

TRANSCRIPT

LEGISLATIVE ASSEMBLY LEGAL AND SOCIAL ISSUES COMMITTEE

Inquiry into increasing the number of registered organ and tissue donors

Melbourne—Friday 23 June 2023

MEMBERS

Ella George—Chair

Annabelle Cleeland—Deputy Chair

Chris Couzens

Chris Crewther

Gary Maas

Cindy McLeish

Meng Heang Tak

WITNESSES

Mr Brendan Sullivan, Head of Service, and

Ms Chantel Bartolo, Nurse Manager and Tissue Donation Nurse Specialist, Donor Tissue Bank of Victoria; and

Professor Noel Woodford, Professor of Forensic Medicine, Monash University, and Director, Victorian Institute of Forensic Medicine.

The CHAIR: Good afternoon. We will now recommence public hearings of the Legislative Assembly Legal and Social Issues Committee's Inquiry into increasing the number of registered organ and tissue donors.

My name is Ella George, and I am the Chair of the Committee. I am joined today by Annabelle Cleeland, Deputy Chair; Gary Maas; Cindy McLeish; and Chris Crewther.

I welcome representatives from the Donor Tissue Bank of Victoria and the Victorian Institute of Forensic Medicine: Brendan Sullivan, Head of Service, Donor Tissue Bank of Victoria; Professor Noel Woodford, Professor of Forensic Medicine, Monash University and Director, Victorian Institute of Forensic Medicine; and Chantel Bartolo, Nurse Manager and Tissue Donation Nurse Specialist at Donor Tissue Bank of Victoria. Thank you very much for joining us today.

All evidence given today is being recorded by Hansard and broadcast live. While all evidence taken by the Committee is protected by parliamentary privilege, comments repeated outside this hearing may not be protected by this privilege.

Witnesses will be provided with a proof version of the transcript to check. Verified transcripts and other documents provided to the Committee during the hearing will be published on the Committee's website. Witnesses are welcome to take questions on notice, and we ask that questions on notice be returned within two weeks.

I invite you to now make a brief opening statement of around 5 to 10 minutes. This will be followed by questions from Members. Thank you.

Brendan SULLIVAN: Great. Thank you. Thank you very much for the opportunity to make a submission and attend the hearing. I would like to go through in this introductory section some information about who and what is the DTBV, the Donor Tissue Bank of Victoria; some distinction between tissues versus organs; the regulatory landscape in which we operate and how that is different to the organ regulatory landscape; the core changes that we are seeking or proposing and recommending; the tight time frames in which we operate and why we seek change; and the urgency for change in our own sector. With that, I will continue on.

Who are we? The Donor Tissue Bank of Victoria is a small not-for-profit entity of the Victorian Institute of Forensic Medicine, a statutory authority operating within the Victorian Department of Justice and Community Safety. Being outside the health portfolio, it is somewhat of an anomaly in the field of organ and tissue donation around the country and not only donation but supply. We are funded from within the justice budget, and we are not funded by OTA, DonateLife or any other organisations in this space. The DTBV employs only 22 staff. It is based in Southbank adjacent to the Coroners Court and integrated into the VIFM, which is the Victorian Institute of Forensic Medicine—pardon my use of acronyms—and which includes the state mortuary. Our staff include an in-house team of six donation nurse specialists, of which Chantel is the manager.

The DTBV is the largest tissue bank in Victoria, one of the largest in Australia and one of only three multi-tissue banks in the country. When I say multi-tissue banks, the tissue we retrieve, process and supply includes heart valves, skin grafts, tendons and bones. Interestingly, bone allografts are second only to blood as the most commonly implanted tissue.

The CHAIR: What was that, sorry?

Brendan SULLIVAN: Bone allografts are second only to blood in terms of implantation.

I would like to highlight the distinction between tissue donation, which includes corneas, and organ donation. This Committee has read and heard the word 'organ' numerous times in this inquiry. However, the word and concept of tissue donation supply has barely rated a mention other than during the appearance of our colleagues the Lions Eye Donation team. Although tissue donations do not always have the same dramatic and life-saving outcomes as organ donation, the impact on the life of the patient can be very significant. This is particularly so with the provision of skin grafts for burns victims and for cardiac valve transplant recipients.

Tissue graft implants are also far more widespread in the community than organ transplants and have a major positive health impact. Just to further draw that comparison, nationally in 2022 there were 454 organ donors and 1224 organ recipients. Referring to just deceased donors only—there are both deceased and living tissue

donors—last year the DTB of Victoria alone had 58 tissue donors and supplied over 3280 human tissue allografts to Australian hospitals. That is one-eighth of the national number of organ donors for three times the national number of grafts just from Victoria, so you can see it is a one-to-many relationship versus the one-to-few relationship in organ donation. That also brings with it some constraints and regulatory requirements because of that potential multiplication of the safety issues.

Our safety and compliance obligations—the DTBV operates under a TGA licence in the highly regulated space of human tissues and biologicals. There are many quality and safety practices which we are mandated to maintain in compliance with the Australian code of good manufacturing practice and the TGA's therapeutic goods orders in relation to tissue retrieval and processing. These are different to what apply to the organ space. We are licensed under the TGA.

Tissue banks across Australia differ in the products they seek to retrieve and process and supply, and while most must not operate as commercial enterprises due to compliance with the various human tissue Acts, in the last five years all tissue banks have had to adopt some commercial-type practices, including widening distribution and protecting intellectual property. Whilst we must retain viability, safety is still paramount. We pride ourselves on our quality and safety record in over 30 years of supplying tissue for transplantation. Our reputation and place in the healthcare community depends upon this, and we will not compromise the health of the community. Our donor selection criteria draws on the best practice guidelines from Australian, UK, Lifeblood and international practices.

While an increase in the number of registered donors would be very welcome, our submission contends that the quantity of tissue donations could be significantly increased without necessarily having to focus on increasing the number of donors registered on the AODR—and I say 'AODR', but it is missing a 'T' you will notice.

The donation process has evolved over many years. We have made many improvements in the process in conjunction with our colleagues at DonateLife and within our own organisation. However, being outside of the health portfolio, we do not have the scope to evaluate whether the tissue donation process as a whole is streamlined and efficient across all the parties, nor do we have the resources to establish data-sharing arrangements with 30-plus hospitals.

