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Current Perspective

Enlisting the willing: A study of healthcare professional–initiated and opt-in biobanking consent reveals improvement opportunities throughout the registration process

Elizabeth A. Fradgley [a,b,*,1], Shu Er Chong [c,1], Martine E. Cox [b], Christine L. Paul [a,b,1], Craig Gedye [c,d,1]

[a] *Priority Research Centre for Cancer Research, Innovation and Translation, University of Newcastle, Callaghan, NSW, Australia*
[b] *School of Medicine and Public Health, University of Newcastle, Callaghan, NSW, Australia*
[c] *Department of Medical Oncology, Calvary Mater Newcastle, Waratah, NSW, Australia*
[d] *School of Biomedical Sciences and Pharmacy, University of Newcastle, Callaghan, NSW, Australia*

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Abstract Biobanking consent processes should accord with patients' preferences and be offered in a consistent and systematic manner. However, these aims can be difficult to achieve under healthcare professionals' (HCPs) time-constrained workflows, resulting in low participation rates.

This current perspective provides a brief overview of HCP involvement in consent and reports new data on participant attrition at each step of the biobanking consent process as experienced by 113 patients at an Australian tertiary cancer centre. To determine attrition in this HCP-driven consent process, we reviewed medical records for the following events: inclusion of biobanking consent forms; visible patient and HCP signatures; consent status selected (decline or accept) and specimen registration with local biobank. Accessible medical records revealed the following data: 75 of 85 records included viewable forms; 22 of 85 records included patient and 19 of 85 included HCP signatures; 15 of 85 records included signed and completed forms and 3 of 85 had samples banked with annotated clinical data. We compared these data with self-reported experiences of being approached to participate by HCPs. Of the 15 participants (17.6%) who successfully completed consent, only five could recall being asked and providing consent.

* *Corresponding author:* Level 4 West, HMRI Building, University of Newcastle, Callaghan, NSW, 2308, Australia.
E-mail address: Elizabeth.fradgley@newcastle.edu.au (E.A. Fradgley).
[1] Equal contribution.

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The low enrolment rate is a considerable lost opportunity because most patients (59%) who were not asked to participate indicated they would have consented if asked. Furthermore, in comparing self-reported experiences with medical records, we believe cancer patients' preferences for participation are mismatched with actual biobanking enrolment, which has considerable attrition at each step in the consent process.

1. Introduction to healthcare professionals' involvement in biobanking consent processes

The advent of personalised medicine has increased the value of biospecimens, particularly those with annotated clinical data. Institutional biobanks are under increasing pressure to maximise the systematic and efficient capture of high-quality biospecimens and support biomedical research efforts by providing timely and cost-effective access to a wide range of specimens [1,2]. Although the rate of biobanking participation is proposed as a key performance indicator [3], the proportion of Australian cancer patients donating tissue at the time of surgery is poorly reported. However, there is consensus that most patients are not participating in biobanking [4], despite many cross-sectional surveys reporting that high proportions of patients are hypothetically willing to donate biospecimens for research [4–7].

Low participation rates may be a result of many factors including limited funding to support biobanking infrastructure within health services or poor integration of recruitment approaches into workflow processes. In this respect, one of the key checkpoints for biobanking under an opt-in model is ensuring that all patients who might be eligible are approached for consent. Australian legislation currently defaults to an opt-in consent system which is typically led and coordinated by healthcare professionals (HCPs), except in well-resourced areas which may have an embedded biobank officer. HCPs such as physicians and surgeons have become *de facto* gatekeepers to the biobanking process and are by default being delegated a vital role in consulting with patients about participation and providing sufficient detail to satisfy informed consent requirements [8]. However, there is support for alternative consent processes which may minimise HCP involvement such as opt-out models with blanket consent if best-practice conditions are met such as minimal threshold opportunities to register objection and knowledgeable staff in the event of potential participants' questions or concerns [9–16].

