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Australian Donation and Transplantation Biobank: A Research Biobank Integrated Within a Deceased Organ and Tissue Donation Program

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Background. We aimed to facilitate the donation of tissue samples for research by establishing a centralized system integrated in the organ donation program for collection, storage, and distribution of samples (the Australian Donation and Transplantation Biobank [ADTB]). **Methods.** Feasibility of a research biobank integrated within the deceased organ and tissue donation program was assessed. DonateLife Victoria sought consent for ADTB donation after consent was received for organ donation for transplantation from the donor's senior available next of kin. ADTB samples were collected during donation surgery and distributed fresh to researchers or stored for future research. The main outcome measures were ADTB donation rates, ADTB sample collection, ADTB sample use, and to identify ethical considerations. **Results.** Over 2 y, samples were collected for the ADTB from 69 donors (28% of 249 donors). Samples were obtained from the spleen (n = 59, 86%), colon (n = 57, 83%), ileum (n = 56, 82%), duodenum (n = 55, 80%), blood (n = 55, 80%), bone marrow (n = 55, 80%), skin (n = 54, 78%), mesenteric lymph nodes (n = 56, 81%), liver (n = 21, 30%), lung (n = 29, 42%), and lung-draining lymph node (n = 29, 42%). Heart (n = 20), breast (n = 1), and lower urinary tract (n = 1) samples were obtained in the second year. Five hundred fifty-six samples were used in 19 ethics-approved research projects spanning the fields of immunology, microbiology, oncology, anatomy, physiology, and surgery. **Conclusions.** The integration of routine deceased donation and transplantation activities with a coordinated system for retrieval and allocation of donor samples for use in a range of research projects is feasible and valuable.

(*Transplantation Direct* 2023;9: e1422; doi: 10.1097/TXD.0000000000001422).

Received 22 September 2022.

Accepted 4 October 2022.

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V.J.S. was involved in writing, data collection, and final approval; G.S. was involved in project conception, writing, and final approval; R.D. was involved in project conception, writing, and final approval; F.J. was involved in project management, writing, and final approval; E.M. was involved in project writing and final approval; L.D. was involved in project writing and final approval; B.Z.W. was involved in data collection and final approval; A.V. was involved in data collection and final approval; J.R. was involved in project conception, writing, and final approval; L.M. was involved in project conception; H.O. was involved in project conception, writing, and final approval; R.J. was involved in project conception and final approval; M.L.G. was involved in final approval; D.E.M. was involved in writing and final approval; C.L.G. was involved in project conception, data collection, writing, and final approval.

C.L.G was supported by a National Health and Medical Research Council (NHMRC) Early Career Fellowship (GNT 1160963) and a Royal Australasian College of Physicians Research Establishment Grant. The ADTB initiative was supported by a Doherty Institute Collaborative Seed Grant, a Doherty Institute Translational and Clinical Research Discipline Seed Grant, internal Dept. of Infectious Diseases Austin Health funding, and an Austin Medical Research Fund Grant awarded to C.L.G. V.J.S is a recipient of the Heart Foundation PhD Scholarship, National Heart Foundation of Australia.

The authors declare no conflicts of interest

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ISSN: 2373-8731

DOI: 10.1097/TXD.0000000000001422

INTRODUCTION

Difficulty obtaining human tissue samples is a major barrier to translating basic science research findings into clinical care.[1,2] Although several tissue research biobanks exist in Australia, stored samples are mostly collected during treatment from patients with known diseases (eg, cancer) and may only be suitable for research into those diseases.[3-6] Moreover, the process of fixing or freezing samples for storage results in nonviable cells or tissues, precluding many studies of human biology.[7] Consequently, animal models are often used to study biological processes, yet their value is limited because of species-specific differences in biology and disease pathogenesis, a lack of genetic diversity of in-bred strains, and an inability to mimic many aspects of the human experience, such as repeated exposure to infections.[8,9] These differences have major implications for the translation of scientific discoveries into new therapies because the results of many animal model studies are not reproduced when tested in human trials.[10]

Deceased organ and tissue donors are an important source of previously healthy, viable human tissue that can be readily acquired for use in research. Sample collection for research can be undertaken at the time of organ retrieval for transplantation, providing fresh tissue for more realistic simulations of human biology.[11-14] Donating to research also provides donors and their families with an additional opportunity to help others. Donation of organs or tissues for use in research has always been an option at the time of deceased donation for transplantation in Australia; however, there has been no systematic approach to coordination of donation for research. Opportunities to donate samples for use in research have been ad hoc, and researchers unfamiliar with deceased donation programs have had to liaise directly with state or territory DonateLife offices, which coordinate deceased donation activities.

