Barrières et incitations pour les politiques de partage pour les biobanques

Heidi Carmen Howard, PhD
Senior researcher
Centre for Research Ethics and Bioethics

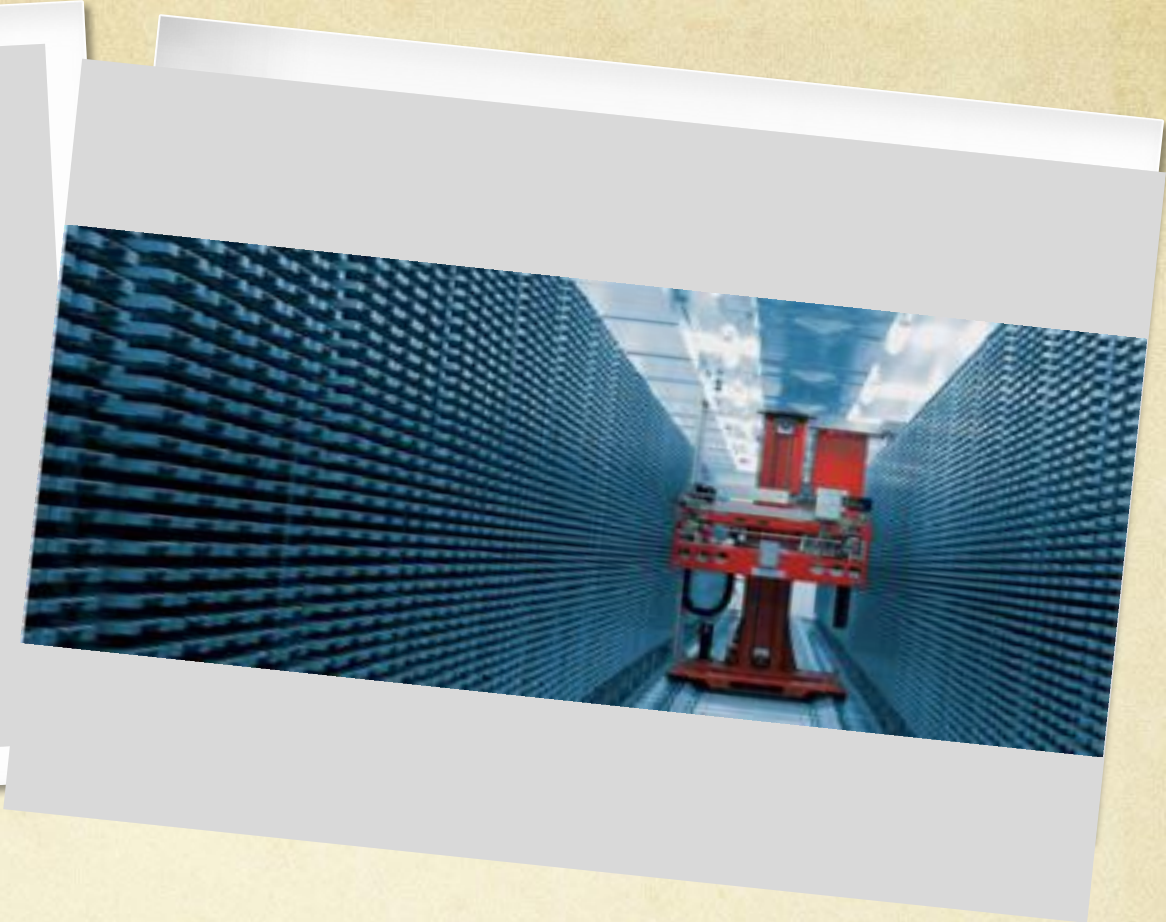
UPPSALA UNIVERSITET

ATELIER 2015 de la PLATEFORME GENETIQUE ET SOCIETE, Toulouse, le 7 mai, 2015

Pour toute utilisation du contenu de cette présentation, veuillez citer l'auteur, son organisme d'appartenance, le volet 2 des ateliers « Ressources biologiques : diversité, usages et enjeux sociétaux » de la plateforme « génétique et société » de Toulouse, le titre du document ainsi que la date. Merci.

