

Biobanken als Regulierungsherausforderung ethische und rechtliche Fragen in der internationalen Diskussion

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- Law is abstract and tries to avoid *sui generis* rules for individual cases □ potential for unfairness / ill-fitting regulation
- Law is (mostly) responsive □ something (innovative technology) has to come along, be poorly regulated and then things will change
- Technologies should (also) be drivers for appropriate regulation

Challenges

- Innovative health technologies regularly challenge ossified societal conceptions
- It takes a while / very long for there to be clarity about a new technology's benefit, which then - in turn - opens the door for more permissive regulation
- In health technologies: this creates a 'valley of tears'; period of time in which a new technology is handicapped by inappropriately prohibitive regulation

- Extreme examples of regulatory responses to new technologies:
 - *First heart Tx in UK*: 1968 – donor (26yo Patrick Ryan); non-heart-beating donation by law (otherwise homicide offence) □ development of rules on brain (stem) death in UK (1968 Harvard Ad Hoc Cttee, 1976 Royal Medical Colleges)
 - *Development of anaesthesia*: “Whosoever shall unlawfully apply (...) Chloroform, Laudanum, or any other stupefying or overpowering drug (...) shall be kept in Penal Servitude for life (...)” (s 22 OAPA 1861)

- Biobanks, as manifestation of new technologies / methodologies, present new challenges to regulation
- Biobanks also promise to be the method of choice to answer many pressing health research questions
- Work with material and data of individuals *prima facie* requirement of full, informed consent (based on abstract rules re self determination, etc)

Biobanks and informed consent

- This is sometimes unproblematic:
 - Procurement (?);
 - Processing;
 - Storage, destruction.
- But becomes problematic later:
 - Data sharing;
 - Material sharing;
 - Secondary *use*.

- Material and data procured for an unknown later purpose challenges regulation on basis of feasibility of obtaining *sufficiently informed* consent:
 - *Procurement*: existing collections, surgical waste, diagnostic surplus, deceased patients, ...
 - *Secondary use*: unknown research use, informed consent only extends to procurement, storage, etc
technically, material and data not available for secondary use

- *This means:*
The current paradigm of informed consent as the gold standard in interacting with patients and research participants, if followed to the letter, prevents biobanking or makes biobanking disproportionately costly.
- *Resulting in:*
 - Forget biobanking and do something else; *or*
 - Sometimes work without informed consent in biobanking.

Changes in perception: consent

- For the avoidance of doubt: consent is vital
- *Informed* consent is a standard of consent designed to give maximum protection to individual autonomy
- In its application, informed consent has undergone a metamorphosis in the last 60+ years: *From mechanism to underpin individual autonomy to mechanism to negate liability*
- Liberty (rights) can be limited by individuals to give effect to overriding preferences

- **Continuation** of informed consent, prolongation of ‘valley of tears’: no deviation from standard, IC as immovable benchmark
- **Reconsenting, dynamic consent**: using technology to ensure ongoing contact with participants
- **Broad consent**: ask for permission for a broader range of activities (“medical research, but not X”)
- **Waiver**: ask for irrevocable relinquishing of rights
- **Conscription**: contribution to research is a social/moral duty

Changes again: responses

- We ought to prevent overregulation: *sui generis* rules prevent private arrangements that may be best placed to protect autonomy
- We ought to be mindful of not turning informed consent into a paternalistic device: it is compatible with notions of individual autonomy to enable people to say “I don’t care.”
- We need to see the ‘consent complex’ as, well, complex: there is a cascade of different consents, not one consent; these consents can have different qualities – it’s the mix that counts

Changes again: consent

A cascade of consent quality adequately protects the autonomy of individuals and does not inappropriately tie up resources. It's the consent mix that determines governance:

Step	Consent / rule	Protection	Effect
Procurement	IC, proxy IC, existing collections rules	Unchanged, public	Good biobank governance
Processing
Storage
Destruction / withdrawal	Waiver	Changed, private	More certainty, flexible, less resources
Sharing	Waiver, broad consent	Changed, private	...
Secondary use	Waiver, broad consent	Changed, private	...

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