The burden of different consent models must be considered in the context of workloads of HCPs, particularly as the process can take up to 30 minutes [5]. Within Australia, the concept of embedding consent into routine workflows has been evaluated from HCP perspectives [17,18]. Survey data from 95 HCPs found that although 87% agreed or strongly agreed that cancer biobanks are beneficial, the majority did not believe or questioned if they had the time to be involved [18]. Qualitative work found there were inadequate resources or support provided in which to encourage the ongoing role of recruitment as perceived by HCPs [17]. Unfortunately, HCPs also viewed their role in this workflow as providing little tangible personal benefit, suggesting there is potential to lead to disengagement and resistance to further involvement [17]. With perceived lack of support along with consistent reports of considerable paperwork [19,20], it is understandable that administrative activities that are not directly related to patient outcomes are deprioritised. Overall, the success of biobanking under an HCP-led model will be dependent on how well the consent process operates within existing workflows [21].

From an organisational perspective, to ensure that all eligible individuals are enabled to participate, consent processes would be seamlessly integrated into routine healthcare workflow. However, previous research suggests HCPs are overlooked as key facilitators in the biobanking process [8,17,18]. In particular, it is unknown how often HCPs discuss biobanking participation with their patients and if these discussions could translate into successful biospecimen registration. Information which describes how consent processes occur within workflow processes may help to determine if rate-limiting steps (RLSs) occur at the patient–HCP discussion, consent or enrolment stages.

2. Data exploring the rate-limiting steps in an opt-in, HCP-led consent model

We sought to identify the RLSs in an opt-in biobanking consent process coordinated by the HCPs. We evaluated the outcomes of this process by examining if patients who indicated willingness to participate in biobanking were approached to donate and had biospecimens successfully registered with annotated clinical data. Consent for biobanking in the local health district is assigned by default to surgical team members as part of consent for surgical procedures; consent is provided using a standard, paper-copy Health Consent for Treatment form that includes biobanking information and options. Medical records, including the consent form, are scanned

into a digital medical record by administrative staff and maintained under patients' unique identifiers. For the sample to be registered with the biobank with annotated clinical data via medical record access, the consent form must be accessible, signed by a physician (registrar level or above) and with the patient consent to donate option being clearly selected. If these steps are not satisfied, any tissue specimens will be stored under waiver—in de-identified form and with access restricted to specific purposes pending further ethical approval [4,9,10]. Without access to individuals' medical history or longitudinal outcomes, the utility of biospecimens collected under a waiver system is limited.

A cross-sectional patient survey and medical record review was conducted in a large tertiary oncology centre located in New South Wales, Australia. Eligible individuals were as follows: English-speaking, 18 years or older, receiving adjuvant chemotherapy and had a confirmed cancer diagnosis for which they underwent surgery from March 2014 to the time of recruitment. Consenting individuals completed study-specific touchscreen surveys and allowed access to their medical records. The following data were extracted from participants' medical records: date and location of surgery; surgeon name; inclusion of a biobanking consent form; completion of this consent form, including visible patient and HCP signatures as well as the selection of consent option (decline or accept) and specimen identification number to confirm if the samples were registered in the local biobank. Medical records were available for participants who were admitted for surgery in the region's public-funded hospitals. Records were unavailable for a small subgroup of survey respondents who were admitted to either a private hospital or a hospital outside of the region. The Hunter New England Human Research Ethics Committee approved this project.

A total of 116 eligible participants were approached to participate, of whom 114 consented (98.3%) and 113 completed (99.1%) surveys. Respondents' demographic characteristics are available in Table 1. Complete medical records for the occasion of surgery were accessible for 85 of 113 (75.2%) survey respondents. A total of 33 surgeons were represented from three health services. One surgeon performed 12 of the procedures in the study sample; 16 surgeons performed only one procedure.

Table 1
Survey respondents' demographic and clinical characteristics (n = 113).

