Biobanks with particular emphasis on human research material

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Outline

- Introduction
- DoH provisions on human material
- Key biobank issues
- Key biobank issues for developing countries: Uganda as example
- Conclusions

Introduction

- Advances in molecular science increasingly provide remarkable capabilities of working with human materials (HM) --- blood, tissue, saliva, hair, etc --- to understand disease, & find novel preventive and therapeutic remedies;

- *What we can't do today may be possible to do in future.*

Introduction…

- Thus, HM are stored for possible uses in future research (i.e. biobanked).

- As it helps to:
    - Preserve valuable biological information;
    - Save time and resources;
    - Less burdensome to sample sources;

- *HM are exchanged across the world in thousands; many from less developed to developed countries.*

Declaration of Helsinki (DoH) on HM

- The DoH intention to provide guidance on HM is clear in para A.1 of the current version,
  - "The WMA has developed the DoH as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data."

DoH on HM…

- But the guidance is limited to consent only as stated in para B.25,
    - "For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse."
- And in situations where consent would be impossible or impractical to obtain, research may proceed with approval of a research ethics committee.

Key biobank issues

- Working with HM involves dealing with a number of complex issues, most of which are not sufficiently provided for in current international research ethics guidelines;

- and it appears no single ethics guidelines (e.g. DoH or CIOMS,) may be able to comprehensively address biobank issues.

Key biobank issues…

- There's need to articulate the issues, but have an integrated mechanism to address them:
  - Scientific concerns
    - Collection, transportation & storage to ensure quality and sustain viability of samples over long periods of time;
  - Ethical issues
    - Demonstrate respect for persons by ensuring proper consent, privacy & confidentiality; addressing risks, avoiding harm, and ensuring responsible use of HM;
  - Socio-economic considerations
    - Provide for fair and equitable sharing of benefits arising from utilization of HM.

Key biobank issues for developing countries: Uganda as example

- Concerns over continuous shipping of HM for storage abroad;
  - Reasons for shipping:
    - Inadequate in-country/local scientific capacity;
    - Weak infrastructure: labs, power cuts, safety & QC measures;
    - Quality assurance at Central lab— especially in multicentre studies;
    - Ugandan citizens studying abroad carry HM with them for their experiments;
    - Cheaper to work with HM in more advanced facilities with more experienced personnel abroad;

Key biobank issues for developing countries: Uganda as example…

- Fear of losing control over HM and data:
  - Common questions people seek answers for:
    - Where are the HM/data being stored?
    - Who owns them?
    - How are the HM being used, for what purpose and by whom?
    - How do we benefit from results or products developed?
    - Will our research partners ever need to come back for research now that they have the HM?

Key biobank issues for developing countries: Uganda as example…

- Thus the debate:

  – Prevent shipment of HM/data for biobanking abroad, and in stead build local biobanks?

  Or

  – Allow shipment of HM/data abroad but under certain terms and conditions clearly stipulated in guidelines, policies, and agreements?

Key biobank issues for developing countries: Uganda as example…

- Lessons:
  - Addressing issues of ownership;
    - Employed a trusteeship model, i.e. where the providing organization holds HM in trust on behalf of research participants; *but a bit complicated for private organizations/biobanks*.
  - Benefit sharing
    - Involving the provider organization in negotiating transfer & storage; use of material transfer agreements or contracts have so far been useful; ideally should include provisions for longer term collaborative partnerships for research.

Key biobank issues for developing countries: Uganda as example…

- Lessons…
  - Rights of HM sources
    - A separate consent process for HM storage, where participant has the option to allow or refuse storage;
    - Research participants having a right to withdraw samples, if linked;
  - Role of the Research Ethics Committees (RECs)
    - RECs to review future studies on stored HM—may help in monitoring use & promoting a culture of responsibility;
    - Approve use of HM collected outside research setting;

Conclusions

- As consensus builds on some of the key biobank issues discussed above, as always new ones will arise. Continued dialogue is necessary.

- No current research ethics guidelines will singly address all biobank issues; probably a separate more inclusive and operational guidance document for biobanking in human research activities may be needed especially for research in countries with less developed human research protection systems.

Conclusions…

- The next DoH version may, however, broaden its scope of guidance on HM & data to take into account other ethical and associated socio-economic considerations involving biobank activities.

Some reading material

1. Budimir, D., Polašek, O., Marušić, A., Kolčić, I., Zemunik, T., Boraska, V., Jerončić, A., et al. (2011). Ethical aspects of human biobanks: a systematic review. *Croatian Medical Journal*, *52*(3), 262–279. doi:10.3325/cmj.2011.52.262
2. Emerson, C. I., Singer, P. a, & Upshur, R. E. G. (2011). Access and use of human tissues from the developing world: ethical challenges and a way forward using a tissue trust. *BMC medical ethics*, *12*(1), 2. doi:10.1186/1472-6939-12-2
3. Hansson, M. G. (2011). *The Need to Downregulate: A Minimal Ethical Framework for Biobank Research in Methods in Biobanking*. (J. Dillner, Ed.) (pp. 39–59). Humana Press, Springer Science+Business Media, LLC. doi:10.1007/978-1-59745-423-0_2
4. Harris, J. R., Burton, P., Knoppers, B. M., Lindpaintner, K., Bledsoe, M., Brookes, A. J., Budin-Ljøsne, I., et al. (2012). Toward a roadmap in global biobanking for health. *European journal of human genetics : EJHG*, *20*(11), 1105–11. doi:10.1038/ejhg.2012.96
5. Hewitt, R., & Hainaut, P. (2011). Biobanking in a fast moving world: an international perspective. *Journal of the National Cancer Institute. Monographs*, *2011*(42), 50–1. doi:10.1093/jncimonographs/lgr005
6. Igbe, M. a, & Adebamowo, C. a. (2012). Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria. *BMC medical ethics*, *13*(1), 27. doi:10.1186/1472-6939-13-27
7. Kiehntopf, M. & Krawczak, M. (2011). Biobanking and international interoperability: samples. Human Genetics: 2011, 130: 369-376, Spinger
8. Kumar Patra, P., & Sleeboom-Faulkner, M. (2012). Informed consent and benefit sharing in genetic research and biobanking in India, *33*, 237–256.
9. Nietfeld, J. J., Sugarman, J., & Litton, J. (2011). Author version The Bio-PIN : A concept to improve biobanking, *308*, 303–308.
10. Rudan, I., Marušic, A., & Campbell, H. (2011). Developing biobanks in developing countries, *1*(1), 2–4.
11. Vaught, J. & Lockhart, N.C. (2012). The evolution of biobanking best practices. Clinica Chimica Acta, 413(2012) 1569-1575. Elservier.