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Sample and data sharing barriers in biobanking: consent, committees, and compromises☆,☆☆

Flora Colledge, MA [1], Kirsten Persson, MA, MSc *,[1], Bernice Elger, PhD, MD, David Shaw, PhD

Institute for Biomedical Ethics, University of Basel, Basel, Switzerland

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ABSTRACT

The ability to exchange samples and data is crucial for the rapidly growth of biobanking. However, sharing is based on the assumption that the donor has given consent to a given use of her or his sample. Biobanking stakeholders, therefore, must choose 1 of 3 options: obtain general consent enabling multiple future uses before taking a sample from the donor, try to obtain consent again before sharing a previously obtained sample, or look for a legally endorsed way to share a sample without the donor's consent. In this study, we present the results of 36 semistructured qualitative interviews with Swiss biobanking stakeholders regarding these options and the role of ethics committees in the process of authorizing sharing. Our results show that despite a lack of legal or guideline-based barriers to general consent, some stakeholders and ethics committees have reservations about this method of consent. In most cases, however, a general consent form is already in use. Many interviewees describe processes involving the ethics committees as time-consuming and cumbersome and their requirements as too demanding for donors/patients. Greater awareness of donors' opinions and preferences and the content of guidelines and recommendations could therefore be helpful for a better justified perspective of biobanking stakeholders and ethical committee members, equally. Finally, it may be necessary to differentiate between procedures governing future samples, where general consent is clearly desirable, and the use of old yet still relevant samples, where the option of using them without consent can be highly beneficial for research.

1. Introduction

The rapid evolution of the field of biobanking has presented clinicians and researchers with a number of challenges that require different approaches to those faced in research involving human subjects. The potentially huge benefits of accessing samples from large pools, spanning decades, are accompanied by certain difficulties. Stored biosamples must be cleared for use in research projects in line with departmental, national, and international laws and guidelines. The focus of the most stringent of these requirements is the form of consent, which must be obtained before the samples can be made use of.

Owing to the relatively recent developments and wide-ranging applications of biosample research, regulatory documents have emerged at staggered intervals, as international organizations, governments, and institutions seek acceptable solutions to regulating such research [1]. Not surprisingly, the documents produced by these various bodies sometimes contain significantly divergent recommendations on informed consent (IC) [2]. Although some organizations may require a specific consent to be obtained from the sample donor, which covers only one research project, others allow for a general consent to any future use of the sample for research purposes [3]. Within the last few years, attention has been turned to harmonizing the laws regarding the consent requirements for biosamples, in part a reflection of the wide debate in the literature on this topic. Although a number of authors stress the potential risks to donors of giving general consent and suggest that consent to an unknown project is not consent at all [4,5], most articles now call for the widespread implementation of a general consent, so that valuable biosamples can be fully exploited [6–8]. Because a core aspect of the worth of biosample collections is their longevity, it is argued that it makes little sense to effectively impose an expiry date on their use by ruling out the unforeseen research of future years. By the same token, existing sample archives, which may lack general consent from all donors, have also become a focus for medical organizations and governments.

Two options exist for rendering archived material eligible for research: consent can be sought retrospectively (in cases where a limited consent has already been obtained, this is known as "reconsenting") [9], or the requirement to obtain consent can be waived [10]. Seeking consent or reconsent is the responsibility of the

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* Corresponding author. Institute for Biomedical Ethics, Universität Basel, Bernoullistrasse 28, CH-4056 Basel, Switzerland. Tel.: +41 61 267 17 85.

E-mail address: Kirsten.Persson@unibas.ch (K. Persson).

[1] These authors contributed equally.

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researchers and can, particularly in cases where old or poorly catalogued samples are involved, be a time-consuming and complex process. Waivers of consent have therefore become increasingly common; in the absence of laws governing the issue, international and national medical organizations have included this option in their guidelines.

The Declaration of Helsinki (2008) states:

> "[f]or medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee" (§ 25.).