We propose that a reduction or removal of hurdles in the tissue donation pathway could be achieved by increased awareness of tissue donation within both the medical profession, where it still has some shortcomings, and the general community, leading to earlier and increased notifications of deaths and hence higher likelihood of family consent. It could also be achieved by the rapid notification of deaths or impending deaths in hospitals and seamless access to donor medical records, which we currently do not have, to enable the DTBV to quickly identify and screen potential donors.

The reason why this time is so important is that when tissue donation occurs after death, time is of the essence. To comply with the TGA requirements the DTBV must retrieve all consented tissue groups within 24 hours of the person last being seen alive. A full retrieval of the four tissue types I mentioned can take 7 to 10 hours, therefore all of the steps on the tissue donation pathway, including access to medical and social history information, must be expedited to allow for the successful retrieval of tissues from donors with consenting families. There have been many occasions where a donor and a donor's family's wishes for tissue donation have not been fully met due to time constraints. So that is our contention—we would like to have access to that information much earlier than we do.

The reason why there is urgency for change in our sector is that there is unmet demand for our tissue allografts and at the same time we are facing increasing competition from commercial enterprises, whose operations can threaten the existence of public and not-for-profit tissue banks such as us—but not only us. Our operational survival and our supply of human tissue allografts to the community depend upon tissue donations, and each donation is precious and treated as such. Each donation is a unique gift from one human being to another, and we cannot afford to lose opportunities due to a lack of awareness or a lack of an efficient donation process.

We contend that the state needs a donation process where all parties in the donation pipeline work collaboratively and with a sense of urgency to meet the very restrictive tissue donation time frame. Such an initiative does not require unproven technologies or changes in legislation, but it does need resources. However, we view this as an incredible opportunity, given the passion that all the parties so far and you have shown for

improving the organ and tissue donation rates—and I specifically focus on the organ and tissue donation rates, not so much the number of registrants on the AODR.

In conclusion, we very much welcome the Committee's interest regarding opportunities to improve the organ and tissue donation rates in Victoria. Thank you.

The CHAIR: Thank you very much for that. I think we have been focusing more on organ donation, but we did have an excellent conversation with the Lions Eye Donation Service, and that really opened our eyes as a Committee to some of those differences between organ and tissue donations, so it is great to have you here with us today to help us understand that a bit better.

I will start off with some questions. You mentioned in your statement that you think you can increase donations without additional registrations of organ and tissue donors. I am just wondering if you can expand on that a bit further and what you mean by that.

Brendan SULLIVAN: Certainly. It is a critical time line between either a person going into end-of-life care or being considered for organ donation or even being deceased, and being able to be available for retrieval of tissues from them. And that time line has a number of hurdles in it that delay the time. Perhaps I can ask Chantel to expand upon some of those, but it includes things like even just being notified of a death within a hospital or an impending death within a hospital. That does not occur naturally now. It does occur where we have good relationships with DonateLife staff in those hospitals, but it is not a guaranteed thing.

And then there is the medical-social history that must be gone through with the donor's family, and that can have delays. There is gaining consent from the family. A lot of these things are excess time-wasters, and with either improved communication in the community or understanding in the community about the existence, even, of tissue donation as a sector, it would not be surprising to families, as it often is, to learn that there is such a thing as tissue donation, with or without organ donation. So a lot of time is spent having families go through that consideration. A lot of time is spent in us trying to get some immediate medical records from the hospital system when we do not have eyes into that. There is a distinction between ourselves and the Lions Eye Donation Service in that they are based in a hospital, in the healthcare system, and they can immediately see on their own computers the patient's medical record in another hospital, so that is shared, and instantly. We do not have that connection at all—it is going to be a paper-based system or a fax-based system or an email-based system, based upon the goodwill of someone on the other end in the hospital letting us know. Would you like to comment on those elements?

Chantel BARTOLO: Yes. I think trying to obtain information—so like Brendan said, we work quite well with our DonateLife colleagues and are reliant on them to help share information about people who might be suitable for tissue donation, but that is when organ donation is possible. When organ donation is not possible, it can be a lot harder to obtain that information. Sometimes DonateLife do help us with that if they have the resources available, but if they do not—they might be working up another case or might be busy within their own hospitals doing their own things—we are reliant on medical practitioners or bedside nurses giving us information about a potential candidate for tissue donation. There is very little knowledge in the medical community about tissue donation and knowledge about the Donor Tissue Bank and what we do. Sometimes having a doctor or nurse share information with us can be really, really tricky—there are a lot of hurdles we need to jump to make sure that they are aware that they are allowed to share that information under the *Human Tissue Act* and that we need that information within a very time-critical, short space of time.

Following that, once we obtain the information we need from the medical practitioner, the next hurdle we face is more with hospital mortuaries. Again, a lot of people do not necessarily know what we do or why we do it or do not really understand the work of the Donor Tissue Bank. It can be actually very hard to release a deceased person from a hospital mortuary to the Victorian Institute of Forensic Medicine for the purpose of tissue donation. We meet a lot of issues there, and that can very much delay transferring someone over to us. Like Brendan mentioned, there is a 24-hour time window; if someone is delayed in the hospital for several hours, that might mean that instead of someone being able to donate all the tissues that their family have consented for, it might limit the amount of tissues that they can actually donate.

The CHAIR: Okay. Are you able to explain the relationship between the Donor Tissue Bank of Victoria and the Organ and Tissue Authority?

Brendan SULLIVAN: We are not linked in any way funding-wise other than that we have a relationship with them and we are a representative on the eye and tissue advisory committee that the OTA runs and conducts meetings of approximately three times a year. So they do consult with us and consult with the tissue sector, but as I said, we are not funded in any way. We rely on goodwill existing between ourselves and their arm in Victoria, DonateLife Victoria. Is there anything else you would like to comment on?

Noel WOODFORD: No, not on there.

The CHAIR: I suppose the reason for that question is because they are obviously working very closely with DonateLife Victoria to be having those conversations in hospitals with family members to commence that process of organ donation, but from what you are saying, am I right in thinking there is a bit of a missing gap when it comes to conversations around tissue donations?

Noel WOODFORD: Can I give you an example of that?

The CHAIR: Please.

