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# Examining diversity in public willingness to participate in offshore human biobanking: An Australian mixed methods study

## 1. Introduction

Over the past two decades, there has been increasing use of biobanks (also known as tissue banks, biorepositories or tissue repositories) to facilitate research into the aetiology and pathogenesis of human disease, and the development of more effective diagnostic tools, treatments and preventative mechanisms. In order to maximise scientific utility, biobanks must recruit large numbers of participants to obtain sufficient diversity and statistical power. Scientific necessities, as well as the need for economic efficiency, have driven the development of formal and informal biobank networks nationally and internationally. As a result, samples and data now travel routinely across the globe (Dive, Mason, Light, Kerridge and Lipworth, 2017).

Biobank networks—particularly those that cross jurisdictions—intensify and add to the existing ethical, legal, social issues (ELSI) and practical challenges experienced by non-networked biobanks. ELSI challenges associated with obtaining meaningful consent, privacy protection, commercialisation, benefit sharing and return of incidental findings become more complex as the size, diversity and locations of networks increase, as do the practical challenges of harmonising governance mechanisms, standardising scientific and technical procedures, and resolving funding and intellectual property arrangements (Dive et al., 2017; Lipworth and Kerridge, 2015; Minssen, Rothmar, Jens and Jens, 2019).

If biobanks are to recruit sufficient numbers of participants, patients and the public must believe that there is merit in donating, and trust that the biobank will act responsibly and ethically. It has been suggested that fear of losing control and risks to privacy are amplified when samples are sent offshore to often unknown destinations and regulatory environments,

whereas support is assumed to be driven by an altruistic desire to help others (Dive et al., 2017). However, no research has explicitly examined the reasons underlying willingness to donate to an international biobank network, and why certain members of the public are willing to participate, while others are not.

Research suggests that willingness to participate in biobanking is high in Australia (Critchley, Nicol, Otlowski and Stranger, 2010; Critchley, Nicol, and McWhirter, 2017) and internationally (van Zon, Scholtens, Rejneveid et al., 2016), but is dependent on trust in the biobank, its staff and regulatory mechanisms (Critchley et al., 2010; Ahram, Othman, Shahroui, and Mustafa, 2014). This trust may be compromised, however, if data or samples are shared or stored offshore and subject to different standards. Willingness to participate may diminish due to increased concern (relative to local biobanks) about privacy breaches, lack of control over how data is used and reduced access to benefits (Nanibaa, Sathe, Antommaria, et al., 2016; Shabani, Bezuidenhout, and Borry, 2014).

Despite the risks, we know very little about how different publics perceive the issues associated with the international networking of biobanks, and what the impact may be on their willingness to donate. The data that does exist primarily relates to only genetic data sharing, and is inconsistent. Some studies reveal a reluctance to share with researchers outside their countries (US and Finland) (Majumder, Cook-Deegan, and McGuire, 2016; Kaufman, Baker, Milner, Devaney, et al., 2016; Tupasela, Sihvo, Snell, Jallinoja, et al., 2010), while other publics are supportive (Australia, Jordan and Canada) (Ahram, et al., 2014; Critchley et al., 2015; Joly, Dalpé, So and Birko, 2015).

The aim of this mixed methods study was to examine the impact of location on willingness to participate in various aspects of biobank research (i.e., tissue sharing, storage, usage). Importantly, we also attempted to uncover the extent to which willingness is driven by increased concerns about privacy and/or beliefs about who should primarily benefit

(Australians or foreigners), and whether distinct publics may vary in terms of their preparedness to donate tissue under different conditions. Finally, in depth qualitative interviews were utilised to validate the quantitative findings and explore additional issues that influence willingness to participate.

## **2. Methods**

### **Survey participants and procedure**

A total of 750 Australians over the age of 18 years who could speak English participated in a Computer Assisted Telephone Interview (CATI) survey which ran for three weeks in November 2017. Telephone numbers (61.3% mobile, 38.7% landline) were randomly generated and validated, and represented the proportion of residents residing in each Australian State and Territory. The margin of error was 3.5% at the 95% confidence interval where responses are assumed to be evenly split (i.e., 50%), and response rates according to the American Association of Public Opinion Research (AAPOR)'s (2009) definitions and calculations (i.e., RR1 – RR4) ranged from 6.0% - 9.0% with a cooperation rate of between 13.8% - 15.4%. The sample was representative of the Australian population in relation to state and territory, gender (52.4% female) and employment status, but was overrepresented by older people ( $M = 50.85$ ,  $SD = 18.01$ ,  $Range = 18 - 91$ ) and those with a university education (48.3%). A total of 82.1% described their ethnicity as Australian, and 26.4% indicated that they “know enough about medical research involving biobanks?”.

