Australian Government

Organan and Tissue Authority

Australian Vigilance & Surveillance System

ORGAN DONATION FOR TRANSPLANTATION

The Australian Vigilance and Surveillance System

2023 REPORT

Contents

1 Foreword

Transplant recipients, donors and their families, and the Australian community trust that the organ donation and transplantation system is as safe and effective as possible. Ideally any potential problems should be identified before they become actual failures in this complex system. All potential issues should be identified, analysed, and discussed so that preventive actions can be taken to keep patients safe and to strive for the best possible outcomes.

The Australian Vigilance and Surveillance System complements the state and territory clinical incident management and reporting systems for deceased organ donation and transplantation. It provides a national reporting and evaluation process to help inform national advice, recommendations, and guidelines.

The lives of 1,396 Australians were changed when they received an organ transplant from a deceased organ donor in 2023. This was only possible thanks to the generosity of 513 deceased organ donors, and their families who said yes to donation.

Organ donation and transplantation comprises many different people, organisations, and protocols, making it a very complex process. All health professionals across the donation and transplantation sector have continued to navigate a challenging healthcare and operational environment in the last few years, to achieve the best possible outcomes from organ donation and transplantation. There continues to be improvements to clinical practices across the donation and transplantation sectors with the goal of keeping patients safe, providing quality care and optimising donation and transplantation.

The Australian Vigilance and Surveillance System plays a vital role in improving the quality and safety of organ donation and transplantation in Australia. The Vigilance and Surveillance Expert Advisory Committee (VSEAC) is integral to this system. It has continued to review reported events and make recommendations with the aim of improving practices and access to transplantation. During the past year, this has included recommendations resulting in updates to key clinical guidelines, the development of the National Organ Retrieval Theatre Guidelines (NORTG) for donation specialists, and a review of the Australian Donor Risk Assessment Interview (AUS-DRAI) that is used to obtain important health and risk information at the time of donor assessment. In addition, regular communiques have been issued to the clinical sector that have highlighted key practices and learnings, as well as information from international publications considered relevant to safe donation and transplantation practice.

This report contains an analysis of 43 serious adverse event and/or reaction (SAER) notifications reported to the VSEAC. Events are rare, for context there were 1,458 transplant procedures in 2023, with 28 SAER notifications to VSEAC. This equates to an event in 1.92% of all transplant procedures. In this report we provide the collated information and trends to provide insights into the types of events being reported and that have led to positive practice changes.

Feedback on the Report or any VSEAC activities is welcomed and can be sent by email to the mailbox: SAEN@donatelife.gov.au

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 so that knowledge can be gained to help inform future advice, recommendations, and guidelines. This will improve the safety and quality of donation and transplantation and enhance Australia's system.

Professor Jeremy Chapman AC FRACP FRCP
Chair
Vigilance Surveillance Expert Advisory Committee

Associate Professor Helen Opdam
Deputy Chair
Vigilance Surveillance Expert Advisory Committee
National Medical Director
Organ and Tissue Authority

Lucinda Barry AM
CEO
Organ and Tissue Authority

2 Background, update and reporting

Vigilance and surveillance are an essential part of any health care system.

For organ donation and transplantation, vigilance and surveillance systems are established to maintain quality and safety throughout the complex process of:

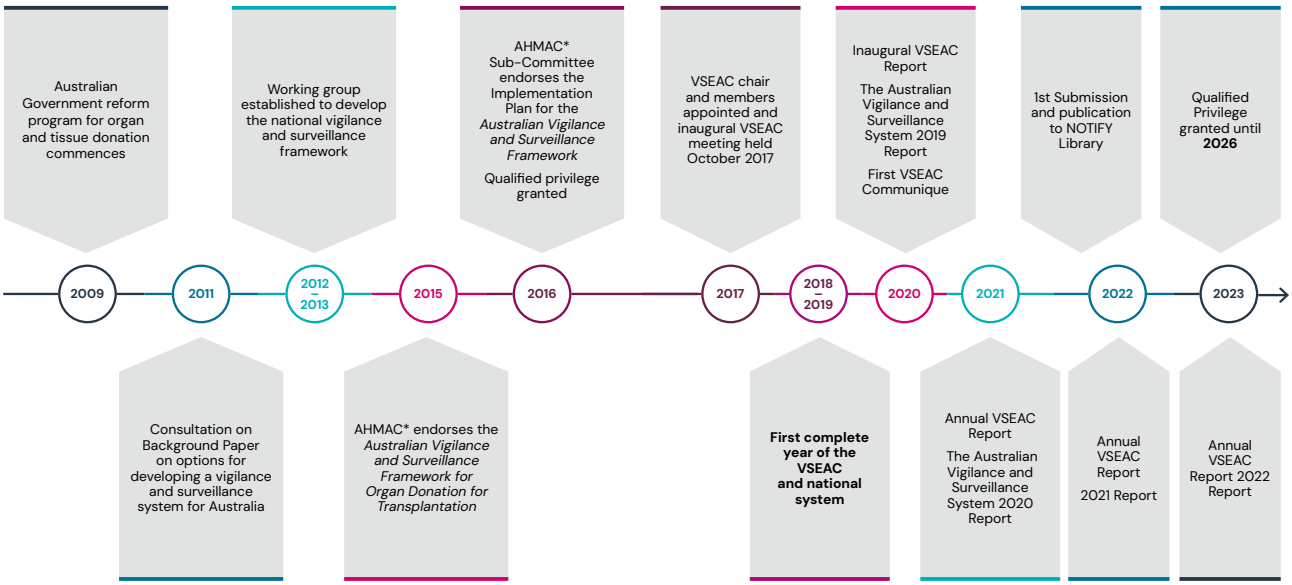
- donor evaluation
- organ allocation
- retrieval and transport
- transplantation surgery, and
- post-transplant care.

