Australian Vigilance & Surveillance System
ORGAN DONATION FOR TRANSPLANTATION

Australian Government
Organ and Tissue Authority

The Australian Vigilance and Surveillance System for Organ Donation for Transplantation

Inaugural Report
May 2020

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Foreword

There has been an important increase in the number of people donating their organs leading to a substantial increase in organ and tissue transplantation since the Australian Government's national program began in 2009. In 2019 the lives of 1,683 Australians were saved by organ transplants made possible through the generosity of 548 deceased organ donors and 239 living organ donors.

The success of our nationally coordinated program is the result of implementing a best-practice clinical system in our hospitals, combined with increasing community awareness.

It is crucial that Australians receiving a transplant can have confidence in the high quality and safety of our donation system. Serious adverse events are rare in organ donation for transplantation, however as in all health initiatives, it is important to have a robust system to identify all problems and adverse events so they can be reported and reviewed to work out how to stop them happening again and make the system safer. Each state and territory has always and will continue to capture clinical incidents through their own clinical incident reporting systems. 'The Australian Vigilance and Surveillance System for Organ Donation for Transplantation', commenced in 2017. The Australian system works in parallel with existing state and territory clinical incident reporting systems, which have responsibility for local reporting and clinical management of any incident. The national system enables a nationally coordinated process for the notification, monitoring, recording ,and analysis of adverse events.

This is the first report on the Australian Vigilance and Surveillance System following two full years of operation by the Vigilance and Surveillance Expert Advisory Committee (VSEAC) which has established an effective review and communication process. The experts in the various areas of activity are now monitoring, analysing and communicating with all who work in field of donation and transplantation.

This report is to provide the Australian community with a clear view of vigilance and surveillance in the system and provides confidence to those who need a transplant that we are doing everything we can to make it as safe as possible.

We thank and acknowledge the generous Australians and their families who have saved and transformed the lives of people needing a transplant through organ and tissue donation. We also acknowledge the dedication and commitment of our donation and transplantation specialists. Transplantation, and its life-changing benefits, would not be possible without this shared commitment.

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1 The Australian Vigilance and Surveillance System for Organ Donation for Transplantation

1.1 Background

Vigilance and surveillance are an essential part of any health care system. For organ donation and transplantation, vigilance and surveillance systems are established to ensure better quality and safety in organs donated and used for transplantation. Importantly these systems aim to review and avoid reoccurrence of a serious adverse event and/or reaction (SAER).

SAERs are infrequent and when seen individually may appear as simple isolated incidents, so it is important to have a central system to capture all incidents to gain a full picture and identifying trends. A national monitoring system enables the development of recommendations for system and process improvements, provides an opportunity for shared learnings, and ultimately improves the functioning and safety of the overall organ donation for transplantation system.

Reporting de-identified information on SAERs for shared learning is a critical component of any vigilance and surveillance system. This reporting enables clinicians working in the donation and transplantation system to improve clinical practice to further enhance patient safety.

Internationally, vigilance and surveillance systems to monitor and trace the safety of donated and transplanted organs are at various stages of development and implementation. Australia is in an early phase of implementation of our system which is gaining momentum following two full years of formal operation.

In 2010 the World Health Assembly endorsed a global mandate for Member States to collect 'appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions'[1]. This aligned with a priority of the Organ and Tissue Authority (OTA) to enhance the safety of organ and tissue donation and transplantation in Australia. Plans for the development of a national Australian Vigilance and Surveillance System for organ donation for transplantation commenced in 2011. A brief history of the development and implementation of this system is illustrated in Figure 1.

1.2 Defining serious adverse events and reactions

We have sought to include definitions of both events and reactions to review while aligning with international definitions. The Vigilance and Surveillance reporting criteria are based on the European Framework for Evaluation of Organ Transplantation (EFRETOS).

A **serious adverse event** is any 'undesired and unexpected occurrence associated with any stage of the chain from the donation to transplantation **that might** lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity'.

A **serious adverse reaction** is an 'unintended response, including a communicable disease in the recipient that might be associated with any stage of the chain from to donation to transplantation **that is** fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity'.