Sixteen participants were purposively sampled from survey respondents who consented to a further qualitative interview ( $n = 623$ ). To ensure a range of perspectives were included, participants were randomly selected from four groups until 4 in each group were obtained. The groups were younger ( $<$  the median age of 53) and older ( $\geq 53$ ) participants who had either responded “yes” ( $n = 336$ ) or “no” ( $n = 95$ ) to donating to, and allowing their coded, anonymous and identified samples to be stored by a biobank located overseas. Ethics

approval for the CATI survey and interviews was granted by Swinburne University and The University of Sydney human research ethics committees.

### **Survey measures**

The measures used in this research were derived from a larger and newly developed survey (by scale development and content experts) consisting of 48 forced choice questions designed to compare 10 topics across Australian and international biobanks. The findings reported are those directly relating to overall willingness to donate, identification of samples, and beliefs about the distribution of benefits. The response options for all questions were “Yes”, “No” and “Unsure” (see S1 in supplemental material for the survey script).

### **Willingness to participate**

All respondents were read a definition of biobanks before being asked whether they would consider donating their tissue under 4 different conditions. The conditions were:

1. A biobank that was located entirely within Australia and used only by Australian researchers
2. An Australian biobank that allows its samples to be used by researchers located overseas
3. An Australian biobank that sent some of its samples to be stored in a biobank overseas
4. A biobank located overseas (i.e. a bank that is located entirely overseas and used by researchers located overseas)”

### **Identifiability**

Six questions were designed to assess respondents’ willingness to allow coded, anonymous and identifiable samples to be stored and used by Australian and foreign biobanks. Degrees of anonymity were defined to respondents before being asked two questions (for each degree of anonymity), “Would you be willing to have a coded/anonymous/identifiable sample stored and used by an Australian biobank”, and, “Would you be willing to have a

coded/anonymous/identifiable sample used and stored by biobank researchers located overseas.

### **Benefit sharing**

The desire for shared benefits that may arise from biobank research was assessed by asking “Do you think that the majority of benefits coming from Australian biobanks should go to Australians?”; and “Would you want benefits from research using samples from an Australian biobank to go to people from other countries?”.

### **Qualitative interviews**

A semi-structured interview schedule was designed to gain a comprehensive and nuanced understanding of the reasons why participants were willing or unwilling to donate to local and international biobank networks. It was developed in consultation with expert members of the research team and was designed to elicit participants’ views associated with donating to, and allowing Australian and overseas biobanks to store their tissue samples. Participants were prompted to reflect on their reasons for being willing or unwilling to donate across different situations (see S2 in supplemental material for the interview script and S3 for the analysis strategy).

### **Statistical analyses**

A segmentation/ latent class analysis (LCA) using Mplus Version 7.1 was utilised to detect the existence of distinct publics who may vary in terms of their preparedness to donate tissue under different conditions, and to highlight any impact of identification of samples and type of biobank activity. The analysis consisted of the four willingness to participate and six identification questions. Sequential logistic regression analyses using SPSS Version 25 were employed to examine whether beliefs about the distribution of benefits in combination with the demographic variables significantly predicted class membership.

### **3. Results**

The majority of participants (>90%) were willing to donate tissue to an Australian biobank that was used by Australian researchers and to have it stored in an Australian biobank if it were anonymous (see Table 1). Willingness decreased, however, as the biobank became increasingly international, either in terms of its location or access by non-Australian researchers. It did not seem to matter to participants whether a biobank located in Australia allows access to international researchers or sends some of its samples overseas. However, willingness dropped considerably when the biobank was located overseas.

In relation to identification, a small drop in willingness to donate tissue occurred when an Australian biobank used coded compared to anonymous samples (6.6%), with a further drop of 21.6% when the sample was identifiable (compared to coded). When the biobank was described as being located overseas, the same trend occurred, though willingness was lower overall. That is, 76.0% (compared to 94.1% for an Australian biobank) would allow their anonymous sample to be stored overseas, which was 16.3% higher than a coded sample, which was in turn 17.8% higher than an identifiable sample.