Importantly these systems aim to review and avoid reoccurrence of SAERs.

SAERs are infrequent and when seen individually may appear as simple isolated occurrences, so it is important to have a central system to capture all incidents to gain a complete representation of all issues and trends. A national monitoring system for detection, analysis and reporting provides an invaluable component of a feedback and improvement cycle.

It leads to recommendations for practice improvements, an opportunity for shared learning, identification of trends and ultimately a more effective and safer organ donation for transplantation system.

Figure 1 Overview of the evolution of the Australian Vigilance and Surveillance System for organ donation and transplantation.



States and territories are responsible for management of SAERs that occur within their jurisdiction.

Reporting de-identified information on SAERs and 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 and enhance patient outcomes.

International vigilance and surveillance systems that monitor and trace the safety of donated and transplanted organs are at various stages of development and implementation. 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 aligns with the Organ and Tissue Authority (OTA) strategy to enhance the safety of organ donation and transplantation in Australia [2].

A brief history is presented in Figure 1 illustrating how the Australian Vigilance and Surveillance System has developed over time.

*AHMAC = The Australian Health Ministers' Advisory Committee, a former committee comprised of the heads of the federal, state and territory government health authorities with the role of considering matters related to co-ordinating health services across the nation.

2.1 Australian Vigilance and Surveillance System for Organ Donation and Transplantation Reports

The Australian Vigilance and Surveillance System has published four Annual Reports since 2020, collating all notifications received since 2012. This 2023 Annual Report is the fifth release, reporting on all notifications received between 1 January and 31 December 2023. The system and its functions are described below. Each notification is assessed, reviewed, and classified into a notification type and category, including broader system issues, serious adverse events, and serious adverse reactions. The Australian Vigilance and Surveillance System reviews every SAER notification with consideration towards improvement and prevention of recurrence.

2.2 VSEAC communiques

In addition to the Annual Report, the VSEAC regularly dispatches clinical communiques. The purpose of the VSEAC clinical communiques is to raise awareness of current recommended clinical practices and convey new issues, risks, and recommendations to enhance patient safety, donation, and transplantation outcomes.

2.3 Clinical guidelines

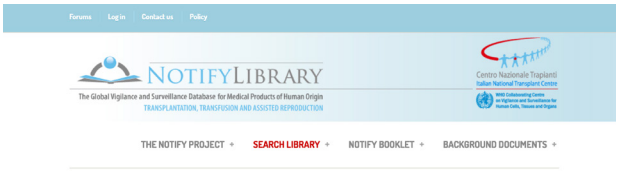
The VSEAC provides advice and recommendations regarding clinical guidelines and standard operating procedures, where inconsistencies in clinical practice are identified through the vigilance and surveillance process. Since its inception, recommendations from the VSEAC have prompted several reviews and updates to the standard operating procedures and clinical guidelines by The Transplantation Society of Australia and New Zealand (TSANZ).

2.4 International reporting

The VSEAC is committed to contributing to the international Notify Library[3] database when Australian SAERs meet the criteria for submission. The Notify Library is an international database that is designed to capture adverse occurrences that take place during organ donation, transplantation, and assisted reproduction procedures. It is intended as a communication hub for organisations and institutions to collaborate on vigilance and surveillance information.

The VSEAC retrospectively reviewed all notifications received from 2012 – the inception of reporting to the Australian Vigilance and Surveillance program – to 31 December 2021 to assess suitability for submission to Project Notify. Since 2021, all SAER notifications are assessed for suitability for submitting to Project Notify at the time of review of the notification by the VSEAC. In 2021, one notification met all criteria and was submitted to Project Notify. The submission was accepted and was published on the Notify Library website in May 2022.

"If we know something important that no one else knows, it is important to share this."



3 The Australian Vigilance and Surveillance System

3.1 The Australian Vigilance and Surveillance System

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

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

The Australian Vigilance and Surveillance System provides a nationally and internationally coordinated notification function.

The core elements of the Australian Vigilance and Surveillance System are the VSEAC and the SAER notification database.

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 relevant clinicians and patients (including interstate where appropriate)
- investigation of the incident
- other aspects of a response to an incident including feedback on policy and clinical practice review
- reporting the incident to the national system.

The Australian Vigilance and Surveillance System works in parallel with State and Territory 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. The System provides a national reporting and evaluation 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.

3.2 Scope of the national system

The Australian Vigilance and Surveillance System applies to solid organs donated for transplantation from deceased donors. It does not apply to tissue and eye-only donation or living donation. The exception is 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 or other diseases.