Noel WOODFORD: I lecture medical students all the time, and one of the first questions I ask, almost as a game, is getting people to put their hand up, saying, 'Who knows about organ donation?' And most do. 'Who's on a register or has had the discussion with their family?' Most do. 'Who knows about tissue donation?' Hardly anybody. And a lot of that goes back to the way our place was conceived and set up.

You might think at first blush that having a tissue bank inside a public mortuary facility is an odd choice in a way, but that was part of the DNA of our institution, if you like. We were founded in 1988 because of significant gaps in the quality of forensic evidence, and my predecessor as director, in the thinking around that time, which included the government at that time, was very influenced by a tissue bank set up in Texas, actually, which was in the setting of the sudden unexpected death of a young person, a tragedy. Families ought to be given the opportunity to salvage something from that grief, and the opportunity for tissue donation when they could not be organ donors was the thing. So the tissue bank became part of the institute in those days. But that means—since the institute is in justice, not in health—we have got a logistical and administrative reach to span every time.

Tissue banking, as Brendan has said, is not front of mind for people, and we need to do a lot of work there to make it front of mind so that when people are having the conversations around organ donation, they also have them around tissue donation. Also, as a consequence, there is a lot of education that is required in the medical profession, because all my friends who are doctors are similarly ignorant about the operations of the tissue bank. And its importance—I just want to add this one last thing—never was more clearly seen than in the wake of the bushfires, a defining moment in the life of the institute, I have to say. 173 people died in 2009, and one of the things that happened as a consequence of that was that the people who did not die and were severely burnt ended up at the Alfred, and they were using our skin as part of that treatment. But very soon we ran out of skin, and that was just an insight into the criticality of supply in this area and how we need to be supported to maintain that supply.

The CHAIR: Okay. I am hoping you can also touch on how you at the tissue bank interact with the Australian organ donation register and how you access it.

Chantel BARTOLO: The nurses have access to the Australian organ donor register. So if we have someone referred to us—we work within the coronial system as well, assessing people reported to the coroner for donation—anyone that we would look at we would check the register for.

The CHAIR: So you have access to the register, but then you also need to go into the hospitals for access to the medical records. Is that correct?

Chantel BARTOLO: If someone dies within a hospital environment, then we do need information from their treating doctor or nurse to get a bit of an idea of what has actually happened to them in hospital.

The CHAIR: And to understand if they would be a suitable tissue donor.

Chantel BARTOLO: Exactly right. It forms part of our suitability assessment to make sure that person would be a suitable candidate for tissue donation.

The CHAIR: Is there any other information that could be recorded on the AODR that would be beneficial to support tissue donations?

Chantel BARTOLO: That is a really good question and not something I have actually given much thought to. I think the Australian organ donor register really forms a basis to open up a conversation with the family. So regardless of whether or not someone is registered, if someone was not registered or was registered as a 'yes', you would still approach the family. Having someone registered opens up that conversation in that you can share that with the family and let them know that this person had made their wishes clear in life that they wanted to donate. So that can help open up the conversation and help guide the family in what their decision-making might be around it. In terms of other information that might be useful, I am not too sure, because it just forms that basis for the start of the conversation.

Brendan SULLIVAN: Currently on the app accessible via Medicare you can select various organs and tissue types, so it is evident there. But perhaps the most common use of the language, the organ donor registry, if that were to be 'organ and tissue donor registry', there would be an immediate advertisement that tissue exists. If that were prevalent in the language more so than organ donation—it is organ and tissue donation—that would be a significant step forward to help us.

The CHAIR: Okay. I would be happy to hand over to some Committee members for questions now. Chris, thank you.

Chris CREWITHER: Firstly, thank you very much for your comprehensive submission and your time giving evidence today. It was good to read your submission as well, because it made a number of different points and unique points compared to other submissions as well, particularly given your experience in the tissue field in particular. And that was reflected in some of the recommendations, which were more unique recommendations as well, so thank you. I just was interested in getting a bit more of your reasoning and the benefits of mandated real-time death reporting beyond what you have said in your submission and just interested in your further thoughts on that and the potential substantial benefits that such mandated real-time death reporting may have.

Brendan SULLIVAN: It is rare that we get notification of potential donors other than those coming through the organ donation pathway. One hospital in particular has developed a method by doing that, and it has been a very useful channel for us to learn from, but it is the exception rather than the rule. If we do not know that there is a potential organ donor—sorry, a potential tissue donor, there you go—then there is no ability for us to make an assessment. Having a mandated notification pathway or some kind of notification pathway, whether it is electronic or whether it is at the moment through human contact, certainly allows us to make a quick assessment, to make a quick check about a potential donor's existence or not on the organ donor register and to make a quick assessment about the cause of death and potential likelihood of being a suitable tissue donor. But the clock is ticking straightaway, so that is the crucial element there. It is not as though the potential donor can be worked up or worked towards a donation event and having the conversation with families prior; all of ours happens after the event, effectively.

Chris CREWITHER: I was also interested in your views and recommendations relating to the real-time death reporting by GPs of those outside the system—the problems of not having such a system in place at the moment and the benefits that such a system may have and whether you think that should be a mandated system or a voluntary system or whether at least having a system in place to start with would be a good thing or not.

Brendan SULLIVAN: Yes, the recommendation for us is that we do not know what potential scope that might have and so the recommendation is that we would like to suggest that there be some research into that area. As Chantel might want to comment on, doctors in general—and I do not mean to demean doctors—have a much greater understanding of the criteria for acceptability for organ donation and a much lesser understanding of the same criteria for tissue donation. Do you want to comment on that?

Chantel BARTOLO: I think there has been a lot of work done over several years in hospitals to make sure that the opportunity for organ donation is not missed. There are a lot of guides out there for doctors and a lot of education for doctors to make sure that, if someone might be suitable for organ donation, they raise that with the DonateLife team. However, many doctors do not realise that tissue donation can happen when organ donation is not possible. It can happen in conjunction with organ donation, but it can also happen on its own,

and many do not know that the Donor Tissue Bank are here to receive referrals and to help them through that process of determining if their patient might be suitable for donation.

I think the same applies obviously in the GP network. A lot of GPs do not necessarily know about tissue donation. If they have gone to someone's home to verify someone as deceased, as needs to be done, and to complete a cause of death medical certificate, then there is an opportunity there that that person might also be a suitable candidate for tissue donation.