Survol

- Biobanks 101: brief review (as needed)
  - Definition matters
  - Differences matter
- Sharing, what do we mean?
- Barriers to Sharing Samples & data in biobanking: a literature review
- Barriers & Solutions: interview results
  - Focus: 1- confusion, 2- will to share & 3- recognition



Biobanks 101

Biobank Definition

“organized collection of biological samples and associated data” A. Cambon-Thomsen, Nat Rev Gen 2004

OECD: “A collection of biological material and the associated data and information stored in an organised system, for a population or a large subset of a population.” (2006)

- Also referred to as Human genetic research database(s) (HGRD) or “population database”.

Biobank Definition

- “structures collecting biomaterial and associated data either for specific disorders or for a group of disorders, in some instances restricted to a specific type of biomaterial, or for a specific subset of the population” Lochmüller and Schneiderat (2010)

- Importance of definition for regulations and guidelines
- Also, different biobanking contexts could have very specific issues, eg: rare diseases

Biobank Types

- Huge diversity of biobanks
- Differ in:
    - Size
    - Degree of access, storage, distribution
    - Types of Materials & data stored
    - Goals/Uses: research, Dx, forensic
    - Type of institution: public, private, for-profit
    - Funding
    - Governance
- Research biobanks: population or disease-specific

Research Biobank Types

Population BBK

- focus more on epidemiology

- “more” recent

-industrial-type bbk

- Focus on Common diseases

Disease-Specific

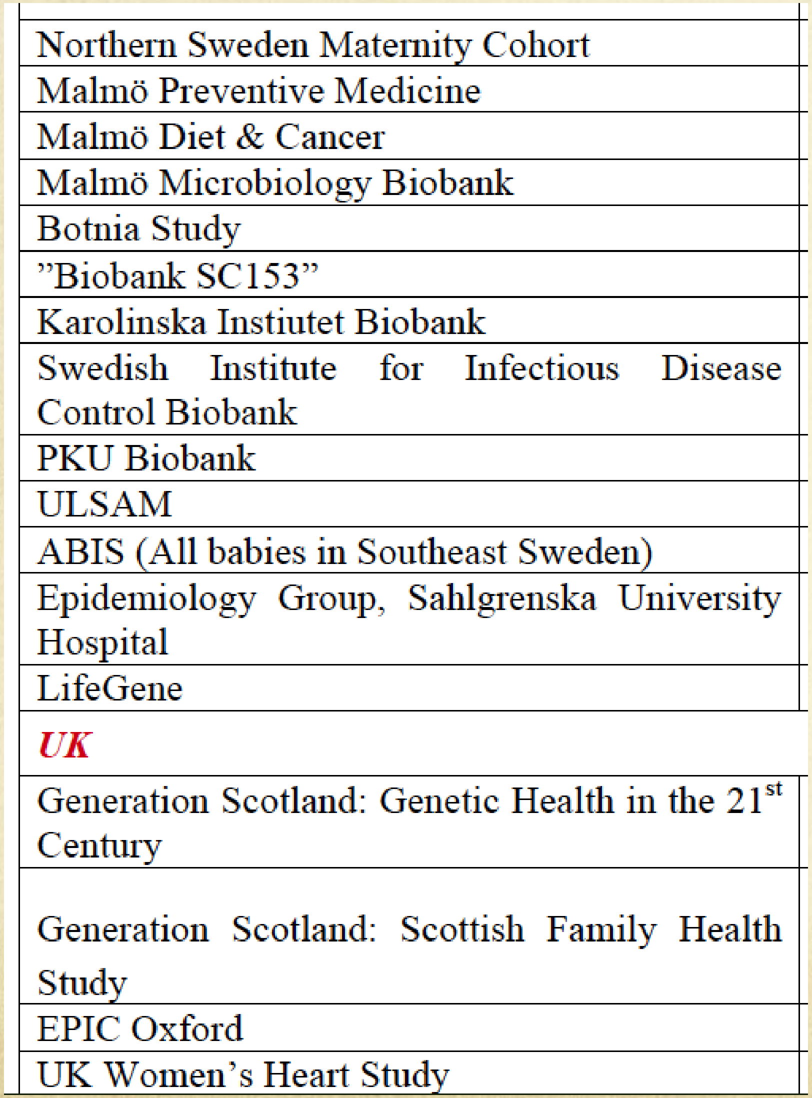
-often built by individual researchers, or groups working on a disease