A key focus is to collate incidents related to potential infectious and malignant disease transmission, including:

- issues with donor screening and assessment
- the intra-operative or post-transplant discovery of potential or actual transmission of disease from a donor to recipient; or
- harm including death of a recipient that may be a result of donor derived disease.

In setting up the Australian process, it was considered that central reporting and review of other types of events may also facilitate opportunities for process improvement. As a result, the scope was broadened beyond possible donor to recipient disease transmission. These events include the avoidable loss of a potential donor or donor organ for transplantation and those related to organ retrieval, perfusion, storage, and transportation.

These process issues are termed 'serious adverse event – broader system' (SAE-BS). They are then considered at a national level to identify where improvements could occur to increase the safety, efficiency, and effectiveness of donation and transplantation.

SAER notifications 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 solid organs for transplantation and the SAER has relevance to organ donation and/or transplantation.

3.3 Defining serious adverse events and reactions

The Australian Vigilance and Surveillance System reporting criteria are based on the 2013 *'Communication and Investigation of Serious Adverse Events and Reactions Associated with Human Tissues and Cell (SOHO V&S)'* [4] . In 2022, chapter 16 in the *'European Directorate for the Quality of Medicines and Healthcare (EDQM) – 8th Edition Guide to the quality and safety of organs for transplantation (2022)* [5]*'* referenced the same document. The VSEAC has not changed the current definitions for serious adverse events and/or reactions or the assessment tools, as they remain aligned with international practice.

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 donation to transplantation ***that is*** fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity'.

A **serious adverse event** is any 'undesired and unexpected occurrence associated with any stage of the chain from 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'.

VSEAC have further broken down serious adverse events (SAEs) into two categories:

- SAE – individual specific (SAE), and
- SAE – broader system (SAE-BS).

3.4 Commonwealth Qualified Privilege

To strengthen and encourage reporting of adverse events and reactions, the VSEAC was granted Commonwealth Qualified Privilege in 2016 for an initial 5 year period. A renewal was applied for in 2021 and another 5 year period of Qualified Privilege was granted, taking effect on 14 December 2021.

The Australian Commonwealth Privilege Scheme grants qualified privilege for eligible quality assurance activities. It prohibits the release of information that may identify a person, including patients and health professionals and protects those taking part in the activity from civil liability and legal action[6]. This is important as these protections encourage health professionals to take part in the vigilance and surveillance system.

3.5 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 committee formally met 4 times in 2023, with a mixture of face to face and virtual meetings. The VSEAC membership from 1 January 2023 to 31 December 2023 is outlined in **Appendix A**.

3.6 The VSEAC process

The Vigilance and Surveillance System process (as outlined in Figure 2) remained unchanged throughout 2023. The figure outlines the pathway that is followed when an adverse event or reaction occurs. The hospitals, states, and territories are responsible for the immediate and ongoing clinical management of the incident. Concurrently, the SAER notification is submitted to the Australian Vigilance and Surveillance System by the State Medical Director or delegate of the DonateLife Agency.