Table 1 here

#### **Segmentation analysis**

The results of the LCA revealed the patterns of nominal responses were best explained by three classes (see S4). The conditional probabilities (see Figure 1 and Figures S1-S3) suggest the first class were primarily concerned about privacy rather than location (labelled “Concerned about privacy”), and the second were highly likely to participate under most conditions (labelled “No concerns”). The third were also slightly concerned about the level of identification of their samples, but were mostly concerned with all offshore biobank activities (labelled “Concerned with offshore biobanking”).

Figure 1 here

The results of the logistic regression analyses revealed that age, education and ethnicity did not significantly (at  $p < .05$ ) predict class membership. While males were found to be significantly more likely than females to demonstrate no concerns, this association was due to greater knowledge of biobanks reported by males relative to females (see S5 in supplemental materials for all results).

The results in S5 revealed that respondents who reported a greater knowledge of biobanks were over 2 ½ times more likely to have no concerns about offshore biobanking. Independent of knowledge, beliefs about who should benefit from biobanking also significantly predicted class membership. Respondents who were concerned about offshore biobanking were more likely to believe that biobanks should mostly benefit Australians and not foreigners, while those with no or privacy concerns supported benefits going to foreigners and not just Australians.

### **Additional reasons for willingness to donate**

When provided with the opportunity to elaborate on reasons for their willingness (or lack thereof), some initially supportive respondents expressed concerns about sharing their sample internationally, while those initially reluctant indicated that they would be willing irrespective of location if other conditions were met. Table 2 provides a summary of the final themes, their definitions and example quote(s).

Table 2 here

### **Altruism, benefit sharing and the common good**

Underlying a willingness to donate regardless of location and degree of identifiability was the belief that “anybody is free to use it” (P5: Older female) so that research can “help people” (P13: younger male). A corollary of this was that those who were reluctant to share samples internationally feared the potential misuse of resources by other countries could undermine



the common good. Others expressed a concern that benefits for the community, themselves or researchers may not be returned to Australia. For example, one participant was particularly concerned about her sample being financially exploited if it were donated to an international biobank, and another disliked the idea of international researchers receiving accolades for the work of Australian researchers who may not receive due credit (see Table 2).

### **Privacy, trust and control**

Underpinning several participants' willingness to allow international networking was the view that the medical profession was inherently trustworthy and would, accordingly, protect their sample and data. For some however, trust in science and biomedicine extended only to national boundaries due to either a general distrust of other countries or fear that their privacy would not be protected. Concerns about privacy shaped willingness to donate—with participants' comments reflecting a readiness to donate to an international biobank for any purpose, but only if their personal information was kept confidential. Other participants focused on loss of control as a reason not to donate—which was either due to a lack of trust in how their donation would be used or the desire to be informed.

### **Ethical and regulatory oversight**

Some participants' concerns about privacy when donating to an overseas biobank were directly attributed to Australia's ethical and legal standards not travelling with their donated sample or information. These participants regarded Australian biobanks as having trustworthy, reliable protocols and procedures in place to maintain a donor's privacy, whereas participants were doubtful that other countries would have the same protections. This was a common concern expressed by those who were more reluctant to donate to an international biobank due to the perception that other countries were more likely to "cut corners", disregard protocols, have less scientific rigour and potentially even misuse participants'

samples. These concerns were also apparent amongst those willing to donate internationally (see P8: Older female in Table 2).

#### **4. Discussion**

The aim of this research was to investigate the extent to which internationally networked biobanks impact on willingness to donate tissue for research and why. The results are the first to demonstrate that some people are reluctant whilst others are not, and that reasons underpinning willingness vary across different publics. The results support initial US (Majumder, et al., 2016) and European (Tupasela, et al., 2010) findings that international biobank networks have the potential to exacerbate the widely documented and largely unresolved public concerns associated with isolated biobanks—privacy protection, benefit sharing, and ethical oversight. Yet they also support findings from previous Canadian (Joly et al., 2015), Australian (Critchley et al., 2015) and Jordanian (Ahram, et al., 2014) surveys that demonstrate people are willing to donate internationally. Indeed, the use of our person centred LCA was able to identify that a sizable proportion of our sample (39.2%) who were keen to see benefits distributed universally, did not report a reluctance to donate under various types of international collaborations even when their donated sample could be identified.