In 2019, a pilot project was initiated by Austin Health and DonateLife Victoria (DLV) that aimed to source tissue samples from deceased organ donors for use in immunological research at the Department of Microbiology and Immunology, Doherty Institute, University of Melbourne. The scope of the pilot rapidly expanded beyond immunology; it is now a service with the potential to become a centralized and coordinated system for collection, distribution, and storage of organ and tissue samples from deceased donors for use in research internationally. Here, we describe this service model, named the Australian Donation and Transplantation Biobank (ADTB), and present the results of 2 y of its operation. Our results show that a centralized system of the collection, provision, and storage of organs and tissue samples ("samples") for research is feasible within the existing infrastructure for deceased donation in Australia. We also identify some logistical challenges and ethical considerations that must be addressed if the program continues to grow.

MATERIALS AND METHODS

The ADTB, which commenced as a pilot study in 2019, is a collaboration between Austin Health and DLV that uses existing infrastructure for donor assessment, consent, and surgical retrieval of organs for transplant for the ADTB sample collection as shown in Figure 1. Austin Health hosts the Victorian Liver Transplant Unit (LTU), which performs retrieval of livers and kidneys from deceased donors in Tasmania and Victoria, as well as liver transplants for Victoria and intestinal transplants for Australia. As thoracic organ retrieval concludes earlier than abdominal organ retrieval, involvement of the LTU ensures that retrieval of samples for use in research does not disrupt the retrieval of organs for transplantation. DLV is hosted by the Australian Red Cross Lifeblood and is responsible for receiving organ donation referrals, obtaining consent for donation, and coordinating organ and tissue retrieval for Victoria. The ADTB is led by a clinician-scientist (C.L.G.) colocated at the Department of Infectious Diseases, Austin Health, and the Department of Microbiology and Immunology, Doherty Institute. The Department of Infectious Diseases hosts the ADTB and manages sample processing, distribution, and storage. The ADTB was financed using establishment grants awarded to C.L.G. (Acknowledgments). This report refers to the first 2 y of ADTB operation and encompasses the pilot (October 2019–December 2020) and development phases (January 2020–October 2020). During the pilot, Doherty Institute researchers were able to request approval for ADTB samples. During the next phase, additional researchers were informed by word of mouth; the ADTB was not actively promoted while new processes were being piloted.

Ethical Governance and Access to Samples

Ethics approval of the pilot and the ongoing project was obtained from the Austin Health Human Research and Ethics Committee (HREC; HREC/4814/Austin-2019) and the Australian Red Cross Lifeblood HREC (Ethics 2019#08). Specific research projects using ADTB samples were approved by the researchers' own institutional HRECs, which were responsible for ensuring the project met ethical standards.[15] After the pilot, research sample requests were evaluated by the ADTB Sample Access Committee for project feasibility, prioritization, and expected sample availability (Figure 2). Sample Access Committee membership included representatives from ADTB, LTU, and DLV. The ADTB How to Apply and Conditions of Use policy and a material transfer agreement (which governs the transfer of samples from ADTB to researchers) were agreed and completed before sample provision.

Donor Recruitment and Consent

All individuals clinically eligible to donate organs for transplantation after neurological or circulatory determination of death were also eligible to donate to ADTB; for logistical reasons, ADTB samples were only collected if donation surgery for transplantation proceeded. After a potential organ donor was notified to DLV, a DLV donation specialist nurse coordinator (DSNC) was assigned as the point of contact for a donor's family. The DSNC first sought consent from the donor's senior available next of kin (SANOK) for organ and tissue donation for transplantation. If consent for this was given, consent was then sought for the donation of samples to the ADTB.