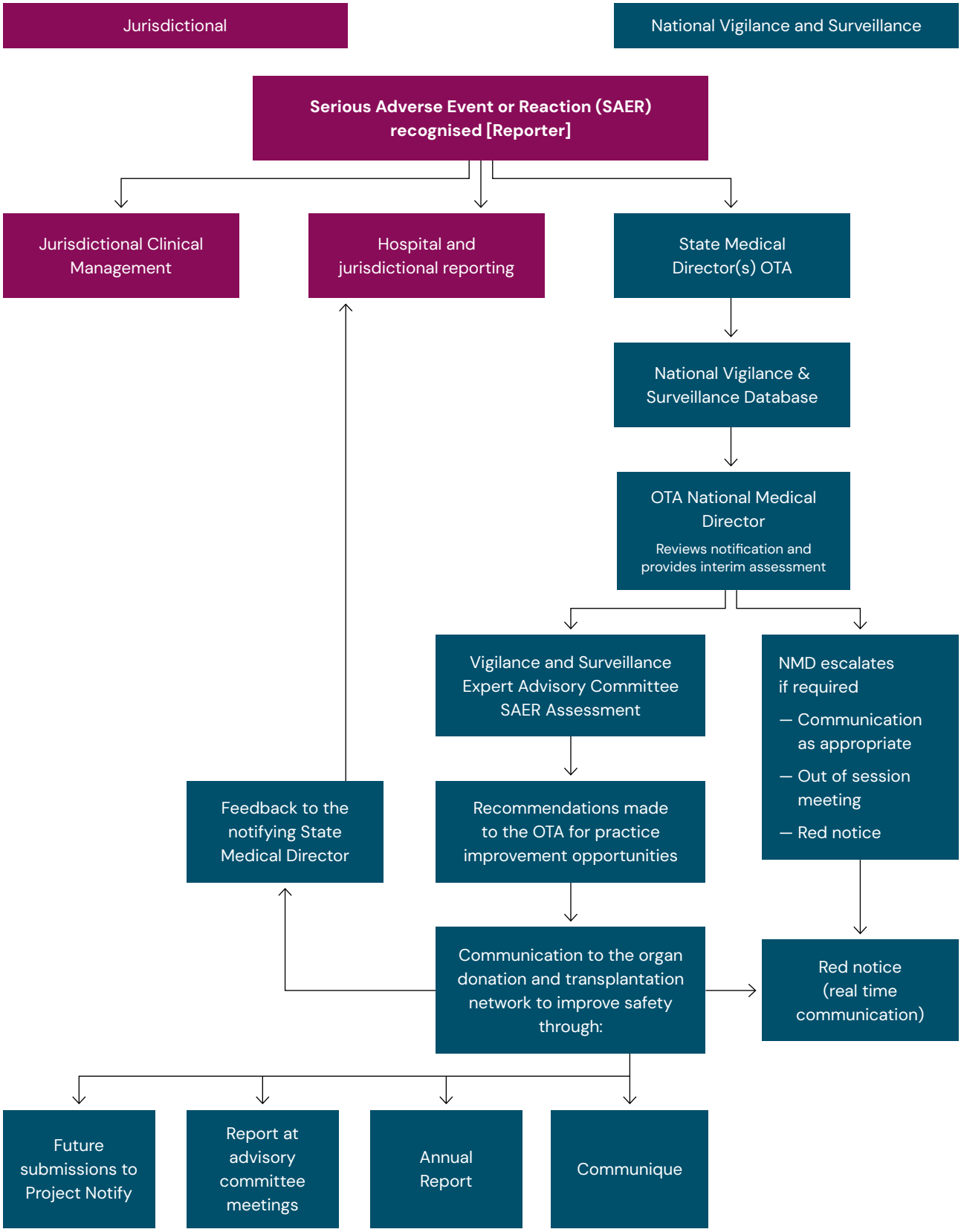
The SAER notification is initially reviewed by the OTA National Medical Director who assesses the notification and determines if any immediate actions are required. The notification is then reviewed by the VSEAC at the next meeting or out of session if a more timely response is required. SAER notifications are assessed according to severity, imputability, recurrence likelihood, and impact. Members are required to declare any conflicts of interest, for example, if there is personal prior knowledge or involvement in an incident, before the consideration of each case.

3.7 SAER notification database

The SAER notification database and its IT infrastructure is managed by the OTA in partnership with its IT provider. It has been enhanced to enable collation, cross referencing, traceability, and trending of SAER notifications. The information contained includes the SAER notification form, all associated documents, and the VSEAC review outcomes including comments, categorisation, and follow up actions. In addition, any literature reviews, Notify Library searches, and correspondence is also stored with each SAER notification.

In 2023, modification to the portal that facilitates online submission of SAER notifications continued with the long-term goal of submission and associated correspondence being stored and edited in a centralised location.

Figure 2 **Notification, communication, review and reporting process for serious adverse event and/or reaction (SAER) notifications.**



4 Overview of all reported serious adverse events and/or reaction notifications

Nationally in 2023, there was a 13% increase in the number of deceased organ donors and a 14% increase in organ transplant recipients compared to 2022.

There has been ongoing recovery from the impacts of COVID-19. Whilst there were variations across states and territories, deceased donation in Australia is now only 6% lower compared with the 2019 pre-pandemic activity. Of note, there were no reported SAER notifications relating to COVID-19 for the year 2023.