The LCA results also revealed that for some, willingness was underpinned by a desire to see benefits distributed universally but was offset by increased concern about privacy protection. For others, reluctance was driven by biobanks, samples and benefits travelling offshore, regardless of levels of identification. The qualitative results validated and extended these findings by suggesting concerns about privacy were associated with uncertainty around foreign ethical and regulatory standards, while concern with offshore locations was due to perceived loss of local health care benefits, reduced scientific rigour, increased possibility of exploitation, and increased competition between scientists, countries and biobanks. A main

contribution of this study, therefore, is that future research needs to take note of differences within as well as between countries, and that international networks raise new concerns for some members of the public beyond those that challenge isolated biobanks. This has significant implications for communication strategies that may need to be tailored to different publics, as well as efforts to align local with international regulatory responses.

### **Ethical and regulatory oversight**

A unifying theme in both the qualitative and quantitative results revealed an important determinant of willingness was the possibility of different ethical standards. This was particularly the case in relation to privacy, where the qualitative interviews highlighted that high levels of trust in ethical oversight and medical professionals alleviated concern. The pattern of quantitative responses across types of biobank activities also supported the importance of regulation. For all classes, the drop in willingness between local and international biobank activities was largest for biobank location compared to where an Australian biobank stored or shared its samples. This suggests that while some Australians might prefer that an Australian biobank not share or store tissue overseas, those that do are still able to maintain some control.

While it is possible, due to the nature of the survey question, that this result may reflect a belief that foreign biobanks may not be accessible to Australian researchers, interview respondents frequently emphasised, and explicitly referred to foreign biobank standards as inferior, and more inclined to disregard Australian protocols. Future research would therefore benefit from including questions that distinguish between a foreign biobank that does not allow local sharing and one that does (as our question did not). Also directly including measures of ethical or regulatory standards across different jurisdictions would help to determine the extent to which reluctance to donate is associated with perceived distributional inequity of tissue to local researchers and/or the inferiority of standards.

## **Benefit sharing and the common good of research**

Consistent with previous research, those willing to allow foreign researchers to access their samples appeared driven by a desire to help others (Ahram, et al., 2014; Critchley et al., 2015; Joly, et al., 2015). The LCA analysis revealed that the “No concerns” class were significantly more likely to believe that people in other countries should also benefit and that the majority of benefits coming from Australian biobanks *should not primarily* go to Australians. The interviews validated this sentiment where the desire to help others in need regardless of their nationality was a strong theme.

Consistent with the general literature on benefit sharing (e.g., Nicol and Critchley, 2012), our study also revealed that for some, there was a belief that donors should benefit from their willingness to participate in biobanking. Those reluctant to donate to a foreign biobank were also more likely to believe that Australians, not foreigners, should be the primary beneficiaries, as foreign biobanks could gain an unfair advantage at Australia’s expense and exploit samples for economic or reputational gain. This fits with Majumder et al. (2016)’s speculation that negative attitudes towards international genomic data sharing may arise from increasing nationalism coupled with the promotion of biobanks as important drivers of economic growth. It also indirectly supports findings that the presence of commercial interests in biobanking generate public unease (Critchley and Nicol, 2017), and that biobanks are creating population or ethnic brands to enhance the economic value of their biomedical collections relative to others (Tupasela, 2016).

## **Conclusions**

An important contribution of these results is they highlight a need for future research, in other countries as well as Australia, to examine within-country variation. Variable centred approaches (i.e. reporting responses to isolated variables across total samples) in national surveys may mask nuanced patterns of concern and thus important factors that could

undermine public willingness to donate. Efforts to harmonise local with global regulatory responses may therefore miss, and in turn, fail to address important principles deemed fundamental to large sections of the public that could also exist across jurisdictions.

Our results suggest that legislative attempts, such as the European Union's General Data Protection Regulation Directive, to standardise the protection of personal data and its usage across data collectors and receivers, may be effective in providing reassurance for members of the public concerned about privacy or the inconsistency of standards across countries. Dynamic consent (Prictor, Teare, & Kaye, 2018) that enables biobank participants to monitor and make decisions about the use of their tissue over time, and as it travels between countries, may also reassure those concerned about loss of control. However, approaches that place decision making in the hands of biobank participants will do little to improve willingness to donate internationally amongst those concerned about commercialisation and inequitable benefit sharing. According to our results, this public are likely to prohibit their samples to travel offshore unless there is a clear obligation to return benefits to the local biobank. Moreover, the strongest materially binding promises may still be insufficient to convince those with a nationalistic orientation or stereotypical bias towards certain countries. For this public, encouraging participation requires a more complex understanding of the socio-political contexts of both the local biobank and its collaborators.

### **Data access**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Supplemental material

Supplemental material is available online.

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