WMA

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):
- Preamble: “There is an increasing tendency towards an intrusion on Medical Secrecy”
- “The GA appeals to the United Nations to give needed help and to show ways ….”

GA in Venice in 1983

The 1973 resolution amended, renamed and extended and is now a statement:

The WMA Statement on the use of Computers in Medicine:

“Medical data banks should never be linked to other central data banks”

Development 1998-2002

In Iceland, plans on central health database on all health data from every person in the country was planned but owned by a private company.

The IcMA brought the issue to the WMA that responded promptly

The issue was on the agenda of WMA meetings for the next two years resulting in an extensive declaration on the ethical use of health data

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 was a solid base for the WMA to use but otherwise, the document was not prominent
- During this period,there was much debate on the DoH with new, minor revision in 2008 followed by an in depth revision process starting in 2011
- In 2012, all 10 year old policies were looked at for possible revision. A decision to make a major revision was made on the Health Data declaration

The 2013 revision on the DoH

- During the process of 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 GA in …with a WG
- At GA in Fort Aleza in 2013, the scope was increased to cover data and material in Biobanks as well
- At GA in Durban in 2014, it was decided to have an open consultation
- The open consultation has now ended, more than 80 partners responded with comments, some extensive

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 but used collectively
- 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 some influence beyond the member societies

Some central themes

- For whom? (the mandate):
  - Par 10: *"The ethical principles outlined in this Declaration must be observed by all those using data and biological material in Health Databases and Biobanks*." (Rewording from the draft for open consultation)

However, special focus is on the role of physicians in other paragraphs, discrepancy?

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 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

  How to handle this has not been resolved

Research Ethics Committees (REC)

Central players for securing good ethical conduct

The role of REC increases if the consent practice diminishes.

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 “high ranking” hacking
- The value of health data is greater than most health professionals realize
- By linking databases, there might be an increased risk of breaches

Caring,
Ethics,
Science

WMA

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