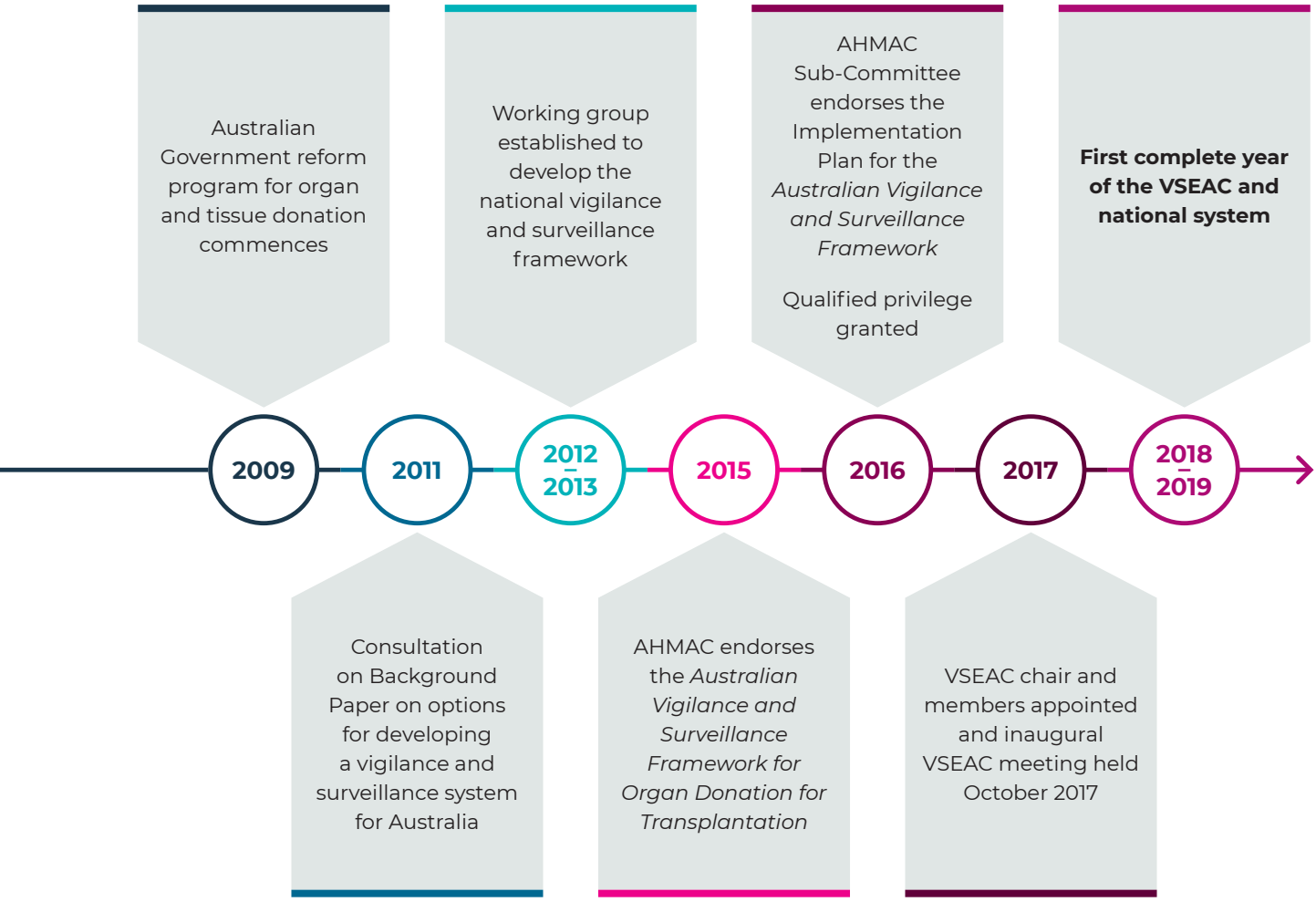
In addition to internationally defined serious adverse events and reactions, the Australian Vigilance and Surveillance System extends its surveillance to include notifications of **broader system issues** where practice improvements could be made. These are unexpected or undesired occurrences that fall outside the above international definitions, but may have consequences for **potential** transplant recipients such as:

- communication delays or miscommunications
- resource or logistic constraints related to surgical retrieval, transportation of organs, donation or transplantation services
- the process of retrieval and perfusion of organs; and
- the storage and transportation of organs and vessels.

These issues are considered at a national level to identify where process improvement should occur in the system to further increase donation opportunities for transplantation. This is a key objective of the OTA's strategic plan *Progressing Australian Organ and Tissue Donation and Transplantation to 2023: The 2019–20 to 2022–23 Strategy*.

1 Sixty-third World Health Assembly (2010) Human organ and tissue transplantation resolution WHA63.22

Figure 1 **Development and implementation of the Australian Vigilance and Surveillance System[2]**



Throughout the development and implementation phases, states and territories were and continue to be responsible for individual management of SAERs that occur within their jurisdiction

2 Figure 1: Australian Health Ministers Advisory Committee (AHMAC); Vigiliance and Surveillance Expert Advisory Committee (VSEAC)

1.3 Components of the national system

The Australian Vigilance and Surveillance System for organ donation for transplantation is designed to:

- work in parallel with jurisdictional clinical incident management systems in deceased organ donation and transplantation
- provide a national and international coordinated notification function
- monitor, record and retrospectively analyse SAERs
- inform future processes in organ donation for transplantation, and
- improve the safety and quality of organ donation and transplantation thereby improving patient outcomes.

The Australian Vigilance and Surveillance System provides a national and international coordinated notification function

The core elements of the Australian Vigilance and Surveillance System are the SAER notification database and the Vigilance and Surveillance Expert Advisory Committee (VSEAC).