Similarly, the recommendation given by the Council of Europe (Steering Committee on Bioethics) states:

> 1.i. If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent, if any, given by the person concerned, reasonable efforts should be made to contact the person in order to obtain consent to the proposed use.ii. If contacting the person concerned is not possible with reasonable efforts, these biological materials should only be used in the research project subject to independent evaluation…"

Finally, although it does not address waivers, the Swiss Academy for Medical Sciences (Schweizerische Akademie der Medizinischen Wissenschaften) recommends general consent in their guidelines on biobanking: "Consent can generally also cover the further use of the samples and data for future research projects (general consent). Restriction of their use to one specific field of research is possible."[2]

The confirmation that all these conditions are fulfilled is the responsibility of the local ethics committee. Thus, researchers must ensure that they have satisfied the committee on all points regarding consent (or the lack of it) before their research can proceed. However, as noted above, the guidelines upon which these committees must base their assessments are evolving and occasionally contradictory; they are also a significant departure from the traditional specific consent requirements for research on human subjects. The extent to which ethics committees influence IC requirements has so far been only sparsely addressed in the literature, yet it is during committee meetings that the debate concerning consent has a tangible impact upon research. We asked a group of biobank stakeholders working in Switzerland to discuss their experiences with consent for biosamples and the ethics approval process. In doing so, we aimed to identify any difficulties in the process that might negatively affect research [11].

2. Methods

We conducted 36 semistructured interviews with key stakeholders in Swiss biobanks (researchers, clinicians, pathologists, lawyers, ethicists, and biobank managers). For a more detailed description of the methods, see Shaw et al [11] (forthcoming).

3. Results

Most of the interviewees identified IC as an important part of their work: most persons mentioned the topic, although they were not explicitly asked about it in many cases. This awareness reflects the enormous number of publications and the broad academic debate about IC in the medical field.

One focus of the presented findings here will be on difficulties regarding samples that had been stored without explicit consent and interaction with ethics committees, which have, among other things, the power to approve the use of samples without (re-)consent.

3.1. Types of consent

Biobanking stakeholders provided several justifications for the type of consent used in their institutes. A majority prefer a general consent because it means flexibility for future projects:

> "I13: […] our informed consent, […] they are very general, […] and based on this we can use these samples for whatever projects […]""I24: […] they gave consent to use it for other projects, except for any germ line analysis. And I could use it for other, I could give it on, and it had to be anonymised[…]""I31: […] the broad consent is actually a good way Switzerland is going, I would say. […]"

Another participant emphasizes the advantage of having an optional general consent on top of the project-specific IC for a clinical study. That way, it is up to the patient to whether to agree to a specific or a general consent:

> "I28: […] we ask that they provide the material for just the basic pathology department assessment review that's part of the clinical trial, but that we then have, like an additional question that they can mark yes to, or no, whether they would agree for this to be held back, banked for yet unknown translational research or so."

The specific IC, in contrast to general consent, is described as an important limitation to data sharing by 2 interviewees:

> "I21: […] it's more tricky thing, because we are bound by ICHGCP, and […] be quite clear what the samples could be used for and where they would go etc., so unless you thought about it in advance, it's difficult to share samples""I31: I think this is important basis for having decent sharing where we work now, is informed consent. […] project specific informed consent, then we don't need to talk about biobanks if we have this, because then we do […] our little own projects, and that's it[…]"

However, if the patients cannot precisely be informed about the future use of the sample they donate, there might be reasons for them not to sign a consent form. More explicitly, interviewee 21 earlier explained:

> "[…] if you want to have high collection rates in a clinical trial, you have to have narrow consents. […] if you want to go broad, […] you reduce the number of patients who would sign up for that"

3.2. The ethics committee

Ethics committees appear to play a crucial role in imposing limitations on biobanking and sample sharing. A particular reluctance is described by some persons when it comes to the approval of general consent:

> "I3: Yes, it was a broad consent, and […] it was long discussions about this, also how[…] valid is it for[…] the genetic analysis, but the ethical committees decided we don't have to go back to it […]"

The IC requirements imposed by ethics committees present a challenge as described by this interviewee:

> "I12: […] we have to… send out forms, four five six pages long, just to get a consent of the patient. So why not say, dear patient,

[2] http://www.samw.ch/dms/de/Ethik/RL/AG/Biobanken_D_06.pdf.