DonateLife agencies and transplant teams have continued to work together throughout this period to navigate the ongoing challenges facing the health system. This includes hospital pressures and staff shortages which can impact donation and transplantation practices.

In 2023, there were 44 notifications received, which were classified by notification type and category. A duplicate SAER notification was identified regarding a potential donor derived infection and a subsequent recipient death. This was classified as a single event and the notifications were combined. Thus, this report provides advice regarding 43 notifications. Events are rare, for context there were 1,458 transplant procedures in 2023, with 28 SAER notifications to VSEAC. This equates to an event in 1.92% of all transplant procedures. Table 1 is a breakdown of the 43 notifications received in 2023, in the types and categories used by the vigilance and surveillance system.

Table 1 SAER Notifications that occurred and were reviewed in 2023

Notification type (total 43 notifications)		
Serious adverse reaction	2	5%
Serious adverse event	26	60%
Serious adverse events – Broader system	15	35%
Other	0	0%
Notification category (total 43 notifications)		
Donation	21	49%
Retrieval	12	28%
Transplantation	10	23%

VSEAC strongly encourages early reporting. In the event that an incident requires local review and evaluation it is desirable that preliminary notification to VSEAC occurs with more complete information provided when it becomes available.

The number of SAER notifications reported to VSEAC in 2023 increased compared to 2022 (43 SAER notifications in 2023, 32 SAER notifications in 2022, 29 SAER notifications in 2021). This is considered likely due to growing awareness of the role and value of the vigilance and surveillance system, leading to increased submission of notifications.

VSEAC also considers serious adverse events that have an impact on the broader system (SAE-BS). As can be seen in Figure 3, there were 43 in-scope SAER notifications submitted to VSEAC during 2023, which were reviewed and assessed and are discussed in this report.

Serious adverse events in organ donation and transplantation are rare in Australia.