- Smaller

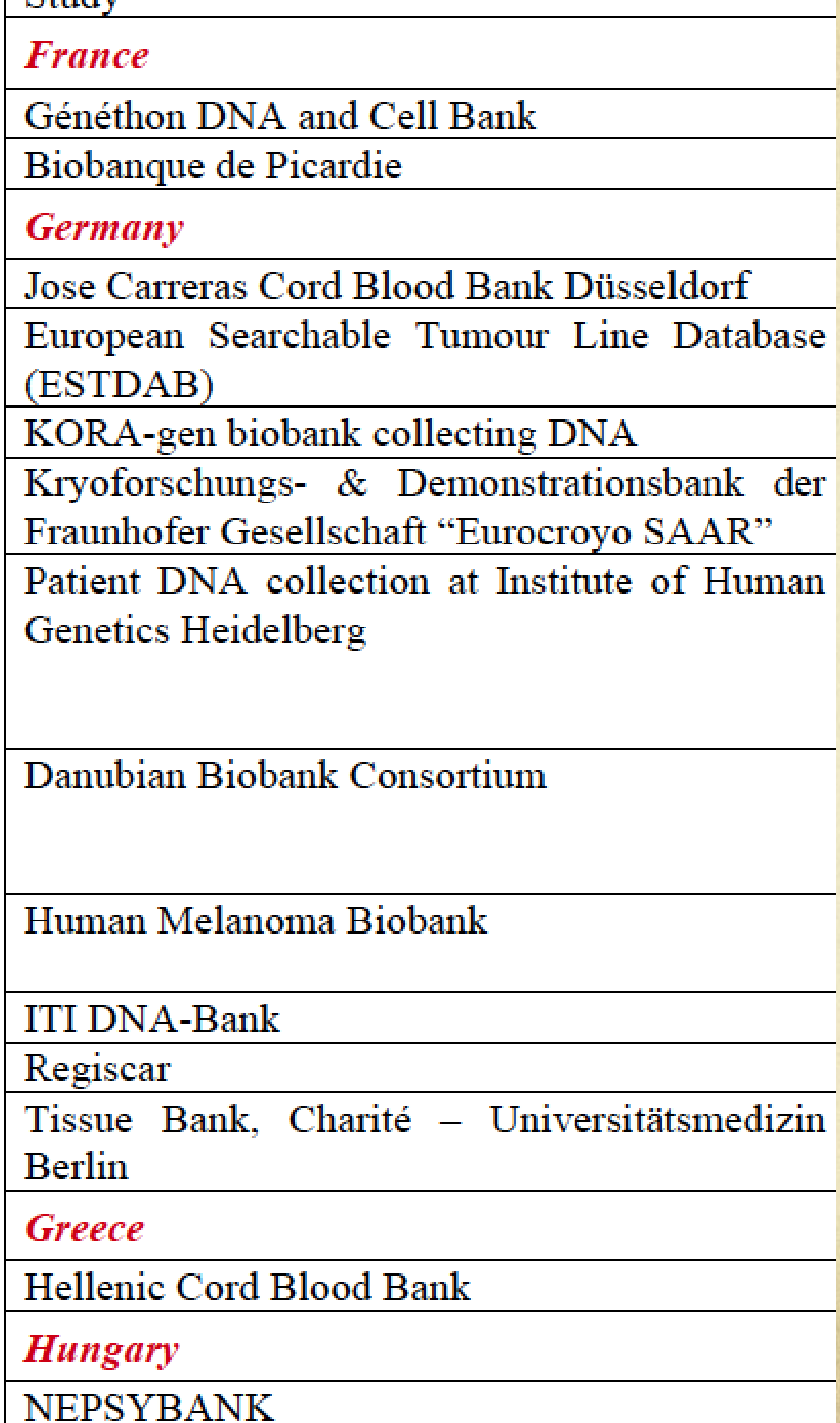
-”older”