We operate very differently in that tissue donation is possible after someone has passed away. We can work that process up, but we only have that very limited time frame of 24 hours to be able to do that. Like Brendan mentioned, we are not sure of what that scope might be. If people are dying in the community, it might be that the reasons why they have passed away are contraindications to tissue donation. We just do not really know whether they may or may not be suitable, and it would be good to be able to do some research into that to see if there are potential candidates out in the community who might be suitable.

Chris CREWETHER: What is the current pathway, for example?

Chantel BARTOLO: We have multiple different ways for how someone can become a tissue donor. As I have mentioned, we work closely with our DonateLife colleagues, and if someone is being worked up for organ donation, they will also be considered for tissue donation. We very rarely—sometimes—have a doctor call us and refer someone who has passed away in a hospital and raise if they might be suitable with us. We also work within the coronial setting, so for every death that is reported to the coroner, we have our in-house team of nurses who will assess them for the potential of tissue donation as well. So those are sort of our main streams of how we might get a tissue donor.

Chris CREWETHER: In terms of, say, a GP seeing someone who might have passed away in their home, what are the current requirements of that GP in terms of reporting that person's death? Obviously GPs are very busy as well, but if they could have some simple system potentially where they could just click a button to report a death and automatically then notify all the relevant bodies that need to be notified—is that some sort of system that you might be thinking of?

Chantel BARTOLO: At this point in time, as you mentioned, GPs are busy, so I think we need to, firstly, do that research to see if there is any value in mandating anything around GPs, because if the deaths that are happening in the community are happening for reasons which might exclude them from tissue donation, we do not want to create extra work for GPs. However, some of these people might be suitable for tissue donation; then we would not necessarily need a lot of information to be able to start the process. Some of the important things that we might need are the person's name and date of birth to check them on the Australian Organ Donor Register. Why they have actually died would also be very handy information to know, and that cause of death would be written on their death certificate of course which, if it had already been entered somewhere else, could just pop into another database.

Brendan SULLIVAN: I think it is important to also highlight that most of our recommendations relate to the potential donors within the healthcare system already, so the GP, or potential deaths in the community, is the final one for just potential investigation. But just to your question earlier, 'What are our pathways?', within our paper you will see that in 2022 we had 58 tissue donors, 20 of whom came through non-DonateLife sources, and 17 of those were coronial cases. But of all the cases coming through the coronial system—for only 17 to become tissue donors means we had a success rate, or a consent rate, there of 0.3%. The reported deaths to the coroner are around about 10% of the deaths in the community, so we are dealing with 10% of deaths that need to be investigated, and 0.3% of those became a tissue donor in 2022. The other 38 donors came through referrals from DonateLife. So it is our greatest source of potential tissue donors, but you have to keep in mind that DonateLife are working in the organ donation system primarily, and where they have offices based in hospitals—and we have had experience with this in a regional hospital—that are not generating organ donation, then they will move those offices to places where their resources are needed, yet that regional hospital was a major source of tissue donations for us in terms of femoral heads from elective surgeries.

Rightly, DonateLife is funded for organ donation, and that is where it has put its resources, and that is a referral pathway for us, but we are advocating for a much greater allocation of resources to DonateLife, because they

are in the hospitals, with an additional focus or a parallel focus on the potential for tissue donation to come through that pathway.

Chris CREWITHER: Yes. Okay. And—you hinted at this in your opening statement—do you believe that the AODR, the Australian Organ Donor Register, needs a name change to include the word ‘tissue’?

Brendan SULLIVAN: I think I have said that already.

Gary MAAS: There is a Dorothy Dixier.

Chris CREWITHER: Almost.

Brendan SULLIVAN: I do not know whether to hit it straight back.

Chris CREWITHER: We can put the ‘tissue’ before the ‘organ’ if you like.

Brendan SULLIVAN: We would love to see that, and we are not the only tissue bank that has that same opinion.

Chris CREWITHER: You talk about decentralisation of tissue retrieval; I wonder if you can elaborate further on your submission in that regard as well.

Brendan SULLIVAN: Again, it is not something that we are capable of with our current resources, given that we are not for profit and we can only manage to do cost recovery and we have only just become self-sufficient in that regard. But other tissue banks in other states will send out teams of retrievalists to hospitals to do tissue retrieval at the hospitals. All of our tissue retrievals done by our own staff are done within the dedicated facility we have at Southbank. It is adjacent to the state mortuary, but it is a dedicated retrieval suite. It has got much better conditions, I must say, than you would find in most hospital settings in terms of air quality, cleanliness, procedures, policies, monitoring, bacterial contamination—all those things are live and active—and it generates for us a better result in terms of less contamination of tissue from potential pathogens or whatever else that can be the reason that tissues have to be discarded down the track after all the effort that has gone on for the donations to occur and for the retrievals to happen.

Tissues that are retrieved in hospitals can come to us either as femoral heads or even donated hearts, which are shipped to us from an organ donor where the heart is not able to be transplanted to another patient, so effectively it is a deceased heart, and we can then retrieve the heart valves from that tissue. But almost invariably the discard rates for tissues that are retrieved in hospitals are greater than what we can achieve in our own dedicated facility. And that is a heartbreaking thing—to have a donation occur but then a discard because of contamination from whatever source. So yes, we are dedicated in Southbank, but we would like to have the additional resources, where it is not possible to transfer a potential donor, to be able to send out retrievalist teams and have access to either an operating theatre or preferably at least a theatre—and if not, then certainly a clean space in a morgue—where retrieval can occur. But we know it will not be the same quality as the air we are operating in now.

Chris CREWITHER: Yes. Last question, if that is okay, Chair.

The CHAIR: Yes.

Chris CREWITHER: On public awareness raising and education, particularly around tissue donations, do you think there needs to be a dedicated, funded campaign by the government, particularly maybe an emotive one that incorporates people’s understanding of fires and so on? Do you think there needs to be such a campaign done in Victoria?

Brendan SULLIVAN: We would welcome and we recommend that there be greater public awareness, so however that is achieved, it would be great. My personal opinion is that a once-a-year campaign to increase registrants on the registry, while it helps us, does not necessarily increase awareness across the board, particularly of tissue donation. So I would much rather see it far more embedded in routine activities across the year. As others have said before in other submissions, where there are particular life events at which registration on the organ donor registry can be brought up, we would like that to be registration on the organ and tissue

donor registry along with potentially some educational information to go with that. So it is absolutely campaigning, but not so much in a dedicated campaign as continuous wider-based knowledge.