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

Figure 3 SAER notifications reviewed in 2023

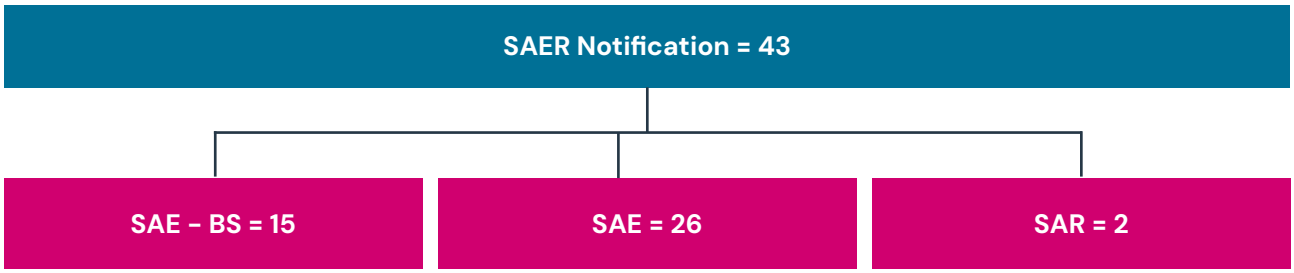


Table 2 demonstrates an increase in the proportion of SAER notifications relative to overall transplant procedures, from 1.09% in 2022 to 1.92% in 2023. The 28 SAER notifications received in 2023 is an increase from the 14 notifications received in 2022. Two of the 28 notifications in 2023 were serious adverse reactions involving possible donor derived infections. There has been progressive uptake and reporting of notifications since the implementation of the Australian Vigilance and Surveillance System.

SAER: Serious adverse event and/or reaction.

NMS: Not medically suitable.

SAE: Serious adverse event.

SAE-BS: Serious adverse event - Broader system.

SAR: Serious adverse reaction.

Table 2 SAER notifications in context of deceased organ donors, transplant procedures and transplant recipients: year of SAER occurrence – 2012 to 2023

						VSEAC established						
Year	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Deceased Organ Donors	354	391	378	435	503	510	554	548	463	421	454	513
Transplant Recipients	1,049	1,121	1,107	1,239	1,447	1,400	1,544	1,444	1,270	1,174	1,224	1,396
Transplant Procedures*	1,100	1,163	1,164	1,301	1,508	1,467	1,618	1,501	1,334	1,227	1,281	1,458
SAER notifications	1	2	6	5	2	3	5	12	4	13	14	28
SAE-BS notifications	1	1	4	8	8	13	11	16	7	20	10	15
Proportion of SAER notifications relative to transplant procedures*	0.09%	0.17%	0.52%	0.38%	0.13%	0.20%	0.31%	0.80%	0.30%	1.06%#	1.09%	1.92%

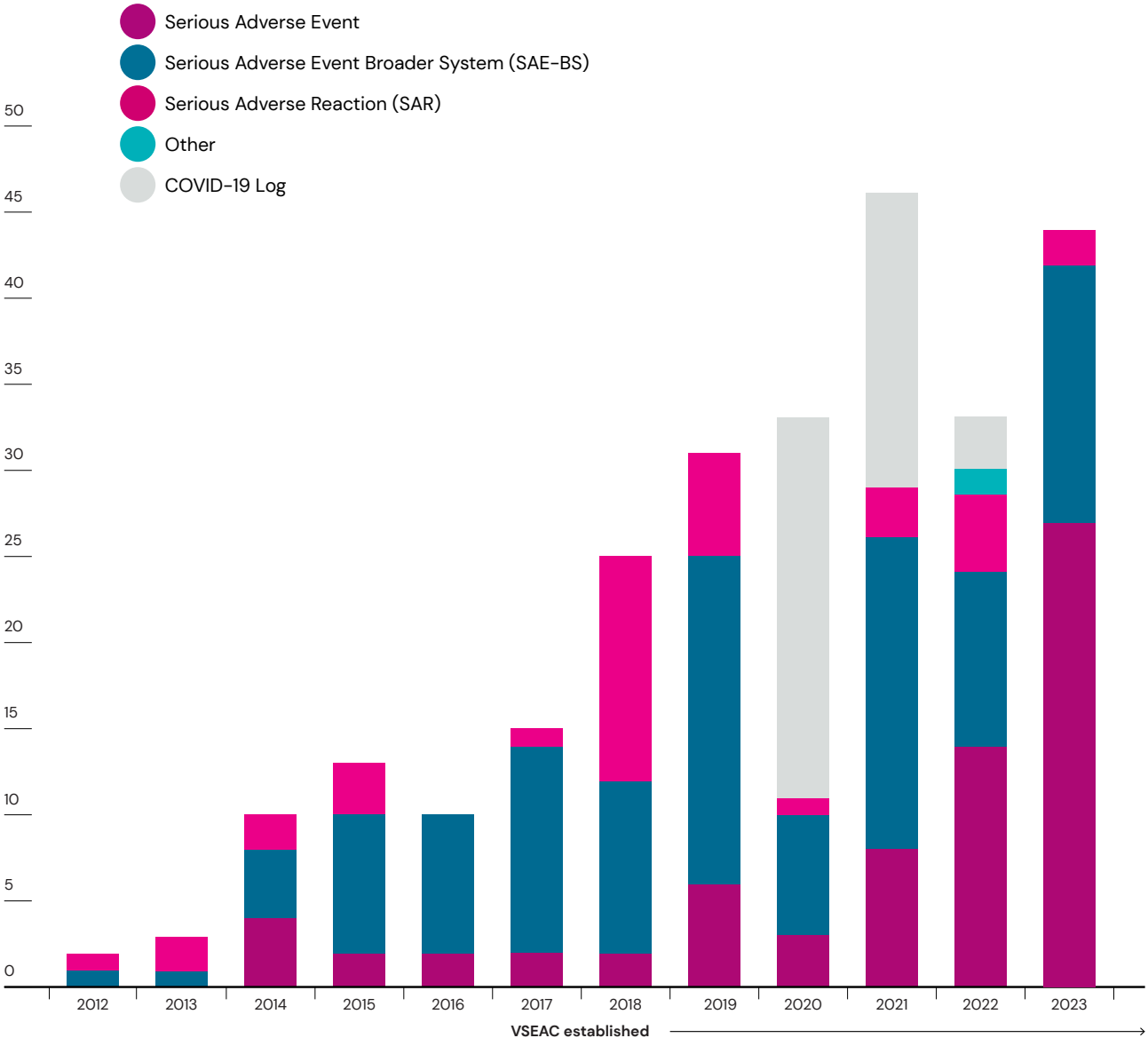
Note, the 2021 percentage has been updated with SAER notifications reported in 2022.
*The percentage proportion of SAER notifications relative to transplant procedures is calculated from SAER notifications over Transplant Procedures.