- Can be common or rare-disease

Examples



Northern Sweden Maternity Cohort
Malmö Preventive Medicine
Malmö Diet & Cancer
Malmö Microbiology Biobank
Botnia Study
”Biobank SC153”
Karolinska Instiutet Biobank
Swedish Institute for Infectious Disease Control Biobank
PKU Biobank
ULSAM
ABIS (All babies in Southeast Sweden)
Epidemiology Group, Sahlgrenska University Hospital
LifeGene
UK
Generation Scotland: Genetic Health in the 21st Century
Generation Scotland: Scottish Family Health Study
EPIC Oxford
UK Women’s Heart Study



Study
France
Généthon DNA and Cell Bank
Biobanque de Picardie
Germany
Jose Carreras Cord Blood Bank Düsseldorf
European Searchable Tumour Line Database (ESTDAB)
KORA-gen biobank collecting DNA
Kryoforschungs- & Demonstrationsbank der Fraunhofer Gesellschaft “Eurocroyo SAAR”
Patient DNA collection at Institute of Human Genetics Heidelberg
Danubian Biobank Consortium
Human Melanoma Biobank
ITI DNA-Bank
Regiscar
Tissue Bank, Charité – Universitätsmedizin Berlin
Greece
Hellenic Cord Blood Bank
Hungary
NEPSYBANK

One size fits all? Really?
Example: rare disease sharing

Interviewer: Do you think that sharing is a problem or not a problem in general?

Respondent: "Well I don't think so. I think that the real problem is that there is not enough money for many projects. There are not many research teams working in the rare disease field."

Importance of Research Biobanks

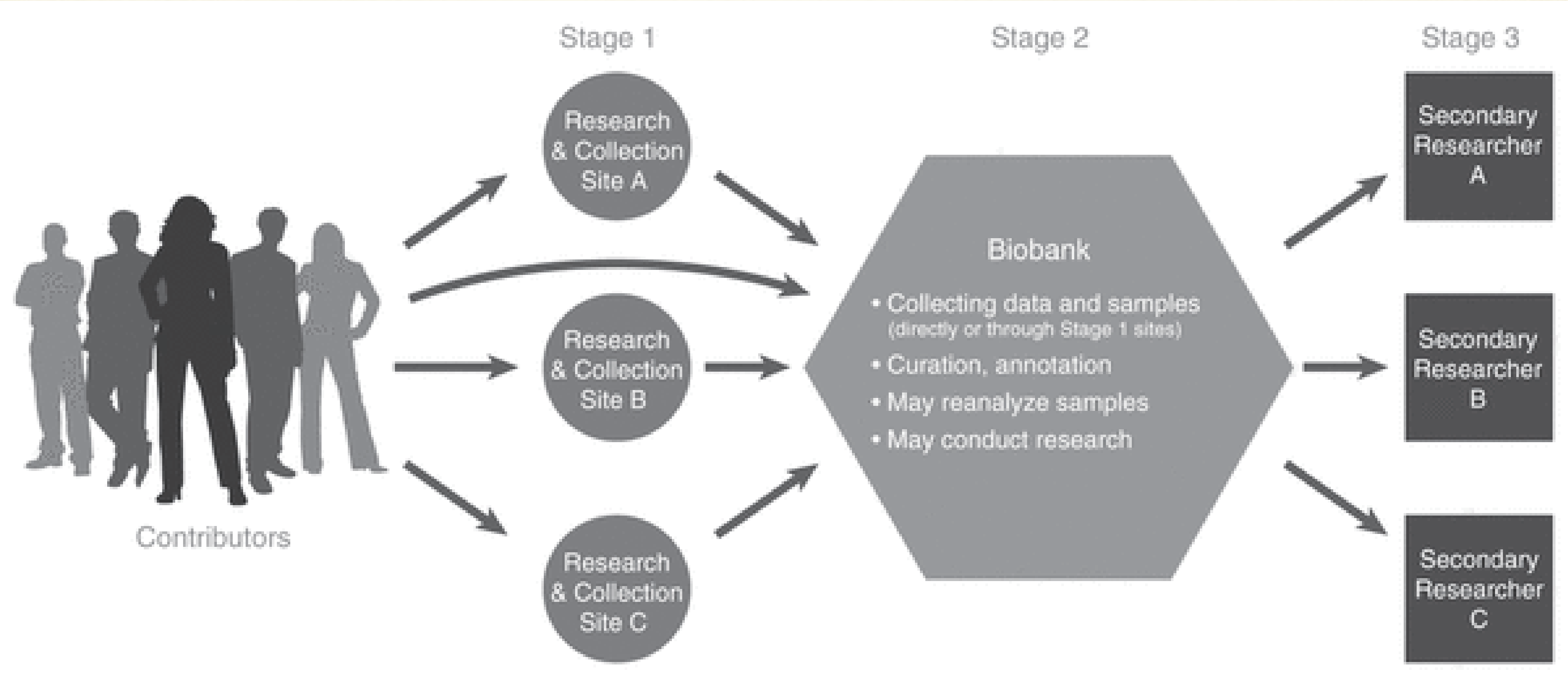
- Provide storage
- Provide access to materials and data more readily (efficiently?)
- Way of maximizing the research potential (of samples and associated data)
- “a key resource in unraveling the association between genetic background, life style and environmental risk factors for various diseases and phenotypes” (BBMRI)
- Biobanking is more than just one piece of this infrastructure: It is the critical platform for achieving convergence, interoperability, and integration of research developed in different centers and across various fields of basic, epidemiological, and translational research. (Hewitt et al. 2011)

