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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

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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.

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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