow 2015, the open consultation had ended, a decision of a new expert meeting in Seoul

Types of databases

- Not single records, even if in electronic form
- Not a collection of records in a hospital/health institution even if kept in a central way
- Data collected for research
- Data collected for quality assurance
- Data collected for epidemiology (cancer registries etc.)
- Data from several sources/databases
- Clouding

The importance of Databases

- Hardly any research is conducted without the use of electronic database
- The use has shifted from gathering information for a specific purpose to data that are collected for different purposes
- Extremely large databases are increasingly established

Some general issues

- For the WMA, the Health Data and Biobank policy must be in line with the DoH, not only by referring to it, but also in content.
- The policy must be accepted by members from all regions of the world
- There is a wish that the policy will have influence beyond the member societies

Identification of data and material

Different concepts, to some extent overlapping:

- Identifiable
- Non-identifiable
- Anonymisation
- Pseudo-anonymisation

An issue to solve:

The problem of inherently identifiable data and material (specific cases, genetics)

Some ethical principles

- The issues of privacy, self determination and confidentiality are not very controversial
- The right of individuals to decide over their data is however debated:
 - For data to be included (some legal aspects)
 - To receive information on which data are included
 - To correct data
 - To withdraw data from a database

Consent issues

- Informed consent for specific purposes
- Legal requirements for data collection (not requiring consent)
- Consent for further/later use:
 - For the same disorder
 - For related disorders etc.
 - For any use

Research Ethics Committees (REC)

Central players for securing good ethical conduct

The role of REC increases if the consent practice decreases.

Problem:

Worldwide, the construction and quality of REC differs

Governance

- Purpose and content
- Consent and time limitation, privacy and autonomy
- Who will have access?
- Responsible person(s)
- How to handle enquiries and complaints
- Security measures

Biobanks

- Biobanks contain data and material
- Same central ethical issues as by databases
- Same security issues

Specific aspects:

- Handling of material

Security

- Security breaches have become a major issue, exemplified by infamous hacking
- The value of health data is greater than most health professionals realize
- By linking databases, there might be an increased risk of breaches