Sharing

Is not just for kindergarten

Sharing Samples & Data

- Biobanks, to a great extent are about “sharing” , distributing, giving access to samples
- Yet….
- Sharing is not optimized for biobanking in general

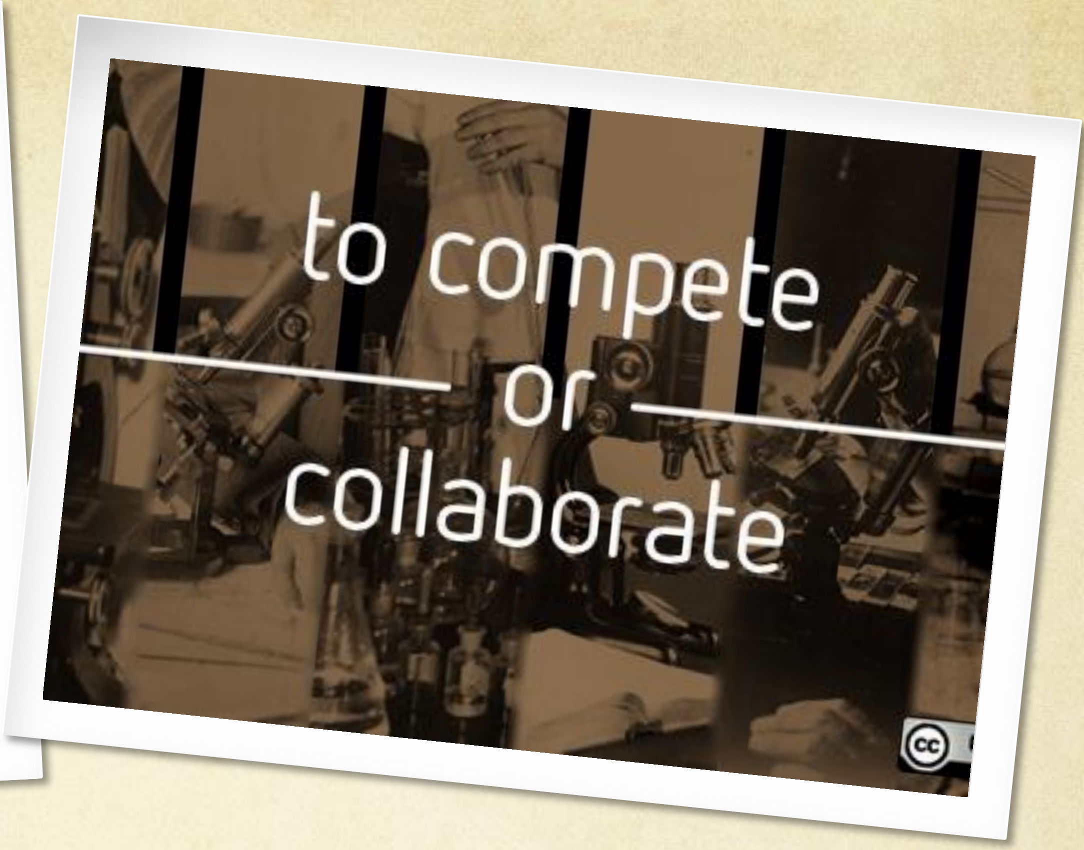


Wolf et al. Genet Med
2012:14(4):361–384

SHIPPING WITH DRY ICE

Requirements For Shipping Non-Hazardous Materials in a Package Containing Dry Ice by AIR