Characteristic	Participants (%)
Age range	
18–49	27 (23.9)
50–64	37 (32.7)
65+	49 (43.4)
Gender	
Female	81 (71.7)
Male	32 (28.3)
Cancer type	
Breast	48 (42.5)
Gastrointestinal	48 (42.5)
Lung	12 (10.6)
Ovarian	5 (4.4)
Speaks a language other than English at home	9 (8.0)
Of Aboriginal and/or Torres Strait Islander origin	2 (1.8)
Identifies as belonging to a religious group	
No	64 (56.6)
Yes	49 (43.4)
Highest level of education attained	
High school or Year 10 completion	78 (69.0)
Post-secondary or technical qualification	35 (31.0)
Preference for involvement in treatment decisions	
Patient decides after hearing the advice of the HCP	30 (26.6)
It is a shared decision with the HCP	67 (59.3)
It is mainly the decision of the HCP	16 (14.2)
Accesses the internet for medical information	
Yes	60 (53.1)
No	53 (46.9)

HCP, healthcare professional.

2.1. Deconstructing the consent process and patient experiences

The total number of individuals who did not complete the consenting process was 70 of 85 (82.4%). Fig. 1 demonstrates the attrition rates between each step (i.e. the number of patients at each step and the proportion decrease between the steps).

Upload consent form in record: Of the 85 accessible records, only 75 records contained a viewable consent form. Of the 10 individuals who did not have a viewable surgical consent form, one survey respondent indicated that they had discussed and consented to the biobank.

Sign consent form, patient and HCP: A total of 53 records contained forms without patient signatures—this is a large attrition rate accounting for 71% of potential biobank participants missed. Of the 22 records that did contain patient signatures, three were missing the HCP signature. Of the 53 unsigned patient consent forms, seven survey respondents reported that they had discussed and consented to the biobank.

Select a consent option: A total of seven records (8.2%) contained an incomplete but signed consent form—that is, the individual did not select a consent option. Two of these forms were also signed by an HCP. Of these seven signed but incomplete consent forms, four survey respondents indicated that they had discussed and consented to the biobank. No participant declined to donate biospecimens.

Register biospecimen with the biobank: The total number of individuals who successfully completed the consenting process was 15 (17.6%). Of these 15 individuals, only five survey respondents reported they had discussed and consented to a biobank; six indicated

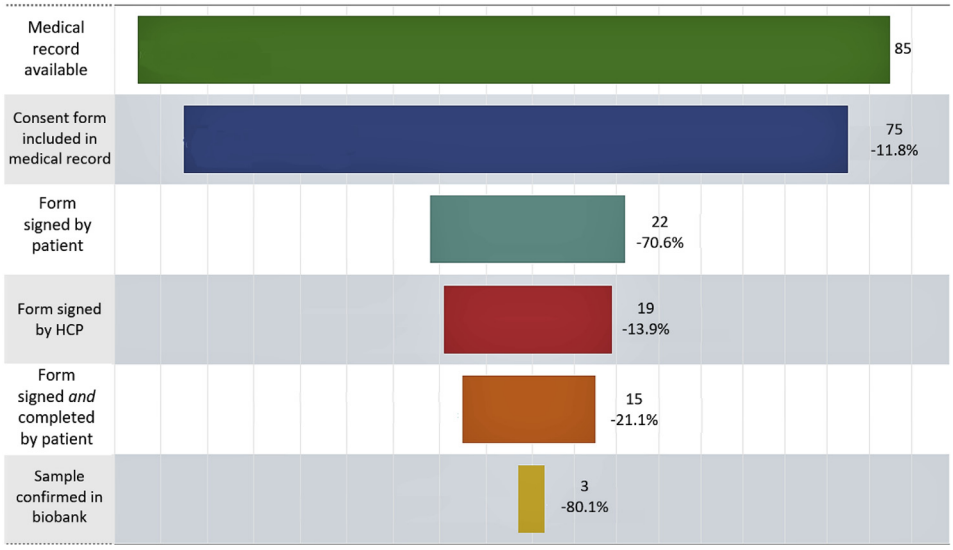

Fig. 1. Number of patients completing each consent step and the relative proportion of participants lost between each subsequent step. HCP, healthcare professional.

that they were not asked before surgery and four individuals could not recall having this discussion or providing consent. Only three individuals (3.5%) had a sample with annotated clinical data registered in the local biobank.