The consent process was designed to support the donation of fresh or stored samples to the ADTB for use in unspecified medical research projects. Noting that the SANOK had already received general information about donation of tissues in the context of donation for transplantation purposes, consent was sought for sample collection, provision of fresh samples, storage "banking" of samples, and collection and storage of the donor's personal health information for use in

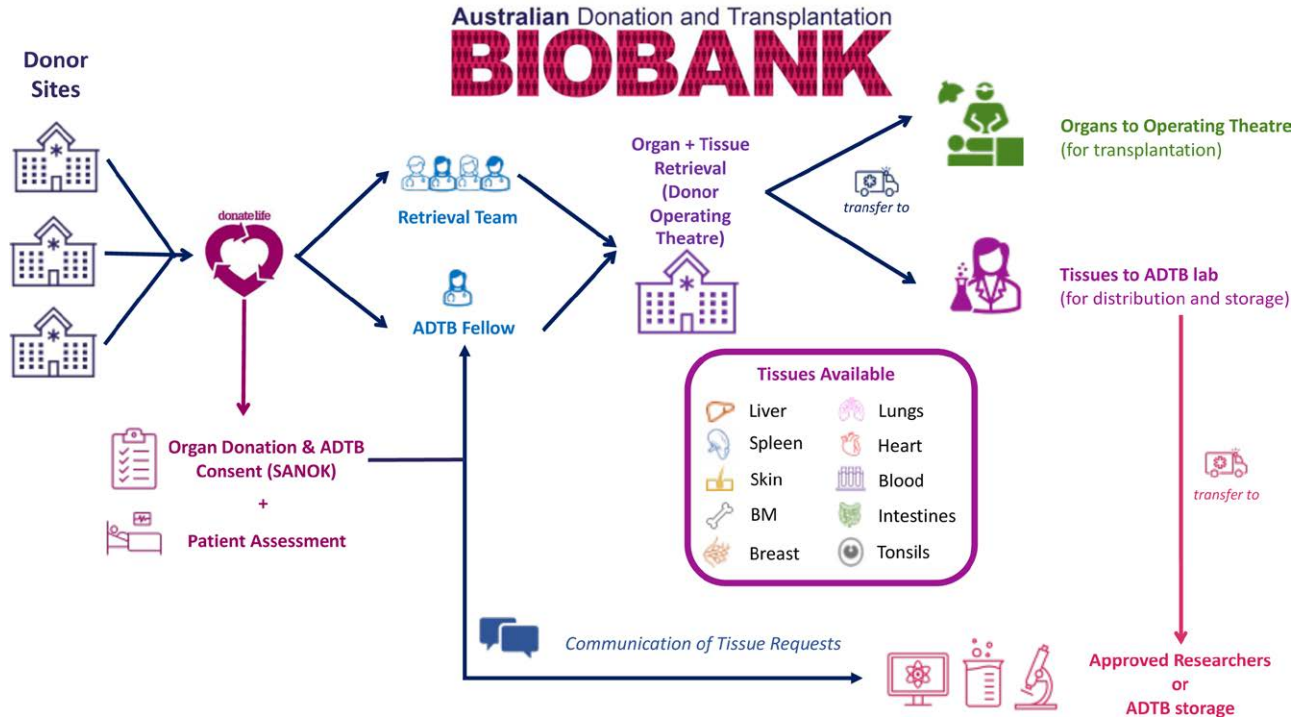

FIGURE 1. Flowchart of ADTB sample procurement and distribution. ADTB, Australian Donation and Transplantation Biobank; BM, bone marrow; SANOK, senior available next of kin.