Chris CREWETHER: Thank you.

The CHAIR: Thank you. Gary, over to you.

Gary MAAS: Yes, thank you. And thanks very much for your appearance today and for the evidence you have given both in your very comprehensive submission and so far at the hearing. You have detailed the low numbers of tissue donation in the state and in the country. I am going to ask you a Dixer as well. What is your view then on family members overriding the wishes of registered donors?

Brendan SULLIVAN: I think that is a much wider discussion point than we can respond to as a tissue bank.

Gary MAAS: It is referred to in your submission, but yes.

Brendan SULLIVAN: I do like what we heard from the Alfred group, and DonateLife in particular, making a distinction between registering on the registry and having informed registration or informed consent, and there are some nuances in between as well. Perhaps this goes to foreshadowing the question about opt-in versus opt-out, but there are distinctions in between those things. It can be from registration to informed registration, and people have also recommended considering having a family sign off on a statement that says they are overriding their loved one's wishes. We recommend that they be considered, but we are not particularly wedded to any one outcome, because I think it is a much broader societal issue than we have the right to step in and state, particularly as a department within the public service.

Gary MAAS: You have also mentioned opt-out, which, if I have correctly noted, other members of the Committee have spoken about as well. Just keeping that in mind—about the donor's wishes versus potentially the family's wishes and the very short period of time that you do have—is there any preferred jurisdiction that you might say does that well, potentially, with the opt-out system?

Brendan SULLIVAN: I am not familiar enough with opt-out systems to be able to answer that. I know in some jurisdictions there are cases where a registrant cannot be overridden by the family member. I know in the US that is the case. That can cause conflict. But I would like to throw this one to Chantel, because I think the importance of family cooperation is critical, so to create a barrier there is to potentially lose a donor. Can you comment on your experience or the experience of your nurses teams in having those conversations?

Chantel BARTOLO: Yes, sure. One of the things that we do when we contact a family to raise donation with them—we obviously raise donation and explore whether that is something their loved one would have wanted. Having them registered on the register is a good starting point for that, like I mentioned before, but if they are not, that is okay. We share information with them for them to be able to make a decision they feel comfortable with. One of the things we very much need in that donation conversation is the cooperation of the family, because one of the things we do during that conversation is complete a medical and social history questionnaire, which goes through the person's past medical history, their social history and lifestyle factors to help us determine whether that person is going to be a suitable tissue donor. We need to be able to complete that. It is one of our screening methods and one of the things that allows us to then release the tissue for transplantation at a later date. So if the family are not comfortable with proceeding with donation, they may not be able to complete that questionnaire with us. So for us, you know, regardless of whether it is opt-in or opt-out, we still need the family's involvement in that donation conversation.

Gary MAAS: It is such a traumatic time that this decision has to be made as well.

Chantel BARTOLO: It is a very sensitive time and a very hard time for the donor families.

Gary MAAS: The next part I wanted to move to is the diversity of donors—so, CALD communities, First Nations people, youth, postcodes. Are there any major differences between any of those groups that you see, and if so, what could be done to help increase the diversity of tissue donors in Victoria?

Chantel BARTOLO: I think we do not collect—and please correct me if I am wrong, Brendan—particular data on that sort of thing. We are quite a small organisation. I think regardless of a family's background, everyone has their own beliefs that come into play when we discuss donation. I think that your question as to

how you might get different engagement is—every conversation needs to be approached with sensitivity to that particular family and that particular family's needs.

Gary MAAS: Did you want to add to that?

Brendan SULLIVAN: No, we do not gather information about the cultural background of donors. In fact we do not have data on the number of registrants on the donor registry and their cultural background. That really is a situation for OTA—and I know you were questioning them this morning about their campaigns and whether they can target other communities. We would welcome that, and we would welcome any increase in numbers on the donor registry.

Gary MAAS: Terrific. No further questions from me. Thank you.

The CHAIR: Thanks, Gary. Cindy.

Cindy McLEISH: Thank you. I have got a few quick yes/no ones to start with—or easy ones. How many tissue banks are there in Australia?

Brendan SULLIVAN: I do not have a quick answer to that, because there are a number of very small ones. There are three large ones, can I say. There is the Queensland Tissue Bank. There is the NSW Tissue Bank, although there are a number of splinter groups within that, particular bone banks that retrieve femoral heads only. There is the tissue bank of Victoria. There is the Barwon Health bank in Geelong, which is a femoral head collection service. I am not counting eye banks here, by the way. Some of them are included—Queensland includes eye; New South Wales includes eye. We do not, because there is the Lions Eye Donation Service. South Australia has an eye bank only—no tissue banks other than that. Western Australia has PlusLife, which is a charity which focuses primarily on bone. So as I said before, multi-tissue banks—there are three in the eastern coast states.

Cindy McLEISH: Are they all not-for-profits, or are some of them linked in to hospitals, like the Barwon Health one?

Brendan SULLIVAN: All the government-owned ones are not-for-profit. There is one commercial enterprise in New South Wales which does tissue processing on behalf of the NSW Tissue Bank, and it has been set up as a for-profit organisation.

Cindy McLEISH: How many tissues can you harvest at once? If you have got 24 hours, and there are delays and you have really got to get things moving, how many –

Brendan SULLIVAN: Well, at least the four tissue groups, plus we also then facilitate access to the Lions institute to come to the mortuary and retrieve corneas. We can have skin, which may be up to 30 pieces of skin which can be used for individual patients or all on one patient. We can have 12 to 14 tendons. We can have four major long bones retrieved and two cardiac valves dissected out of hearts. The bones themselves can then be—typically they are not processed straightaway, but all the other tissues are processed within 24 hours. They are not frozen until they are sized, trimmed, tested –

Cindy McLEISH: Okay. And then you freeze them so then they have got a good shelf life.

Brendan SULLIVAN: Yes. The bones will be frozen but then brought back at some point later on, and they can be turned into potentially 100 different grafts.

Cindy McLEISH: So even with something like a heart valve, you still have to get that out within the 24 hours?

Brendan SULLIVAN: We have to have the retrieval of the heart done within 24 hours. We then have to process the tissue within the next 24 hours and freeze it.

