ETHICS OF BIOBANKING: LOCAL SCENE IN HONG KONG

Chi-kong LI

MBBS, MD, FRCPCH, FHKAM (Paediatrics)

New Territory East Cluster : Prince of Wales Hospital

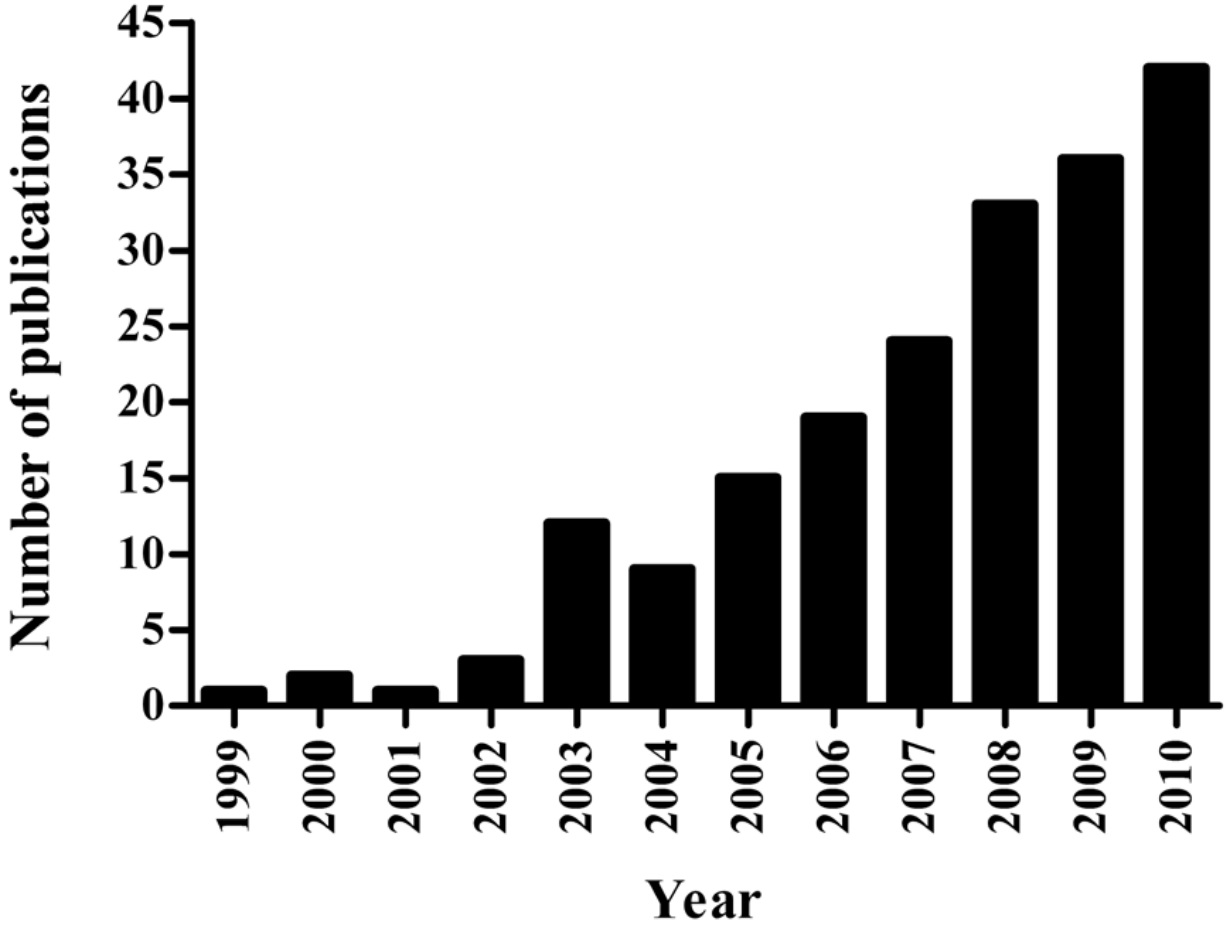
- Chairman, Clinical Ethics Committee, NTEC Cluster, Hospital Authority
- Deputy Chairman, Joint CUHK-NTEC Clinical Research Ethics Committee
- Chairman, Joint CUHK-NTEC Clinical Research Management Committee

- Paediatric oncologist

Important consideration in biobanking

- Medico-legal and professional regulations
- Data protection: public confidence
  - Anonymized
  - Inherent impossibility of completely anonymizing human biomaterials
- Informed consent
  - Sample use and storage
  - Transfer of property right
- Quality control

The yearly distribution of published articles related to ethics in biobanks during 1999-2010 period.



Danijela Budimir et al. Croat Med J. 2011; 52: 262-79

Types of biobanks

- Population Banks
  - Biomarkers of susceptibility, population identity
  - Germ-line DNA from huge number of healthy donors
- Disease-oriented banks for epidemiology
  - Biomarkers of exposure, case-control design or healthy exposed cohorts
- Disease-oriented general banks, ie tumour banks

Establishment of Human Biobanks:

1. **The purpose, both current and for the foreseeable future, of the biobanks should be clearly formulated and communicated.**
2. **The operators of the biobanks should ensure that sufficient professional staff and resources are available to operate effectively.**
3. **The operators of the biobanks should develop a strategy for ensuring its long term sustainability, which also addresses the event that funding is terminated or its nature changed.**
4. **In the establishment of a new biobanks, the operators should consider which relevant stakeholders, including the general public, should be consulted.**

http://www.oecd.org/science/biotech/44054609.pdf

Ethical issues of biobanks

- Who is competent to give informed consent and donate a sample?
  - Minors, incompetent individuals
- Who is the owner of the sample?
- Who should decide how it should be used?
- How to protect privacy?
- Who has the right to know individual results of research?
- Returning of results to participants?