Clinical response management and investigation of SAERs remain the responsibility of the hospitals and jurisdictions in which the incident occurred. States and territories continue to be responsible for:

- local reporting and immediate clinical management of an incident
- communication with associated clinicians and patients (including interstate where appropriate)
- investigation of the incident
- other aspects of a response to an incident including feedback, local policy and clinical practice review, and
- reporting the incident to the national system.

The Australian Vigilance and Surveillance system works in parallel with jurisdictional clinical incident management and reporting systems in deceased organ donation and transplantation.

The Australian Vigilance and Surveillance System complements state and territory clinical incident management and reporting systems by providing a national reporting process where information obtained is shared between states and territories to help inform future national advice, recommendations and guidelines. State and territory DonateLife agencies are required to notify SAERs to the Australian Vigilance and Surveillance System. Transplant units are encouraged to report all SAERs through their local DonateLife agency.

1.4 Scope of the national system

The Australian Vigilance and Surveillance System applies to solid organs donated for transplantation from deceased donors with the exception of issues resulting from the Australian and New Zealand Paired Kidney Exchange (ANZKX) program, which is a living donation program supported by the OTA. The system encompasses all phases of the process from donation to transplantation and post-transplantation, and extends beyond identifying donor derived infections.

SAERs arising from tissue and eye-only donation for transplantation continue to be reported under the Therapeutic Goods Administration (TGA) Biologicals Regulatory Framework and the appropriate jurisdictional incident reporting system. Reporting to the Australian Vigilance and Surveillance System is only required if the donor also donated organs for transplantation and the SAER has relevance to organ donation and/or transplantation.

1.5 The Vigilance and Surveillance Expert Advisory Committee (VSEAC)

The VSEAC comprises high level technical specialists with relevant expertise from key clinical, government and professional organisations. Membership is position- or skills-based, meaning individuals may be a formal representative of their respective organisation or may be appointed based on their expertise to meet the essential skills of the VSEAC membership. The VSEAC membership from October 2017 to December 2019 is at Appendix A.

In 2016 the VSEAC was granted inclusion in the Commonwealth Qualified Privilege Scheme (QPS). Further information on the QPS can be found at https://www1.health.gov.au/internet/main/publishing.nsf/Content/qps-overview.

The first meeting of the VSEAC was held in October 2017. In 2017 and 2018 the VSEAC met biannually and in 2019 the committee met three times. These meetings involved assessing and grading SAER notifications, as well as discussing broader issues for the ongoing development of the system and its process to ensure a robust national system. From 2020 the VSEAC will meet four times a year to allow for more timely review and analysis of the SAER notifications and reporting to the donation and transplantation sector to share learnings for practice improvement.

1.6 The VSEAC process

Figure 2 shows the pathway that is followed when an adverse event or reaction occurs. It demonstrates that hospitals and jurisdictions are responsible for the immediate and ongoing clinical management of the incident and that concurrently the SAER notification is submitted to the National Vigilance and Surveillance System via the State Medical Director of the DonateLife Agency.