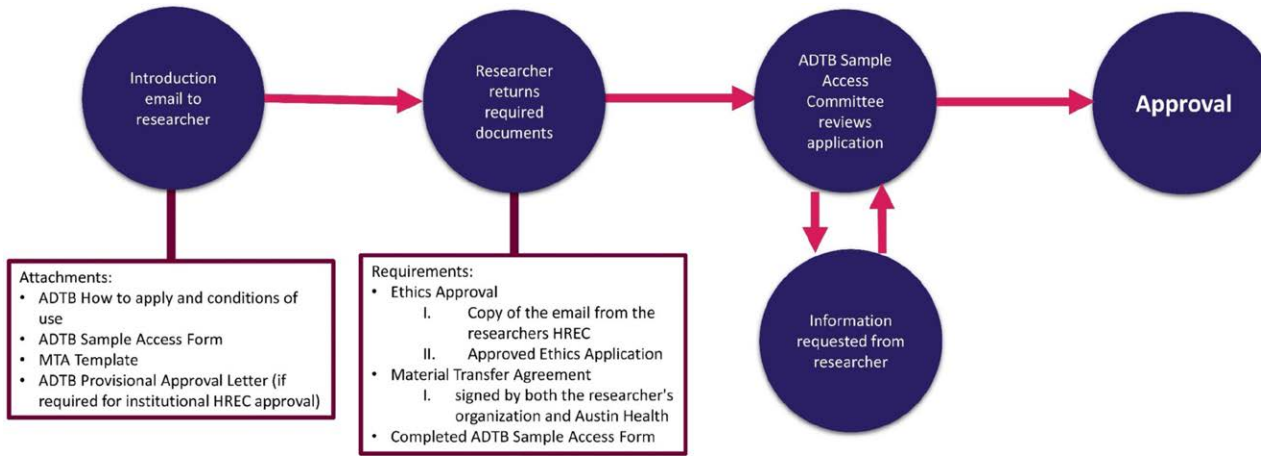

FIGURE 2. Process for approval of researchers to access ADTB samples. ADTB, Australian Donation and Transplantation Biobank; HREC, human research ethics committee; MTA, material transfer agreement.

research. Information provided to decision-makers was tailored to the needs and preferences of decision-makers and "proportional to the project's risks and ethical sensitivity."[15] Consistent with Australian national research ethics standards for unspecified and extended consent for use of donated tissue in research,[15] the DSNC provided the SANOK with a plain language statement summarizing the role of the ADTB and examples of research projects that currently used ADTB samples. When active research projects were directly relevant to specific donations, more detailed information was provided to decision-makers who wished to receive this. The SANOK was informed of the approval process for projects using samples (Figure 2) and, using a tiered consent approach,[16] could choose which organs or tissues would be donated for research; whether donations would be used in genetic research; and whether to be informed if research revealed findings with health implications for their family. The SANOK was informed of their right to withdraw data and donated samples from the ADTB unless these had already been used.

Sample and Data Collection

ADTB sample collection was largely integrated into the organ retrieval process undertaken by the LTU. Initially, the majority of samples were processed and stored for future research; however, researchers expressed little interest in stored samples in comparison to requests for fresh tissue, and the ADTB shifted to predominantly providing fresh samples in early 2020. A dedicated ADTB surgical fellow commenced in January 2021, which enabled the expansion of sampling to up to 14 organs/tissue types per donor (Table 1) and facilitated specific sample requests (eg, collection of disease-free left-anterior-descending artery).

TABLE 1.

Donor characteristics and samples collected

	No. donors, n = 69 (%)
Sex (female)	32 (46)
Age, y (± SD)	51 ± 15
Ethnicity	
Oceanian	56 (81)
Other	23 (19)
Donation type	
Donation after neurological determination of death	48 (70)
Donation after circulatory arrest	21 (30)
Cause of death	
Cerebral anoxia	14 (20)
Stroke	41 (59)
Myocardial event	4 (6)
Trauma	8 (12)
Other	2 (3)
Tissue site donated to ADTB	
Blood	55 (80)
Bone marrow	55 (80)
Spleen	59 (86)
Liver	21 (30)
Lung	29 (42)
Duodenum	55 (80)
Ileum	56 (81)
Colon	57 (83)
Lung lymph nodes	33 (48)
Mesenteric lymph nodes	56 (81)
Skin	54 (79)
Heart[a]	20
Breast[a]	1
Lower urinary tract[a]	1

[a]Organs were only collected in 2021.
ADTB, Australian Donation and Transplantation Biobank.

The ADTB fellow was notified by the DSNC when consent for ADTB donation was obtained, usually the night before donation surgery. This allowed ADTB 12 to 24 h to review and collate current research sample requests. After organs for transplantation were obtained, the ADTB fellow or Austin retrieval team collected ADTB samples. In rare instances, organs retrieved for transplantation were subsequently deemed unsuitable and made available to the ADTB, in which there was family consent. The ADTB fellow and/or ADTB staff collected donor information, which was de-identified and provided to researchers together with samples as per the relevant project protocol.