Figure 4 shows a comparison of the total 2023 incidents compared to SAER notifications in prior years, breaking down SAER notifications into the reported categories.

For 2023 the number in each category is as follows:

- Serious adverse event = 26
- Serious adverse event - Broader system = 15
- Serious adverse reaction = 2
- COVID-19 Log = 0
- Other = 0

Figure 4 SAER notifications by category from 2012 to 2023



5 Analysis of serious adverse events and/or reaction notifications

The incidents reported via the SAER notification process and reviewed by the VSEAC have sufficient detail to enable analysis and categorisation. This is done according to the part of the donation and transplantation continuum they relate to, their classification and their impact. The following sections provide information about the 43 SAER notifications reviewed by the VSEAC in 2023. There were no SAER's relating to COVID-19 reported in 2023.

5.1 Analysis of SAER notification categories for 2023

The SAER notifications can be categorised according to whether they relate to donation, retrieval or transplantation (Figure 5). For 2023, of the 43 notifications, the numbers of categorisation were:

Notification category		
Donation	21	49%
Retrieval	12	28%
Transplantation	10	23%

Figure 6 shows the notifications according to the four types of classifications (serious adverse event, serious adverse reaction, serious adverse event - broader system or other) and the categories of donation, retrieval, and transplantation.

Figure 5 SAER notification by category

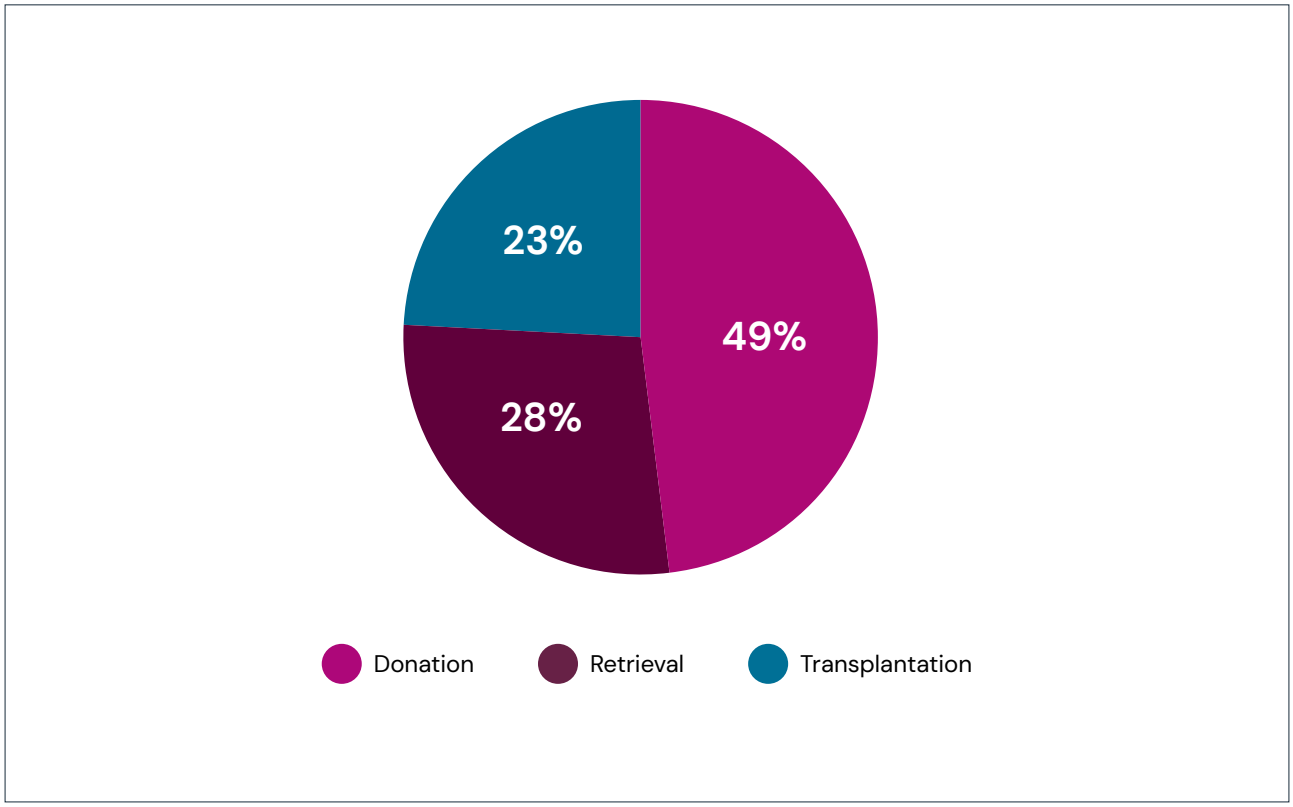
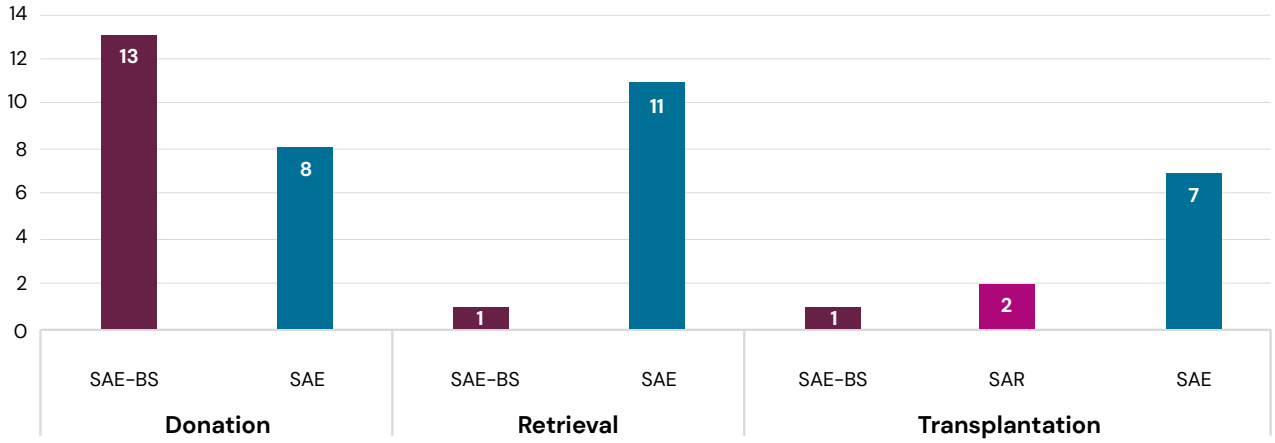