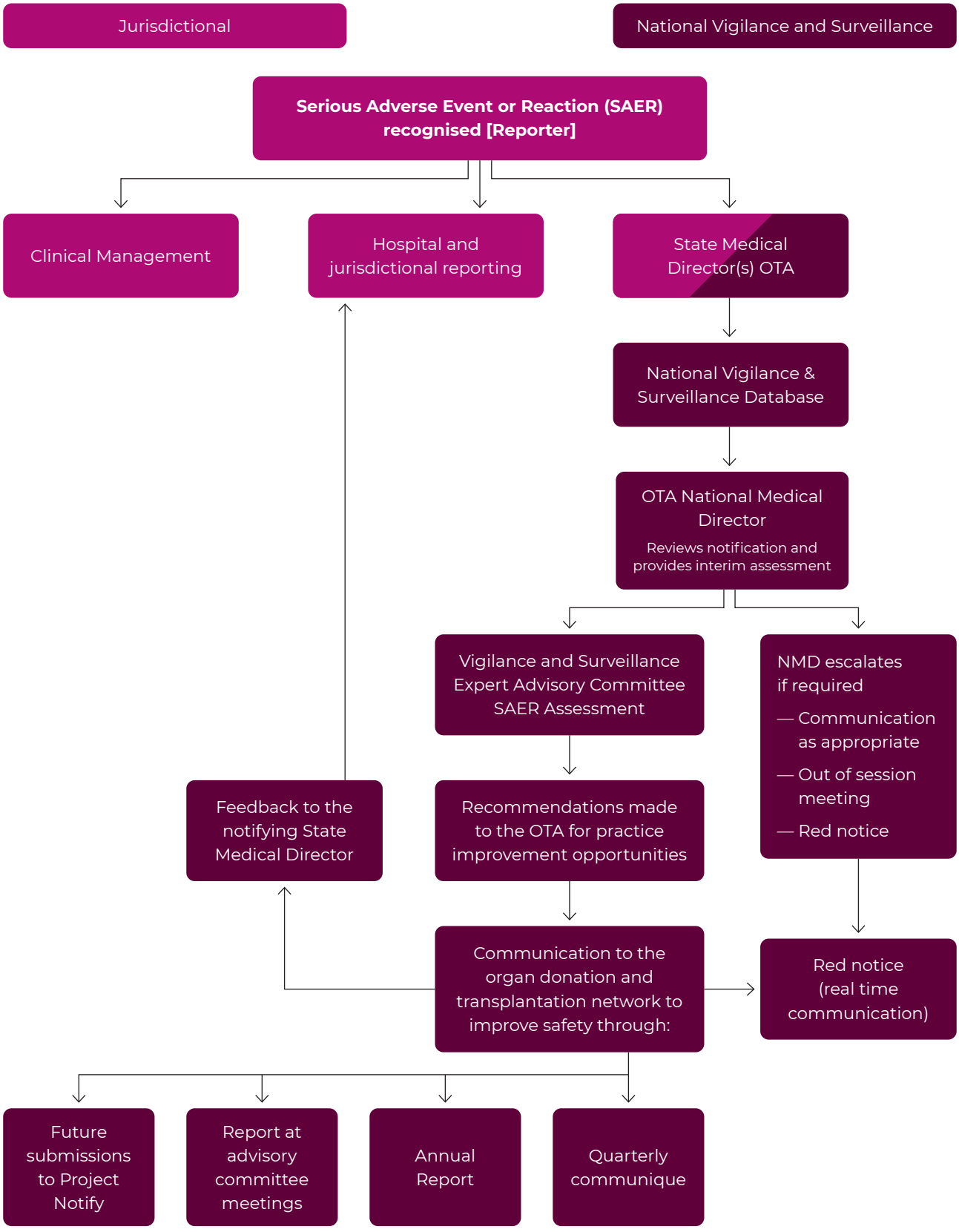
The SAER notification is reviewed by the OTA National Medical Director who assesses the notification and determines if further actions are required immediately. The notification is then reviewed by the VSEAC at the next meeting or out of session if a more timely response is required. SAER notifications are assessed according to severity, imputability, recurrence likelihood and impact of the event or reaction. Members are required to declare any conflicts of interest prior to the consideration of each case.

1.7 International vigilance and surveillance systems

The World Health Organisation 'Project Notify' was established in 2010 as a collaboration between international authorities in response to the 2010 World Health Assembly mandate to collect 'appropriate information on the donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions'[3]. The Project Notify library provides a catalogue of international documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The library can be found at https://www.notifylibrary.org/ and is intended as a communication hub for institutions and organisations worldwide which are collaborating in providing access to global vigilance and surveillance information. In 2020 the work of the VSEAC will include determining whether any Australian SAER notifications should be submitted to Project Notify, noting that relevant submissions would be those that relate to disease transmission from donors to recipients.

3 Sixty-third World Health Assembly (2010) Human organ and tissue transplantation resolution WHA63.22

Figure 2 **Communication pathway for SAER notifications**



2 Summary of adverse events and/or reactions reported nationally

The number of notifications by year from 2012 to 2019 is shown in Figure 3. The graph shows in each year the number of SAER notifications which meet the definitions of 'a serious adverse event' and 'a serious adverse reaction' consistent with international reporting practices and as outlined in section 1.2 of this report. It also includes the notifications that relate to broader system issues which are captured to reflect areas where practice improvement should occur. Often these notifications do not have adverse outcomes for an individual patient but could be a missed opportunity for donation which is reportable under the Australian Vigilance and Surveillance System framework. The graph shows that broader system issues were the predominant type of notifications in each year.

Serious adverse events and reactions in organ donation and transplantation are extremely rare in Australia

While the number of notifications submitted to the national system each year has been increasing since 2012, the total number of deceased organ donors, transplant recipients and transplant surgical procedures has also increased (Table 1). In 2019, the number of SAER notifications relative to the number of donor and transplant procedures was very low, with the vast majority of donation and transplantation occurring without incident.