Informed consent: Broad or Blanket?

- Most investigators supported broad consent as most applicable,
- the future research in which the details of research are not known at the time when the consent is obtained. (genetic research)
- some conditions that must be respected when using broad consent:
  - research must be of great importance,
  - maximum protection of privacy to participants,
  - Participants must be allowed anytime to withdraw the consent,
  - every future research should be approved by an ethical review board (ERB).
  - Furthermore, if patients have indicated that they do not wish to participate in any future research, this decision must be respected

Hansson MG. The need to downregulate: a minimal ethical framework for biobank research. Methods Mol Biol. 2011;675:39-59.

Re-contact study participants

- re-contacting the study participants to provide additional or new consent for every future research question or technology
  - can be very impractical,
  - time consuming,
  - expensive,
  - and even confusing (or harassing or worrying) to the participants.
- Thus, broad consent has an advantage that it does not require re-contact.

Left-over specimen

- very large collections of human samples collected for diagnostic or clinical purposes with left-over specimen.
- Is it acceptable to use the samples that did not have consent?
- In most cases, it is impossible to recontact people to obtain an informed consent, and these samples are not utilized, the potential for research could be significantly reduced.
- Most ERB agree that the use of such samples in research could be permitted without consent if they are fully anonymized or carry a minimal risk of breaking privacy and thus should not harm the donors;
- However, every such research must be approved by an ERB

Helgesson G, Ethical framework for previously collected biobank samples. Nat Biotechnol. 2007;25:973-6

Privacy and identifiability of the samples

- Biobanks, mostly genetic ones, usually store genomic information that is linked to a particular phenotype.
- That link between two types of information presents a major threat to individual's privacy
- a widespread concern that insurance companies and employers could access personal information
- Using anonymous or anonymized samples (no link to other data or a destroyed link) is the best way to protect personal information.
- But limits the research utility especially the potential to transform biobanks into longitudinal epidemiological studies

Issues of destroying link

- re-contacting specific participants to provide new informed consent unachievable.
- no possibility of returning the results.
- Withdrawal of consent also impossible
- many biobanks decline the permanent anonymization and support coding of information as the most appropriate way of ensuring privacy.
- Simple coding, double-coding, or even triple-coding (one to three codes are needed to provide a link between sample and data) are acceptable and at the same time are safe enough to ensure a satisfactory level of privacy

Returning results to participants

- the governing policy of most biobanks is not to return any individual results to their participants
- returning the information can be misinterpreted, especially if information is not of any clinical relevance or results that are not yet validated, understood properly, or informative.
- These results can cause psychological, social, or economic harm to participants
- *But, if a result is clinically important, is it ethical not to return it?*

Returning result to participants

- Most people agree that the only exception to the general rule of not returning the results can be a result of *very high clinical importance*.
- Such a result should be returned and *communicated properly* and *professionally* to each participant

Children and incompetent adults

- Many biobanks do not involve children because of special ethical problems and concerns:
  - However, this could lead medical research on children to lag behind the research on adults, in that way children will eventually suffer relatively more than adults.
- Parents have a right to give informed consent instead of the children in biobank studies.
- However, the children must decide if they want to know about their own results when they reach adulthood.
- But, what should be done with incidental findings that could potentially save a child's life?
- It would be ethical to return this information to parents

Commercialization

- commercialization raises several ethical issues, such as preventing exploitation, ensuring fairness to study participants, and balancing costs and benefits
- the partnership of research and commercial interest could also be very productive and should not be seen as a threat to their interests.

Ownership of biological samples and data

- An ethical and legal issue
- Could biobanks become owners of the sample or does it remain in the ownership of the participants?
- complete anonymization would practically make biological materials ownerless,
- but in instances the donors maintain ownership and then should be able to withdraw both their consent and their biological material donated to the biobank
- biobanks as custodians or trustees, instead of owners, of samples?
- samples should be the shared property of donors, researchers, and institutions?
- the legal position on ownership remained unsettled

Legislative framework for biobanks

- Do we need governments to pass the formal legislation that governs the principles of development and utilization of biobanks with human samples?
- “The Biobank Act” in Icelands
- legislative framework is being developed include France, Estonia, Spain, Scandinavian countries, the United States, and the United Kingdom
- Hong Kong???

Hong Kong Situation

- Biobanking is a recent development
- No legislation or regulations
- Many investigators show great interests in biobanking
- Are these centres ready for biobanking?
- CREC must protect interest of participants, and is CREC ready to approve or disapprove proposals?

CUHK-NTEC CREC

- "When and how consent should be obtained for the use of biological material" CREC seminar 2009
- A review on recommendations for biobanking in 2012
- A standard form for studies involved biobanking
- 2013, 4 biobank studies approved (570 studies)

Establishment of a Tissue Bank:

minimal recommendations from CREC

1. Staffing, Administration and Governance
2. Ownership and Custodianship
3. Facilities, Equipments and Maintenance
4. Quality Management System and Quality Assurance Program
5. Ethics Approval and Informed Consent
6. Privacy Data Protection
7. Access to Biospecimens and Metadata
8. Intellectual Property and Resource Sharing
9. Funding Support

Biobanking in Hong Kong

- At the initial phase of development
- Need more stringent overseeing mechanisms to protect subjects rights
- Sustainability of department based biobanks needs close monitoring