2011



Barriers to Sharing Project

Based on work done in Basel (UNIBAS) & Toulouse (INSERM)
with Dr. Flora Colledge

MARIE CURIE ACTIONS

Barriers to Sharing Project

AIM: identify **barriers** **& solutions** to sharing samples and data in biobanking

① **Literature review**: list of 17 barriers

① **Stakeholder interviews**: +40, Switzerland, Sweden, France, Netherlands
  ① Confusion or ignorance of researchers re: consent and/or ethics review
  ② **Lack of Will to share/territoriality**
  ③ **Recognition/authorship**

② Survey : B.R.I.F

Lit review list

NB: articles were included if they explicitly addressed barriers to sample sharing with or without data, in biobanking.

Barriers to Sharing samples and data in biobanking

Barrier	
standard operating procedures (SOPs) (8)	whole process of sample acquisition, sample processing and preservation as well as storage and retrieval
Legal issues (10)	national or international laws that affect directly or indirectly sharing. **The divergence of regulations on the uses, storage, transfer and nature of tissues and data** is repeatedly mentioned as an obstacle to international collaboration.
Intellectual property & patents (6)	When a patent or claim of intellectual property is anticipated on some work deriving from banked samples, access to those samples may be restricted, at least for a set time period.[31]
Governance (4)	systems, procedures and documents which regulate the banks' activity, and to the people who oversee this sphere
Informed consent (4)	

Barriers to Sharing samples and data in biobanking

Barrier	
Territoriality (3)	unwillingness to share data or samples; this can also be described as wanting to keep samples and data exclusively for one's own research
(lack of) networks (3)	Lack of networks = lack of collaboration & thus harmonisation
availability (3)	existence of a useable number of samples in a bank
Fees/financial issues(2)	Cost of sharing samples and data
Confidentiality (2)	ability to **transfer sample data while** maintaining the **confidentiality** of the donors' information while still providing useful data, is held to be a difficulty particularly in international collaboration

Barriers to Sharing samples and data in biobanking

Barrier	
Journal demands	**Demands by journals** that all data from published research should be made public may be considered a confidentiality risk for some types of biobanks, and hence stop them from sharing any part of their data at all, if they opt to publish through a different journal which does not require data disclosure.
Commercialization(2)	biobanks may be prevented from making their samples available, at least to certain groups, or researchers may likewise be prohibited from storing their samples in banks with an open sharing policy, due to the conditions of funding they receive from private biotechnological companies.
Nomenclature (2)	-Different nomenclature may limit sharing Change in nomenclature in time -Pearson (2004) also points out that medical histories which accompany samples are useless if those from different institutions use different words.

Barriers to Sharing samples and data in biobanking

Barrier	
Publication credit (1)	access to samples might be conditional on publication credit.[37]
awareness of existence (1)	Do people know the bbk exists? And, that they could use it and/or donate to it?
Prioritization (1)	to the weight the biobank assigns to competing research projects (i.e. those which seek to use the same samples simultaneously).
Recognition (1)	Indirect, biobanks which are not properly credited or recognised for their work in establishing and maintaining their samples will not receive the public recognition that they need to keep attracting researchers,

Interview Results

1- confusion of requirements
2- territoriality
3- recognition

1- General Confusion or ignorance as to requirements re: consent or ethics review

- Found in both samples of interviews
- Confusion about which consent is needed, which are compatible,
- Confusion about ethics review for single projects

“I was in a meeting in which 20 biobanks were present. Like half of them were not aware that they were supposed to submit to an ethical committee the single project. Or that they should ask the researcher that were submitting our request to them for getting material to make sure that this researcher has an ethical approval. They say, “No, but we have already ethical approval to collect the samples. Yes but.”