Cindy McLEISH: Okay. Why are you in the department of justice? And have you tried to have that changed?

Noel WOODFORD: When you say the tissue bank, the tissue bank is with the justice department because it is part of the Institute of Forensic Medicine, and that was a decision taken way back in the conception about where the Victorian Institute of Forensic Medicine ought to be. We have had discussions with Health over the journey about support for the tissue bank in another location. We have talked to organisations like Lifeblood about partnering, if not full transfer, but over the journey those have been complex conversations that really have not changed the state that—the tissue bank remains with us.

Cindy McLEISH: So which minister is in charge?

Noel WOODFORD: Which minister?

Cindy McLEISH: Is responsible.

Brendan SULLIVAN: The Attorney-General.

Cindy McLEISH: It is under the Attorney-General?

Noel WOODFORD: For us? The Attorney-General, yes.

Cindy McLEISH: It is under the Attorney-General. So we have had before Parliament in the last few years a number of bills with regard to information sharing, and it was always talked about as health sharing—health data sharing. Were you ever consulted about that, about being included? Because you are talking about not having access to a lot of the health data, when the purpose of the bill was to make these sorts of things easier. I am just wondering why that is not the case for you.

Noel WOODFORD: Well, when you are talking about data sharing, a lot of that is in the coronial context for us about getting access to information from hospitals. Brendan has already articulated what the difficulties are. Because we are in justice it is institutionally difficult, so that means that we need to try harder to bridge those gaps. We have been part of conversations in the past –

Cindy McLEISH: But equally, it goes two ways—it is not just you trying harder; it is government trying harder too.

Noel WOODFORD: Yes, I know that.

Brendan SULLIVAN: Thank you.

Noel WOODFORD: Thank you.

Cindy McLEISH: I guess my last question is really: you outlined a few blockers and things that make things really difficult. Why do they exist? How have you tried to knock some of those down? I know you are limited in resources, you are a not-for-profit and you mentioned earlier resources around trying to streamline and make some of the processes more efficient, so I know that you are hard up for time.

Noel WOODFORD: Well, time is the most precious commodity in all of this, and when you are thinking about somebody who dies in hospital, there is conceptualising about whether or not the person might be considered to be a tissue donor and then the practicalities of moving the person to our institution. So anything that we can do to obviate some of those difficulties—and Brendan has mentioned the possibility of tissue donation within the hospital environment, maybe after the organ retrieval procedure or in a niche area of the operating theatre complex—we would welcome a discussion around. But the clock starts ticking, and the difference between us and organ donors is that there can be a certain amount of planning with organ donation. In terms of withdrawal of support, it is often planned in advance so surgical teams can arrive, but the information deficit or the lack of communication with us often means that we are the last in the chain to find out, and the clock has been ticking all of that time.

Cindy McLEISH: Yes. That is right, you are the last in the chain, so how do we change that to knock that barrier down?

Noel WOODFORD: Well, we have talked a little bit about those obligatory notifications at the time when DonateLife is notified.

Cindy McLEISH: And that is working through the department of justice, or getting a round table with the health department—how is that –

Noel WOODFORD: Exactly. Both.

Brendan SULLIVAN: I think a key thing is a simple thing such as we do not have an email address that ends with health.vic.gov.au, so the information sharing does not go beyond the health area because we are not in health.

Cindy McLEISH: Yes, it is a silo. Okay, thank you.

The CHAIR: Thank you, Cindy. Annabelle.

Annabelle CLEELAND: Thank you. Mind blown; this is very interesting. Have you participated in previous inquiries from a state or federal level or even in a department investigation in this space?

Brendan SULLIVAN: Look, I am aware that before my time we were part of the PricewaterhouseCoopers investigation in 2016 into the Australian tissue landscape. Since then we have been involved in a number of federally based discussions and inquiries, but it is all about funding and pricing and prostheses list reforms, so not so much about structural issues in the tissue sector.

Annabelle CLEELAND: In terms of donor and tissue inquiries, is this the first time that you have been included in a donor inquiry?

Brendan SULLIVAN: I believe so.

Noel WOODFORD: To the best of my knowledge, yes.

Annabelle CLEELAND: Were you a part of the Victorian Department of Health's 2020 review into the donor inquiry? Did you contribute to that?

Brendan SULLIVAN: No.

Annabelle CLEELAND: You were not invited.

Brendan SULLIVAN: No, that was about organs.

Annabelle CLEELAND: Just organs, yes—just clarifying. In terms of supply and demand—not to be insensitive about my terminology, I am sorry—are you currently meeting the volume of demand for tissues in Victoria with your supply barriers?

Brendan SULLIVAN: No, we are not able to. The Alfred Hospital is where virtually all of our skin donations go, and they are constantly looking for more supply from us. They sometimes have had to, in recent times, seek skin tissue from the NSW Tissue Bank, which is retrieved by a different method. They prefer to use the tissue processing method that we use, but they have had to take that option because we have been out of tissue periodically regularly over the last several months. A good example was in particular the White Island volcano disaster in 2019, where the Australians who were on that cruise were repatriated back here. The Victorians were treated at the Alfred, and we could not meet that supply. Again it was before my time, but we had to apply to the TGA to get a special access scheme import approval to import skin from the US to meet that demand.

Annabelle CLEELAND: And is the standard different to what we expect in terms of tissue retrieval? Like, what are the health risks for importing tissue internationally?

Brendan SULLIVAN: In that case, that was not a concern as far as I am aware. It is an exportable product, so it is approved by their local health authorities. So I do not believe that is an issue in terms of quality.

Annabelle CLEELAND: I know that you do not really have reserves, but just explain your storage capacity and the longevity when you do have a tissue. How long are you able to have it in storage?

Brendan SULLIVAN: All of our tissues can be stored for up to five years in a frozen state. Sometimes there is risk in doing that. As part of cardiac retrieval we used to retrieve the pericardium, the sac around the heart, which was used in paediatric surgeries. So we have had that frozen in freezers, but the practitioners have moved away from using that tissue. In terms of us trying to run a not-for-profit operation, there is opportunity cost in that; there is time and effort expended in doing that and processing that tissue and freezing it for it to come to five years later and have some of that tissue that is unfortunately still in our freezers. We have to respectfully discard that; it goes through a cremation process and has a chain of custody et cetera, all documented. So there are risks in what we do with a five-year time frame, but they can last that long.