Figure 3 SAER notifications by year: 2012 to 2019

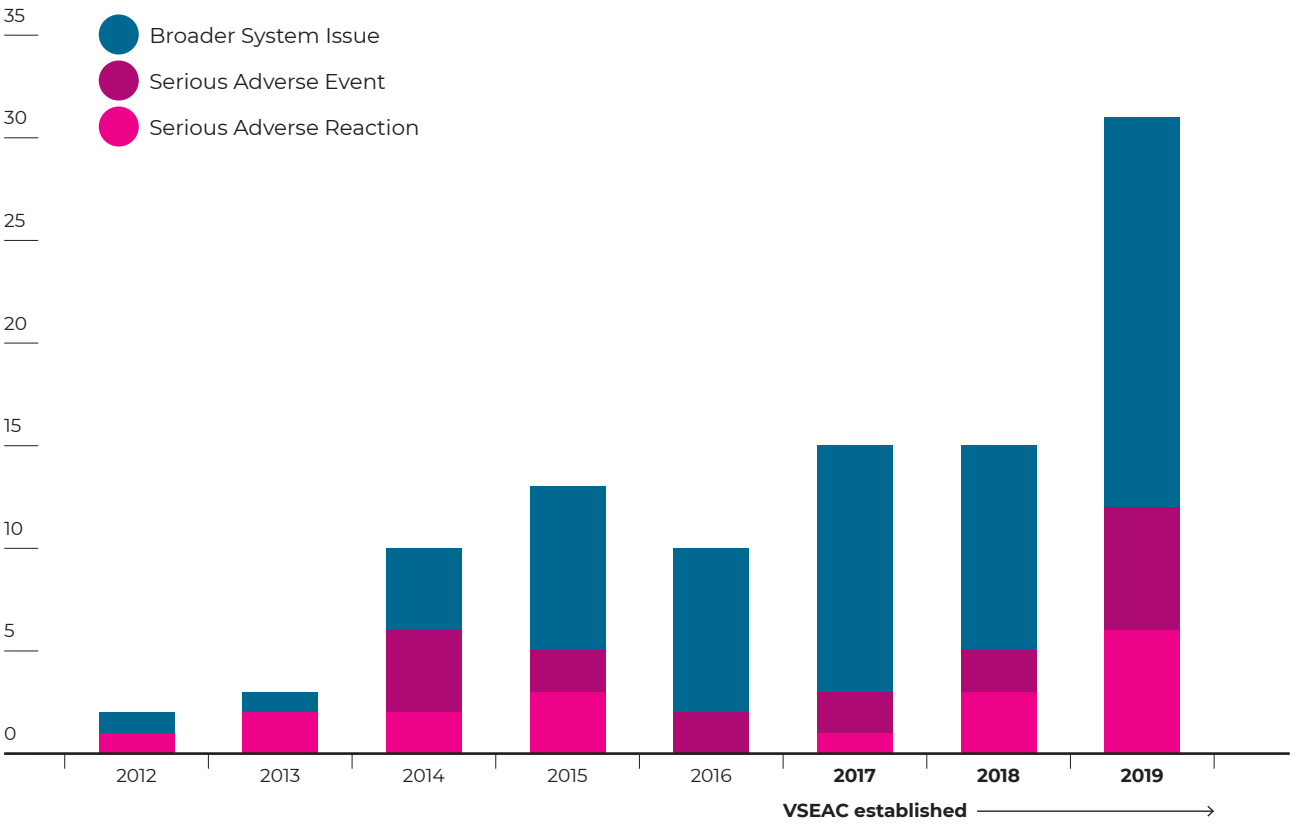


Table 1 SAER Notifications in context of deceased organ donors, transplant procedures and transplant recipients: 2012 to 2019

						VSEAC established		
Year	2012	2013	2014	2015	2016	**2017**	**2018**	**2019**
Deceased Organ Donors	354	391	378	435	503	510	554	548
Transplant Recipients	1,049	1,121	1,107	1,239	1,447	1,400	1,544	1,444
Transplant Procedures	1,100	1,163	1,164	1,301	1,508	1,467	1,618	1,501
Serious adverse event and/or reaction notifications submitted	1	2	6	5	2	3	5	12
Proportion of serious adverse event and/or reaction notifications relative to Transplant Procedures (per cent)	0.09%	0.17%	0.52%	0.38%	0.13%	0.20%	0.31%	0.80%

It is also likely that the increase in SAER notifications reflects a greater awareness of the Australian Vigilance and Surveillance System amongst clinicians and an increased willingness to contribute to national shared learnings.

As has been seen in other countries in the early stages of development of their vigilance systems, it is anticipated that the number of notifications will continue to increase as the system matures.

The increase in notifications each year reflects the evolution of the Australian Vigilance and Surveillance System and a greater transparency and willingness to report

2.1 A summary of SAER notification categories from 2012 to 2019

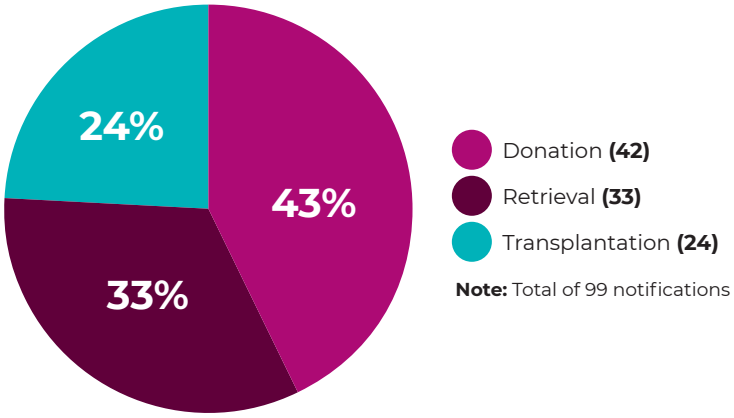
Within the national vigilance and surveillance database, SAER notifications are categorised according to the stage from donation to transplantation when the event or reaction occurred. The broadest categories are donation, retrieval and transplantation shown in Figure 4. The number of SAER notifications was greatest in the donation category, followed by retrieval then transplantation.