Sample Distribution, Processing, and Storage

Samples were suspended in organ perfusion fluid (eg, Soltran, Baxter Healthcare, UK) or in media specified by the requesting researcher (eg, RPMI-1640, ThermoFisher Scientific, Australia) and kept on ice.

Samples were transported to the ADTB, Austin Health, for distribution, storage, or immediate use in experiments. Most samples were divided and transported immediately to researchers. Occasionally, samples were collected by researchers directly from the donation hospital or Austin Health for use in time-critical experiments. A small proportion of samples were sectioned and stored frozen or formalin-fixed paraffin embedded in secure and monitored facilities at Austin Health.

All samples were labeled with a unique reidentifiable ADTB code, collection date, and sample type. Donor and sample distribution information was securely stored in a REDCap database (Research Electronic Data Capture, Vanderbilt University) hosted and protected by Austin Health. Stored tissue was securely catalogued using Freezer^{PRO} (Brooks Life Sciences).

Statistical Analysis

Descriptive statistics including the calculation of means, proportions, and standard deviation were performed using MS Excel (Microsoft Corporation) and Stata, version 15.1 (StataCorp LLC).

RESULTS

Donor and Sample Characteristics

Between October 21, 2019, and October 27, 2021, 3225 routine end-of-life notifications were made to DLV from 23 hospitals (Figure 3). Of the 249 notifications that progressed to organ donation, 28% also donated to the ADTB (69/249). ADTB samples were sometimes unable to be collected from ADTB-consented donors because of logistical reasons, including that ADTB sample collection was typically only available on weekdays, the ADTB surgical fellow was unavailable, multiple donation surgeries occurred simultaneously, prohibitively long travel distances, and researchers were not available to accept samples (this was more common in the pilot study). The proportion of organ donors who had ADTB samples collected increased from 21% in 2019 to 37% in 2021 (Figure 3B) as the ADTB expanded. For logistical reasons, hospitals where donors contributed tissue for research were mostly located in metropolitan Melbourne (approximately 85% of ADTB donors). The demographics of ADTB donors (Table 1) were similar to the general deceased donor population.[3,17,18] The median age of ADTB donors was 51 y, and 46% were female; 70% donated after neurological determination of death.

Table 1 shows the frequency of sites sampled. Organs that were frequently utilized for transplantation and sites for which collection only commenced late in the project were less frequently sampled.

Provision of Samples to Research Projects

Before ADTB commenced, DonateLife provided access to donated organs or tissues to 5 research projects in an ad hoc manner. In comparison, ADTB provided 556 tissue samples that were provided to 13 research groups located at the University of Melbourne or the Walter and Eliza Hall Institute of Medical Research and supported 19 individual research projects[19-21] spanning the fields of immunology, microbiology, oncology, anatomy, physiology, and surgery over the study period.

The majority of samples were immediately transported fresh on ice and delivered to researchers within 4 h of collection. Samples were occasionally shipped the next day if donation surgery occurred in the evening or if samples were fixed in formalin.

DISCUSSION

Little is known about organ or tissue donations for research that are made in the context of deceased donation for transplantation in Australia. We believe that many