You asked before about shortage of tissue. We do not have sufficient tendon tissue to satisfy the orthopaedic surgeons, necessarily, doing joint repairs and things. We have a shortage, often, of cardiac valves of the right size. Most of our cardiac valves are used at the Royal Children's Hospital and some at other major public hospitals in Melbourne. They are very size-specific, depending upon the patient. So while we might retrieve cardiac valves, they are not always the right size for that particular patient that is coming up for surgery.

Annabelle CLEELAND: And—Chantel, this might be your question—how many conversations do you initiate with a potential tissue donor where donation does not get executed because it is beyond the 24-hour time limit?

Chantel BARTOLO: If we think that we might meet that 24-hour time period—we allow ourselves enough time for the retrieval of the tissue groups. At times someone might be age appropriate to donate multiple tissue groups, but we have to limit that down to one because we only have enough time to retrieve one of those tissue groups and we need enough time to have a conversation with the family—a family who may or may not have spoken about tissue donation before. So we need to allow enough time for the family to have time to consider the information given, to discuss with relatives and to make a decision that they are comfortable with. If we deem in the process that we are going to hit that 24-hour time period, we cannot proceed. We do not want to raise donation with the family and then turn around and say, 'Hey, we didn't have enough time, sorry.' So we need to make sure that there is enough time.

Annabelle CLEELAND: I might reframe that then: how many potential donors are you notified of where you know you will not achieve that 24-hour limitation because of the clunkiness of the process?

Chantel BARTOLO: When we are notified of a donor, we are usually notified through the DonateLife network, and these are cases that are being worked up for organ donation. We are notified before they actually go for the organ retrieval procedure, so we are able to facilitate most of what is consented for, within restrictions with our own resources sometimes.

Annabelle CLEELAND: Okay. Being a part of the department of justice, what do you see as the greatest barrier to trying to achieve an increase in tissue donors, while in, effectively, the wrong department?

Brendan SULLIVAN: It is simply I think the flow of information from hospitals to us. That is by far the greatest opportunity that we see that is not maximised.

Annabelle CLEELAND: Can you give us an example of where that has occurred and has limited tissue donations?

Brendan SULLIVAN: It is difficult sometimes to know when we have not been notified. In fact it is difficult in every case when we have not been notified. But there have certainly been delays. Chantel's team have had times where phone calls through to hospitals to seek information about a potential donor have been rejected because they thought it was a hoax or because they had not heard of tissue donation at all.

The CHAIR: Can I ask a question to follow up on that one, though? Could you give us an example of when it has worked well or what you see as best practice?

Chantel BARTOLO: Yes. I think best practice would be if—I want to focus on tissue-only donors, because I think we have developed this process with DonateLife for when someone is suitable for organ donation, and we do work well with our DonateLife colleagues. I think we have done a bit there. Just looking at someone who would be specifically only for tissue donation, being notified by someone in the hospital, either before that person is going down an end-of-life care pathway or if their death is unexpected, as soon as possible after that

person is deceased would mean we might be able to conduct a bit of a suitability assessment with the treating doctor or the treating nurse over the phone, obtaining a bit of a medical history, obtaining a bit of a social history and finding out who might be the best person to speak with about tissue donation for that particular person. From there we would contact the family and raise donation with them and explore whether that is something their loved one would have wanted and, if the family consents, complete our history questionnaire to help again determine suitability. From there we would transfer the deceased person from the hospital mortuary to our own facilities for the tissue retrieval process. So that would be a nice, streamlined process—everyone is sharing information and there are no obstacles.

One of the biggest obstacles, like Brendan mentioned, is that information sharing at the start. We do not know if someone has passed away in a hospital. We are reliant on our DonateLife colleagues to be in hospitals telling us when that is happening. There are many deaths that happen in hospitals that may be suitable for tissue donation, but that is not really being explored at this particular point in time. The next barrier is speaking with healthcare professionals. They do not necessarily know that we are here, that we are facilitating tissue donation, that they are allowed to share information with us and that they are allowed to do that under the *Human Tissue Act*, so they might blatantly refuse to share information with us. That has happened. They might be a little bit obstructive and not want to share particular pieces of information. So that is sort of the next step.

The next big barrier that we tend to come up against is the transfer of the person from the hospital to us. Again, a mortuary technician might not understand what we do. It is just general lack of knowledge and awareness in the community and in the hospitals about tissue donation. We have had cases where we have had to go to senior chief medical officers within the hospital to try and release a person from a hospital mortuary to our facility for tissue donation, and that was where the family had consented to tissue donation. If you are hitting those sorts of barriers, there goes time, and time is of the essence.

Annabelle CLEELAND: You are dependent on DonateLife donor coordinators to have this conversation. Is that a –

Chantel BARTOLO: Not necessarily to have this conversation—when there is an opportunity for organ donation, then the DonateLife nurses will raise organ, tissue and potentially eye donation, depending on what the person is suitable for. If the person is not suitable for organ donation, then we would raise tissue donation with the family. We are reliant on being notified that the person is either going down an end-of-life care pathway or is deceased and may be suitable for tissue donation. Does that clarify?

Annabelle CLEELAND: Yes. But is that a kind of voluntary or in-kind commitment from DonateLife? I am just wondering—is there any sort of formal collaboration that needs to be established between you and DonateLife and their coordinators to ensure that you have a greater –

Chantel BARTOLO: We have an MOU with DonateLife to facilitate that.

Annabelle CLEELAND: Sorry, I am conscious I have just taken advantage of your time. You mentioned about your operational costs. How have you become financially sustainable now as a not-for-profit when—I think you raised that you had some challenges in the past?

Brendan SULLIVAN: Yes. For many years the tissue bank was run at a deficit and funded out of surplus VIFM funds—Noel would say they are not surplus at all. They have made a dedicated commitment to maintaining the service that we provide.

Part of our funding comes from recovery of costs. So we are permitted to make tissues available for a cost-recovery price based upon the listing on the prostheses list. By having an improved product developed in-house in the last few years, which can be transported without having to be frozen—so a bone product that is freeze-dried—it has allowed us to transport it further from the Melbourne metropolitan area. So we have been able to have more of that available, and that therefore generates a return that helps cover the cost. Really it is a cost recovery only, and that is all we have been permitted to do—recover the cost of the retrieval, processing, storage and distribution.