Figure 5 on the next page shows the notifications according to the three types of notifications (serious adverse event, serious adverse reaction, broader system issues) and the categories of donation, retrieval and transplantation. As the notifications are submitted by DonateLife State Medical Directors it is more likely that notifications are made within the donation and retrieval categories although reporting from the transplant sector, through DonateLife, is encouraged.

Notifications can be further classified into the following sub-categories: donor assessment; donor management; offer and allocation; information and data transcription; retrieval surgery; perfusion and preservation; storage and transport; transplant surgery; post-transplant; possible donor derived infection; and possible donor derived malignancy.

Figure 6 shows the number of notifications in each sub-category from 2012 to 2019. It shows the retrieval surgery sub-category had the most notifications followed by information and data transcription issues.

Figure 4 SAER notifications by Donation, Retrieval and Transplantation categories, from 2012 to 2019



Note: Total of 99 notifications

Figure 5 SAER notifications by category and notification type, from 2012 to 2019

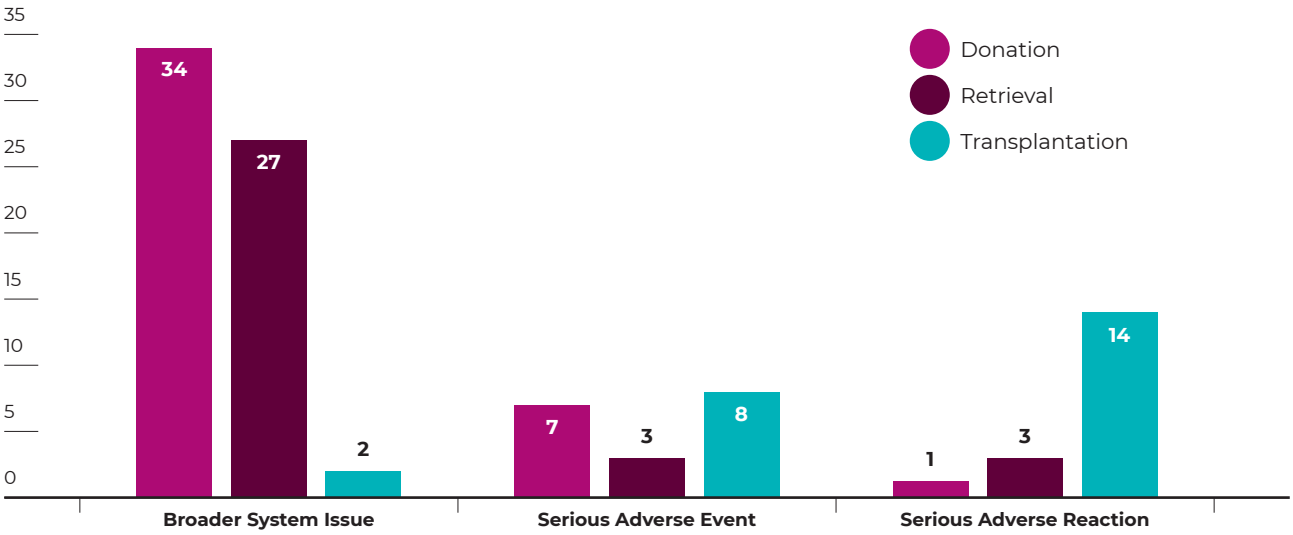
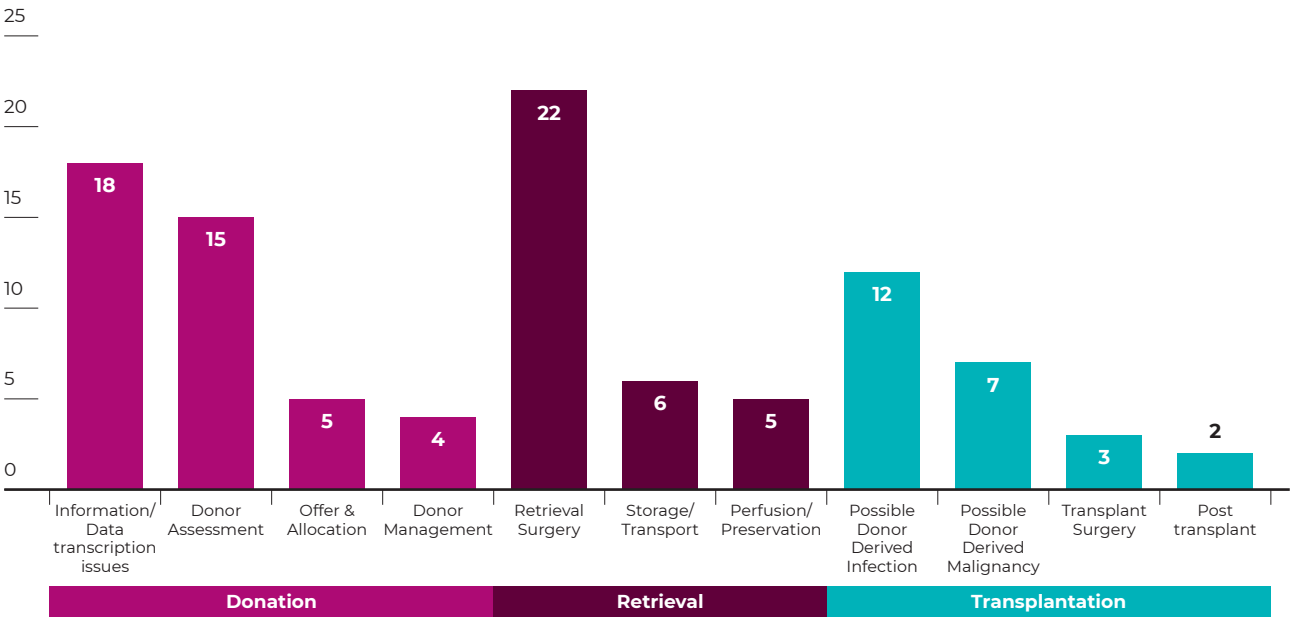