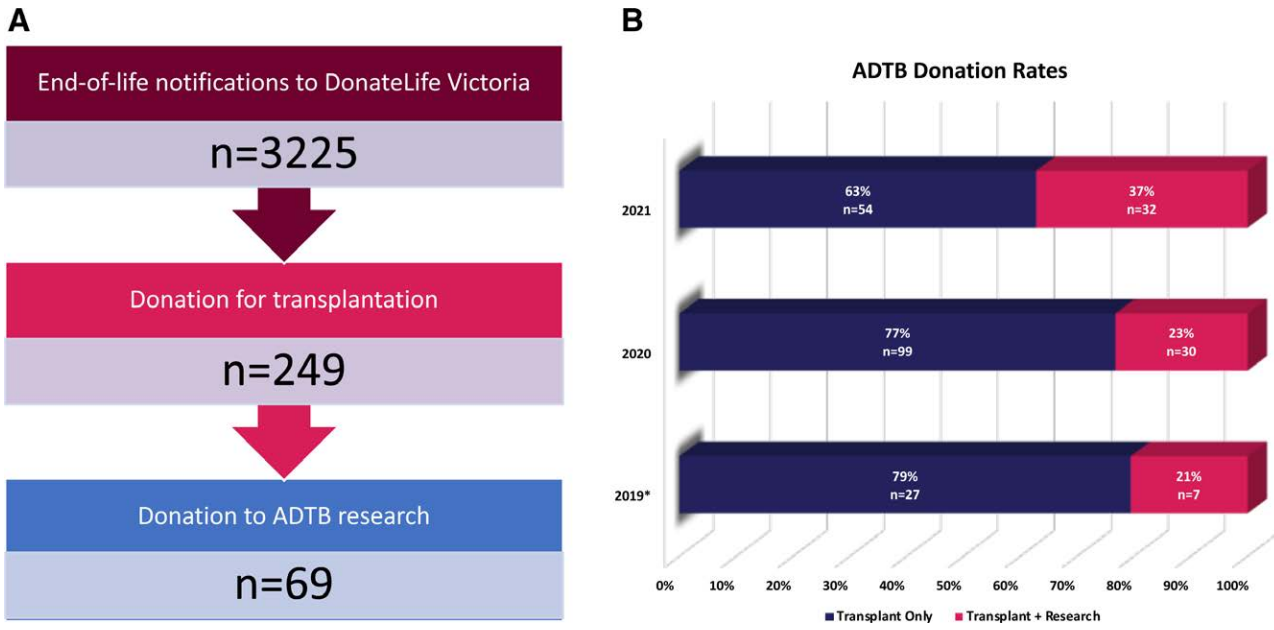

FIGURE 3. Donation to ADTB research over the 2-y period (October 21, 2019–October 27, 2021: *2019 represents the pilot phase of the program). A, Number of donors who donated samples to ADTB in relation to the total number of notifications to DonateLife Victoria and total number of donation operations. B, Number of donors (% total) who donated to ADTB research by year as a proportion of all organ donors. ADTB, Australian Donation and Transplantation Biobank.

donation agencies provide access to donated organs or tissues for research largely in an ad hoc manner. Neglect of donation for research may be due to the perception that this is a secondary responsibility of donation agencies and one that may distract from their primary purpose of supporting donation for transplantation. Donation agencies have limited resources and may be unable to devote time to activities that are necessary for donation for research, for example, review of sample requests, consent of donor families, and collection and transfer of samples to researchers.

To our knowledge, the ADTB is the first Australian biobank that has been integrated with a program of deceased donation of organs and tissue for transplantation. Before the ADTB, DLV provided samples to 5 research groups on an ad hoc basis, and specific consent was sought for each research group. Internationally, research biobanking in deceased organ donation is further developed. In the United States, the International Institute for the Advancement of Medicine has worked with organ procurement organizations to provide fresh nontransplantable human organs and tissues for medical research, education, and development for over 35 y.[22] Similarly, the National Disease Research Interchange in the United States is a large research tissue agency that has worked with organ recover programs for decades.[23] Donna Farber, Columbia University, New York, has a long-standing program of donation for research[24-30]; however, their sample collection model/process involves the donation agency responding directly to individual requests for samples rather than centralized integration of sample collection into the organ and tissue donation for transplantation program and coordinated distribution of samples to multiple unrelated projects.[7]

The experience of the ADTB suggests that integration of routine deceased donation and transplantation activities with a coordinated system for retrieval and allocation of deceased donor samples for use in a range of research projects is feasible and valuable. It notably provides the opportunity to obtain fresh tissues during the process of organ retrieval, as shown by the demand we observed in researcher requests for fresh samples. The minimal cold ischemic time achieved in our study is particularly important because it may facilitate a range of research applications, including genomics, transcriptomics, proteomics, and metabolomics.[31,32] DSNCs report positive responses from the SANOK when organ and tissue donation to research is raised, which is consistent with known public attitudes toward donation of samples after death for research.[33]

Effective cooperation between researchers, the ADTB, surgeons, and DonateLife Victoria was clearly demonstrated; however, it is unclear if this approach will prove efficient on a larger scale. Funding will likely be needed to support staffing of the ADTB and infrastructure for collection, storage, and allocation of samples and related data. Currently, some costs are recovered via payment from researchers for ADTB services. Long-term philanthropic or governmental funding for the ADTB would be helpful in ensuring the sustainability of the biobank and minimizing inequities in access to donated samples for research that may result from a user-pays model. On the other hand, integration of biobanking with donation services also presents opportunities to reduce the costs that may otherwise be associated with the collection of samples, especially when fresh samples are needed for research. Centralized and dedicated management of donation for research enables efficient oversight of researcher requests and coordination of sample collection, storage, and allocation. This is likely to more efficient than ad hoc responses to individual research project teams by DonateLife.