2.2. The lost opportunities resulting from the opt-in, HCP-initiated consent model

The survey also captured patients' willingness to participate and decisional regret if their indicated consent was given. The majority of participants (59.3%) indicated that they were not asked to participate but would have consented. Furthermore, of the 33 individuals (29.2%) who reported they were asked to participate, all indicated that they provided consent and did not regret this decision. A small proportion of respondents (11.5%) indicated that they were not asked to participate and were unsure if they would have consented.

3. Summary of the rate-limiting steps and patient recall of consent process

There were several RLSs in the consenting process which led to a low proportion of participants successfully completing the consent process. In the 75 records with a viewable form, the majority of patients (70.6%, 53/75) did not sign the form, with a minority signing the form but not selecting a consent option (9.3%, 7/75). Collectively, these two steps represent a total of 60 possible biobanking participants, whereby either the form was not presented to the patient and they were not provided the opportunity to participate or there was little guidance provided on how to complete the form. Although the signature step was responsible for the largest number of potential participants lost (53 individuals) and the second highest percentage attrition between steps (−70.6%), the greatest percentage of attrition was observed at the specimen registration phase (-80.6%), suggesting that there are also structural barriers within the process.

3.1. Recalling consent to biobank

Overall, there was clear discrepancy between self-reported experiences and the medical record data; for example, only 5 of the 15 individuals who indicated consent to participate had completed a form. Furthermore, 6 of the 50 who indicated that they had not been asked but would have liked to participate had completed forms. This finding of poor recall is consistent with a cross-sectional survey of 574 French cancer patients who had been approached to participate under a similar opt-in consent model [22]. In this study, of the 213 patients who indicated that they had provided consent, only 131 (62%) had consent registered, and of the 143 patients who declared that they had not received, completed, or had declined via a consent form, 45 (31.5%) had indeed completed and signed a form. This discrepancy highlights the need to improve the consent process, particularly because it is unclear whether patients are indeed informed participants if it is difficult to recall their decision.

3.2. Streamlining the consent process

Participation rates under an HCP-led opt-in model were low within this study. As many biobanks do not recover the costs of collating and preserving specimens and in light of reduced government funding for

biobanking, recruitment methods need to be streamlined while ensuring informed consent is obtained and clearly documented [4]. With many experts concluding that patients and the general public are willing to participate in biobanking [9–15], an opt-out model should be considered because it reduces the burden placed on both patients and HCPs. Within this study, support for an opt-out model is evidenced by none of the participants declining to provide consent and an opt-out model would address many of the RLSs observed within this study. Similar health service research and policy studies support alternative consent processes which may minimise HCP involvement, such as opt-out models with blanket consent, if best-practice conditions are met such as a minimal threshold opportunities to register objection and knowledgeable staff in the event of potential participants' questions or concerns [9–16].

4. Limitations

The study results are inclusive of 33 HCPs across three health services, thus providing a snapshot of practices across different HCPs. However, the results may not be generalisable to other health services. Furthermore, 16 HCPs were represented only once within the data set and additional cases to confirm the consistency of their consent practices and if they enrolled patients independent of demographic characteristics would be valuable. This current perspective did not examine differences in the characteristics of the patients who completed each step of the consent process—it is possible that HCPs perceive a greater literacy or education level that is required to successfully complete the consent form and therefore, approach only specific subgroups of patients to participate. It should also be noted that the last step in the biobanking workflow contains a number of sub-steps involving the sample collection during surgery, preparation and storage of the sample, which were not able to be separately examined. It is also important to consider that our finding of low registration may be a result of many of the biospecimens not being of sufficient quality. However, discussion with the biobank technical staff and supervising pathologists indicates that in the vast majority of situations an additional specimen for unspecified future research can be saved after diagnostic specimens are selected.

5. Conclusions

Owing to poor reproducibility of the informed consent procedures under a *de facto* HCP-led, opt-in model, many patients were either not approached to participate or were unable to correctly complete the consent process. This very low proportion of patients approached and enrolled into biobanking, in contrasts to the high individual and public acceptance of the process, represents an actionable opportunity to increase engagement of patients in cancer research to provide research programs with the needed materials to advance cancer treatments and knowledge. Both patients and HCPs urgently need new models of consent to augment biobanking initiatives.

Conflict of interest statement

None declared.

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