Confusion supported by lack of time and guidance

"… like for researchers they really never have time and knowledge to deal with the bureaucracy that is behind … (biobanking or research). This is hampering their research. They have no ideas where to get MTAs, how to do it."

Solutions?

- Better collaboration between ethics committees, and ethics centres and research groups
- Universities finance & offer ethics service and education for researchers

2- territoriality/défense de son térritoire

- ter·ri·to·ri·al·i·ty \-ˌtȯr-ē-ˈa-lə-tē\. : the behavior of animals or people that try to keep others away from an area that they use or control.

- Will of researcher to share/la volonté du chercheur de partager

- Found in both sets of interviews

- “my expereince, the biggest barrier is the will of the researcher.” … “in the sense that everyone in (location x) is very concerned about keeping their collection for themselves, and very often … things such as privacy laws and so on are used as excuses.”

Not new or specific to biobaking

Savage & Vickers looked at different disciplines: reasons to withhold datasets include concerns about:

  - Privacy
  - future publishing oppportunities
  - Wanting to retain exclusive rights to data that took many years to produce

- Sharing or not depends on the point in time the request is made WRT publishing (eg: before or after)
- Campbell et al. suggest with holding may be more common in Genetics… why??
  - Geophysics, biodiversity and astronomy do better

Solutions?

- Very difficult as the culture of biomedical culture is based on competition and we “chose for” those who are most successful at competing
- Culture change could be done through early education of next generation of researchers… but will talk be enough?

3- Barrier: lack of recognition

- Found in both samples,

“Yes. I think they were really related to the first point I was mentioning, so the will of the researchers really. The fact that there is no system in place yet to ensure the recognition of the biobank. If you know there is no acknowledgement in the publication, or something like that.”

Solution? Or further problem

Solution Recognition: Authorship as a motivating factor to share ((Colledge et al. PLOS, 2013 “Conferring Authorship”: Biobank Stakeholders’ Experiences with Publication Credit in Collaborative Research)

- **Majority of interviewees felt it was an incentive**
- **Why?**
  - **Form of payment/compensation “**“Authorship is a kind of payment.”
  - **Prestige of good journals “**“…there’s another opportunity to put your laboratory in a bigger paper that will make *Nature* again, then you share the samples.”
  - **Important for careers (eg to get funding) and institutions Visibility (even for non academic biobanks)**
  - **“**“…people … wanted to be recognized for the work they are doing ... And recognition in university, is authorship.”
- Smaller group claim authorship is not main motivator

Problems with attributing authorship as incentive

- may not meet international rules of authorship (International Committee of Medical Journal Editors (ICMJE))
  - “substantial contribution” to the conception, analysis or obtainment of the material,
  - the drafting or revision of the manuscript,
  - *and* approval of the final version.

- “normal” disagreements over authorship
- Some disagree that offering samples is not academic work

“Absolutely no. Absolutely no. This is … so … underestimated, our effort. So you need a lot, a lot of time, manpower also.”

problems

- The interpretation of the rules differs
- Justice? The line between who can be an author and who may not be an author may be very subjectively decided (eg: based on number of samples provided)

“Now this is not always easy, because some senders they give me fifteen patients, others they give me one patient, and then each one of them wants to be recognized, because, someone gave me one patient, four clinicians were involved in that or whatever, and the sender that gave me fifteen patients gives me only two clinicians, so how do I keep … a sense of justice?”

Solution?

- Beyond authorship, BRIF!
- Other problems

Conclusion

- Many different barriers exist in biobanking
  - FOCUS of this presentation
  - confusion; better collaboration, education
  - Territoriality; ??? Change the culture??
  - Recognition/authorship; BRIF!

- Different for different biobank types, countries,

- Warning: to find ways of aiding sharing we need to identify specific problems and describe them properly, including the context, in order to find specific solutions
  - Generalization, especially from qualitative data may not always be helpful for all biobanks

Merci!

Flora Colledge (UNIBAS)

Anne Cambon-Thomsen et son équipe! (INSERM)

Emmanuelle Rial-Sebbag (INSERM)

heidi.howard@crb.uu.se