OFFICE FOR
RESEARCH ETHICS
& BIOETHICS

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On Health Databases and Biobanks
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Third panel (Biobank issues and genomics):

Comments on the draft declaration

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Disclaimer

The views expressed in this talk are my own.

They do not reflect any position or policy of NCVC, the Ministry of Health, Labour, and Welfare, or the Japanese government.

There is no conflict of interests.

Major problems with the draft decl.

- At least 3 major problems:
    - Too broad scope
    - Too narrow visions
    - No clear definitions of key-concept terms

Drafted scope of the decl.

- Giving *additional* principles to DoH [1.][2.]
  - More specific to issues on health databases & ***biobanks***

⬄

- Any use beyond the *individual care of patients* [4.]:
  - ➢ For *research*, and [2.]
  - ➢ For *other purposes* [2.]

e.g.

- For commercial/industry-use purposes
- For public health purposes
- For administrative /policy-making purposes

Problems with the draft decl.

- Too broad scopes
  - For *research*, and [2]
  - For ***other purposes*** [2]
    - For commercial/industry-use purposes
    - For public health purposes
    - For administrative /policy-making purposes

- Lack of due considerations to the consequences

  e.g.

  - **?** A dedicated independent ***ethics committee must approve*** the establishment of health databases and biobanks for other purposes than for research [20][18][21]
  - **?** An appropriately qualified ***physician*** should be appointed to safeguard [25]
  - **?** The privacy of a ***patient****'s* information is secured by the physician's duty [14]

Problems with the draft decl.

- Too narrow: No exceptional circumstances are appropriately considered.

  e.g.

  - **?** Individuals ***must*** be given the opportunity to decide whether their identifiable information will, or will not be included in … [15]
  - **?** Individuals ***must*** have the right to, at any time and without reprisal, withdraw their consent… [17]

⬄ Cf. the 2000 Decl. on Ethical Considerations regarding Health Databases:

  - …unless there are exceptional circumstances as described in paragraph 11/…unless exceptional circumstances apply… [the 2000 Decl. 10 & 12.]
  - Under certain conditions, personal health information may be included on a database without consent, for example… [the 2000 Decl. 11.]

Problems with the draft decl.

- Giving no clear definitions of key terms will only make confusions:

  especially,

  - What is ***"identifiable"*** data? [9][15][17]

    ⇔ **?** fully anonymised; non-identifiable; anonymous; peudo anonymous [8[[9]

  - What is ***"conditional broad"*** consent? [18]

    ⇔ **?** blanket consent; open consent [18]

Concluding suggestions

1. Should simply focus on issues on databases/biobanks for “research” purposes
2. Should see the reality of databases/biobanks managements (not so many physicians are involved ⇔ those other than patients are included in databases/biobanks)
3. Need careful and due considerations to exceptional circumstances
4. Need careful and clear wording
5. More important matter for the WMA seems giving principles on ethical conduct of genetic medical practices in clinical settings