Figure 6 SAER notifications by sub-category 2012 to 2019



3 Assessment of SAER notifications reported nationally January 2017–December 2019

The following is a summary of the issues considered by the VSEAC since it's commencement in 2017 and the responses to improve clinical practice, safety and effectiveness of donation, retrieval and transplantation.

This section summarises the notifications from January 2017 to December 2019

3.1 SAER notifications relating to donation

SAER notifications relating to the donation category made up 48% of the total number of notifications from January 2017 to December 2019. These notifications include the following sub-categories:

3.1.1 Donor assessment or management

There were 12 SAER notifications in the 'Donor assessment' and 'Donor management' sub-categories involving communication issues and issues with obtaining relevant and/or accurate clinical test results. Events of this nature can lead to missed donation (and subsequent transplant) opportunities.

Many of these issues were locally reviewed by affected DonateLife agencies and practice changes to improve communication and timely access to relevant reports were implemented.

The VSEAC also recommended a change to the protocol of requesting tests for donor organ suitability and suggested a review of the relevant TSANZ clinical guidelines on routine testing.

3.1.2 Offer and allocation

There were two SAER notifications in the 'Offer and allocation' sub-category concerned with obtaining cross-match results for interstate transplants which impacted timeframes for donation.

The VSEAC noted that while national standard operating procedures for organ allocation, rotation and urgent listings are designed to ensure fairness and equity in the system, there may be rare occasions where a change in practice may be required to optimise donation and transplantation outcomes and avoid losing donation opportunities.

3.1.3 Information and data transcription

There were 15 SAER notifications in the 'Information and data transcription issues' donation sub-category which caused delays in the donation process and have the potential to result in missed donation opportunities. The majority of these involved communication and processes related to identifying patients on the Australian Organ Donor Register (AODR).

The VSEAC rates these notifications seriously as registration to donate on the AODR is associated with a high rate of family consent. Registration status information is routinely conveyed to the family by Donation Specialist staff at the time of offering donation, and inaccurate information may influence a family's final decision about donation.

The OTA is working with the relevant Australian Government portfolio agencies to address these issues.

3.2 SAER notifications relating to retrieval

SAER notifications relating to the 'retrieval' category made up 25% of the total number of notifications from January 2017 to December 2019. These notifications can be broken down into the following sub-categories:

3.2.1 Retrieval surgery

There were ten SAER notifications in the 'Retrieval surgery' sub-category, including issues regarding logistics and capacity, and technical difficulties experienced during the retrieval process. Such events impact the timeframes in which donation and transplantation can occur, and the quality of the retrieved organ, and may result in missed donation and/or transplantation opportunities.

Local reviews of these events resulted in improved logistics arrangements and contingency planning.

The OTA and VSEAC recognise the importance of adequate availability and organisation of retrieval surgical services, noting that staff often work under difficult circumstances and with significant time pressures.

The OTA and VSEAC welcomes the Review of the Australian organ donation, retrieval and transplantation system final report which makes recommendations for improving Australia's health system to support the future growth and sustainability of donation and transplantation. All Australian Governments are working together to form a nationally sustainable system.

3.2.2 Preparation for transport

There were five SAER notifications in the 'Storage and transport' sub-category, including issues with packaging of organs and logistics of transporting organs and/or surgical teams.

The provision of timely surgical retrieval services at hospitals throughout Australia, the movement of teams and organs between hospitals, and at times over long distances and across interstate borders, all pose particular logistic challenges. Adequate resourcing and organisation of surgical retrieval resources is necessary to maximise donation and transplantation outcomes.

Existing national organ packaging procedures provide for a consistent high-quality practice and should be strictly followed. Issues with faulty packaging were addressed with the manufacturer.