Under the national tissue framework, which was mentioned this morning by the OTA team, there is also a provision for funding to help generate sustainability and innovation as well, which can be considered as part of the cost of running that operation. We have not had decent R and D for a long, long time. We have had one R

and D manager who has developed the cancellous bone matrix and demineralised bone matrix, which is freeze-dried tissue, in 20 years. In fact there are commercial players in the market importing processed tissue that are developing far more advanced tissues than we are. So the risk really for our institute or for our tissue bank is that we will be left behind, that the recent growth that we have seen easily peters away and that Victoria then loses a potentially valuable biotechnology enterprise.

Annabelle CLEELAND: And you mentioned the NSW Tissue Bank—I promise this is my second last—which is for profit.

Brendan SULLIVAN: No. It is a tissue processor that the NSW Tissue Bank subcontracts to process their bone tissue and turn it into multiple grafts.

Annabelle CLEELAND: And that is for profit.

Brendan SULLIVAN: Correct.

Annabelle CLEELAND: Are there any risks in that—being majority not-for-profits in this space yet that is for profit?

Brendan SULLIVAN: Risk is an issue that should be regulated by the TGA. They inspect all of us and hold us to high standards, so in terms of quality risk, there should not be any risk. But a profit motive is different to a not-for-profit motive, so that may introduce commercial risk and commercial threat to not-for-profit organisations.

Annabelle CLEELAND: Okay. I have one more question, but I know that –

The CHAIR: I have a question too.

Annabelle CLEELAND: Okay. Just the US market—you mentioned about the mandated rapid reporting of deaths by hospitals to their designated organ procurement organisation. Could you just summarise the biggest barriers to that occurring—quickly—in Victoria at the moment?

Brendan SULLIVAN: I guess in their environment they have organ procurement organisations who have a dedicated territory, and if you are a hospital in that territory, you must report to that organisation. There is not such a territory, if you like, defined in Australia for tissue banks. That is one element.

Another element is that the hospitals there undergo accreditation. I am not sure what the body is, but they accredit the hospital on a whole range of quality and performance metrics, and one of those metrics is that a death in the hospital must be reported within one hour. So it is a metric that that hospital is held to account for. I would love to see an accreditation metric –

Annabelle CLEELAND: Do we have a metric? No.

Brendan SULLIVAN: in hospitals in Victoria that does something similar.

Annabelle CLEELAND: Thank you so much.

The CHAIR: Cindy.

Cindy McLEISH: Mine is another very quick one. You mentioned before that you are having to import skin from the USA—I am not sure how quickly that gets here—but also not being able to meet some of the demands of the orthopaedic surgeons when they are doing the joint work. Is there a lot of work being done in synthetics, or are the surgeons preferring, I guess, the harvested tissue?

Brendan SULLIVAN: I cannot really speak to what happens outside of our own sphere, but there are certainly synthetics across all of those areas, including synthetic skin types and those kinds of things.

Cindy McLEISH: And heart valves.

Brendan SULLIVAN: And heart valves. There are prostheses that exist. But for various types of patients, human tissue is often the best tissue.

Noel WOODFORD: It is surgical preference as well. There are artificial tendons, for instance, out there. Some surgeons for various reasons, including individual patient imperatives, would choose our tendons over a synthetic version. And just on the heart valves: yes, there are a whole lot of prosthetic heart valves out there—mechanical valves, pig-derived valves. One of the reasons our valves are important is that for women of child-bearing years—because it is human tissue, it is easily implantable and does not require anticoagulation in someone who is trying to get pregnant.

Cindy McLEISH: Thank you.

The CHAIR: I just have one question to finish on. Annabelle raised a question earlier about how the Donor Tissue Bank works with DonateLife Victoria, and you mentioned that you have a MOU, which is great to hear. I guess my question is more around national governance and the national eye and tissue sector framework and whether that is an opportunity for the Donor Tissue Bank to work with the Organ and Tissue Authority in a better model, potentially one more similar to DonateLife Victoria's model. Is that something you see as an opportunity?

Brendan SULLIVAN: The framework does not really canvass that, but it is meant to be a guide for all governments, as it says, to help foster the tissue sector—the eye and tissue sector—and encourage investment and innovation but also encourage quality standards increasing. There are some internally conflicting goals within that. There are also cost management and cost constraint, with a hint therefore of benchmarking of tissue prices against each other's tissue banks even though we are all operating in very different circumstances. Some are housed within a hospital and are therefore not paying floor space rent et cetera, so we have all got different cost bases. But the framework is setting an idealistic situation. It does not really canvass the governance of all the tissue banks coming under one roof.

The CHAIR: Does it consider the role of the donor support nurses with DonateLife Victoria who go and look at whether a person would be suitable for organ donation? Does it consider a similar opportunity for people who would be suitable to be tissue donors?

Brendan SULLIVAN: The framework again does not talk about donations so much as the processing of the tissue that follows.

The CHAIR: Okay. Is that something that you would recommend be looked at?

Brendan SULLIVAN: I guess part of what we are saying is we would like to continue our collaboration with DonateLife, and we would like, if we cannot gain resources, DonateLife to gain resources for us to work even closer with them so that they have the flexibility then to expand further into the potential for tissue donors as well. They are the ones on the floor in the hospitals and we are not, so we cannot really make a claim that we would like to be in hospitals alongside them and waste resources. We would much rather have a collaboration that works closer, and we have improved our relationship over time with DonateLife. We attend their quarterly meetings, education events et cetera. We do in-service in hospitals with the DonateLife local member for nurses in hospitals, so there is a lot of that that goes on. But I do not want to duplicate resources. I would rather that we have a much better collaboration and that they be funded better but with a specific purpose of tissue donation.

The CHAIR: Great. Yes. Thank you very much for appearing before the Committee today and for your contribution to this important inquiry. The Committee really appreciates the time and effort that you have taken with your written submission but also in preparation for today's in-person hearing. Responses to any of the questions that you took on notice—I think there might have been one. Was there one in there? No questions on notice—fantastic. If there are any questions on notice, we will follow them up with you. But we will also provide you with a transcript of today's hearing. Thank you again for attending. We will have a short break now before our next witnesses. Thank you.

Witnesses withdrew.