The appropriateness of the broad or unspecified consent model used, which is controversial but common in biobanking,[34] may be questionable in some cases given that the intended use of specific donations may be known to the ADTB at the time of donation decision-making. However, obtaining specific consent for donation to research may require excessively burdensome information loads for the SANOK, especially when donated samples may be distributed across

multiple research projects. In providing consent for donation for transplantation, the SANOK receives detailed information about the donation process and participates in a lengthy donor risk assessment interview. It is important that the information provided is sufficient and tailored to individual needs and is not unnecessarily burdensome to family members, noting that these communications occur at a time of bereavement.[35] Provision of more detailed information does not necessarily result in greater understanding or more effective decision-making about participation in research,[36] nor is detailed understanding always deemed essential by people choosing to donate to biobanks.[37] Debate persists regarding minimum requirements of consent for donation to research biobanks, especially in contexts in which the risks of participation are low. Furthermore, much of the debate regarding the validity of consent and ongoing information sharing by research biobanks and discussions of consent in the context of rapid tissue donation postmortem focus on consent obtained from living donors,[38,39] rather than surrogate consent for research use of donations from deceased persons. More specific consent and provision of detailed ongoing information about research involving deceased donor samples may be considered less relevant to surrogate decision-makers such as the SANOK, except where research may pose risks to living persons such as genetic relatives of donors. In the United States, for example,[40] the elements of informed consent legally required for research in living persons are not applicable to research use of tissues from deceased donors.

The ADTB is developing a more nuanced consent process that will reduce burdens, for example, by streamlining information provided to donation decision-makers using a tiered consent model to obtain consent for standard biomedical science research[16] while promoting autonomy by providing access to more detailed but nonessential information about standard projects for those who desire it. It also involves a dynamic element that enables researchers to seek consent to recontact the SANOK in the future if donated samples may be used in new types of research, for example, genetic testing, which entails specific and complex considerations,[35] or if results of research may have health implications for the donor's family.[41] This approach is consistent with national guidelines[15] and international research ethics recommendations.[42,43] Nevertheless, emerging research concerning the limitations of consent for research, especially when research is embedded in healthcare settings,[37] highlights the importance of ethical governance of research projects and research biobanks to prevent the misuse of donations.[44] Various governance models have been recommended for research biobanks, but the variable nature of individual biobanks requires oversight mechanisms to be tailored to address specific governance needs.[45] The ADTB is developing a framework that operates effectively alongside existing governance mechanisms overseeing programs of deceased donation for transplantation and that provides effective oversight of rapid tissue donation for use of fresh samples in research, as well as more typical biobank activities, such as the storage of samples for use in future research.

The ADTB will continue to expand with the goal of facilitating donation of organ donor samples for research and providing timely high-quality samples to researchers. Although further refinement of ADTB processes and financial sustainability are required, this report demonstrates the significant potential and value of a centralized system integrated in an existing organ donation and transplant program for collection, storage, and distribution of donated tissue samples for research.

ACKNOWLEDGMENTS

We acknowledge the generosity of donors and their families for their contribution to advancing medical research. We thank the DLV DSNCs who assisted in the consent process and donation surgery coordination and acknowledge the support of DLV research coordinators Chelsey Vladic, Monique Drury, and Megan Plas. We thank and acknowledge the many surgical registrars who assisted with the ADTB: Georgina Riddiough, Osamu Yoshino, Thomas Tiang, Eunice Lee, and others. We also acknowledge the researchers involved in the ADTB pilot study and thank them for their support: Allison Clatch, Susan Christo, Hyon-Xhi Tan, Jennifer Juno, Adam Wheatley, Stephen Kent, Yannick Alexandre, Scott Mueller, and Alexander Corbett. Thank you to Wayne Ng, Victorian Cancer Biobank, and Barbara Scher, Doherty Institute, for their guidance and expertise in developing the ADTB.

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