3.3 SAER notifications relating to transplantation

SAER notifications about events relating to the transplantation category made up 27% of the total number of notifications from January 2017 to December 2019. These notifications include the following sub-categories:

3.3.1 Transplant surgery

There were three SAER notifications in the 'Transplant surgery' sub-category including logistical and technical issues, as well as variation in the clinical practice of acceptance of organs for transplant.

3.3.2 Post-transplant

There were 14 notifications about suspected donor derived disease transmission. Although donor assessment and testing to optimise the safety of donation for transplantation is undertaken to a very high level, the risk of disease transmission can never be completely eliminated.

The risk of disease transmission, including malignancy, infection and allergy, from the donor needs to be assessed against the risk of the potential recipient not receiving a transplant, noting the high risk of morbidity and mortality for many people with organ failure waitlisted for transplantation. These risks are clearly discussed as part of the consent process with the transplant recipient.

In particular, greater awareness is required of the risk of potential transmission of allergy from the donor to organ transplant recipients and severe allergy should be highlighted in the donor assessment, documented and communicated to transplant units. Transplant units should inform organ transplant recipients of this risk and provide education on the need to avoid potential allergens and what to do in the event of experiencing a severe allergic reaction.

The clinical management and investigation of these transmissions remains the responsibility of the jurisdictions. The VSEAC notes and acknowledges that in-depth investigations have occurred in the majority of these cases in order to identify potential improvements to procedures and processes with the aim of minimising the risk of donor disease transmission.

These notifications highlight the importance of thorough medical suitability assessment of potential donors and access to guidance and expert advice regarding disease transmission risk. General guidance is available from various sources including the Transplantation Society of Australia and New Zealand (TSANZ) *Clinical Guidelines for Organ Transplantation from Deceased Donors* (available at: https://www.tsanz.com.au/organallocationguidelines/index.asp). A recent revision to these guidelines includes an update to the section on donor assessment for infectious disease and risk, and suitability of organs for transplantation. The guidelines regarding malignancy transmission risk are being reviewed in 2020. In addition, specific advice is commonly obtained from local infectious disease, cancer, donation and transplantation experts on a case by case basis at the time of consideration of donation and transplantation.

4 Next steps for the Australian Vigilance and Surveillance System

4.1 Electronic notifications and database

In 2018 the OTA, in consultation with the VSEAC, developed an electronic SAER notification form and associated database. This electronic form was trialled in 2019 and its effectiveness will be evaluated for ongoing use. It is anticipated this electronic form will facilitate more timely and consistent reporting and provide for improved data analysis.

4.2 International reporting

The VSEAC has now streamlined its reviewing and ranking system for SAER notifications. In the future the VSEAC will contribute to the global vigilance and surveillance collaboration through Project Notify https://www.notifylibrary.org. The VSEAC will continue to consider international vigilance and surveillance systems in its assessment of Australian notifications.

4.3 Improve communication to stakeholders

The VSEAC is committed to reporting de-identified SAER notification data for shared learning and to support improvements in clinical practice to enhance patient safety. De-identified information on SAER notifications and the VSEAC's assessment is routinely shared with relevant clinical committees.

In 2019 the VSEAC formalised its review process to include a more structured approach based on the notifications impact and consequence assessments.

The OTA and VSEAC recognise the hard work of clinicians in the organ donation and transplantation sector who seek to optimise donation outcomes and increase access to safe transplantation. Donation and transplantation are not without risk, even with the most thorough donor and risk assessment processes.

Transparency makes for a safer system, and the OTA and VSEAC continue to strongly encourage the reporting of actual or potential adverse events and reactions to help inform future advice, recommendations and guidelines. This will improve the safety and quality of donation and transplantation, save more lives, and enhance Australia's donation and transplantation system.

Appendix A
VSEAC membership 2017–2019

The Vigilance and Surveillance Expert Advisory Committee (VSEAC) comprises high level technical specialists with relevant expertise from key clinical, government and professional organisations. Membership is position or skills based, meaning individuals may be a formal representative of their respective organisation or may be appointed based on their expertise to meet the essential skills of the VSEAC membership.

The membership of VSEAC from establishment in October 2017 to the end of the reporting period on 31 December 2019 is provided below:

Position	**Committee role** (representative and expertise based)	**Held by**
Chair (CEO appointed)	Vigilance and surveillance	Prof Jeremy Chapman
Deputy Chair	OTA National Medical Director	Dr Helen Opdam
Member	Epidemiology	A/Prof Germaine Wong
Member	Infectious disease with expertise in organ donation and/or transplantation transmission	Prof Lindsay Grayson
Member	Oncology	Dr Brian Stein
Member	Transplantation Society of Australia and New Zealand (TSANZ) surgeon representative	Mr Michael Fink
Member	Transplantation Society of Australia and New Zealand (TSANZ) physician representative	Prof Nicholas Shackel
Member	Australasian Transplant Coordinators Association (ATCA) representative	Paul Robertson
Member	Communicable Diseases Network Australia (CDNA) representative and public health expertise	A/Prof Paul Dugdale
Member	DonateLife State Medical Director representative	Dr Rohit D'Costa