Figure 6 SAER notifications by category and notification

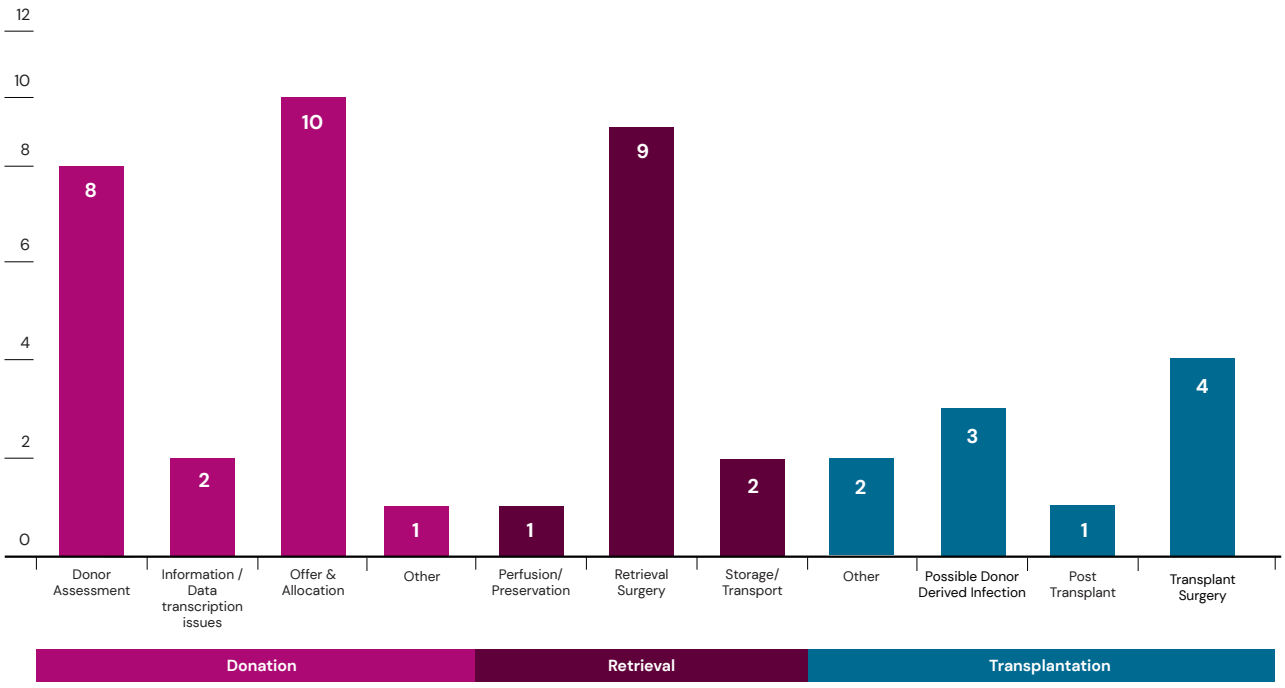


Notifications can be further classified into the following sub-categories:

- donor assessment
- donor management
- information/data transcription
- offer and allocation
- retrieval surgery
- perfusion and preservation
- storage and transport
- post-transplant
- transplant surgery
- possible donor derived infection, and
- donor malignancy.

Figure 7 shows the number of notifications in each sub-category in 2023. The offer and allocation sub-category had the most notifications (10), followed by retrieval surgery (9) and donor assessment (8).

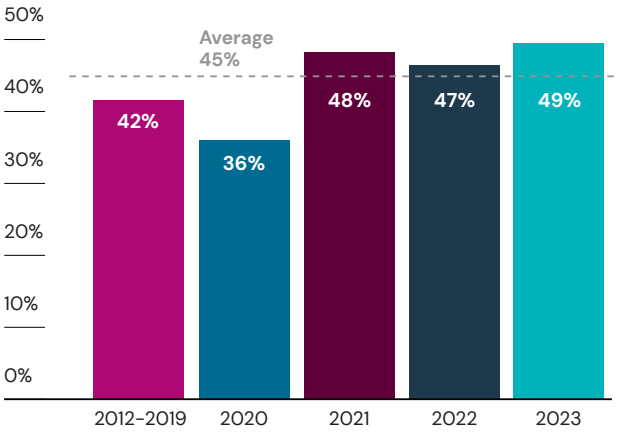
Figure 7 SAER notifications by sub-category in 2023



5.1.1 SAER notifications relating to donation

SAER notifications relating to the donation category made up 49% of the total number of notifications from 1 January 2023 to 31 December 2023. This was 2% higher than 2022 data and 4% higher than the overall average of all SAER notifications relating to the donation category from 1 January 2012 to 31 December 2023 (45%).

Figure 8 SAER notifications related to Donation.



For 2023, these notifications included the following sub-categories:

5.1.1.1 Donor assessment

The notifications in this category are related to the assessment of a potential donor. This involves gathering extensive health information, a detailed consent process with the next of kin, and additional screening tests and assessments. This information is then provided to transplant units who assess this information in relation to potential recipients.

There were 8 notifications in the donor assessment category. There were 5 notifications related to the Australian Organ Donor Register (AODR), which are discussed in section 5.1.1.3. There were 3 notifications related to patient-specific events, including withdrawal of consent due to the length of the Australian Donation Risk Assessment Interview (AUS-DRAI) and logistical issues.

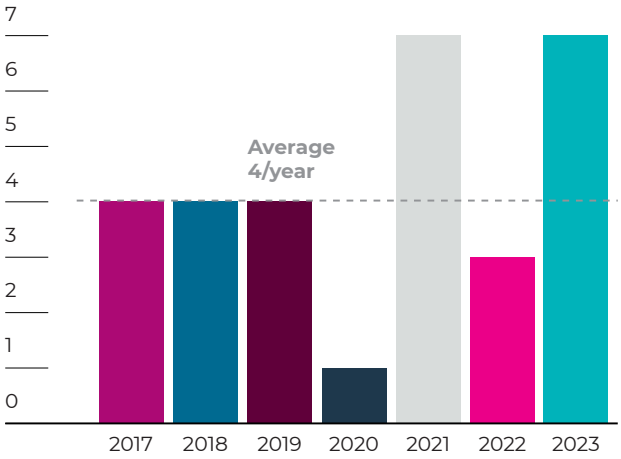
5.1.1.2 Offer and Allocation

There were 10 notifications related to offering and allocation of organs. These notifications were related to organ offer list processes and decline of organs due to logistical issues.

5.1.1.3 Information/transcription issues

In 2023, there were 2 notifications related to information/transcription errors, which both involved the AODR. There were 7 notifications related to discrepancies in the registration status of individuals upon checking the AODR, an increase from previous years due to changes in reporting from DonateLife staff.

Figure 9 Australian Organ Donor Register (AODR) SAER notifications.



5.1.2 SAER notifications relating to retrieval

SAER notifications relating to the retrieval category made up 28% of the total number of notifications from 1 January 2023 to 31 December 2023.

Figure 10 SAER notifications related to Retrieval.

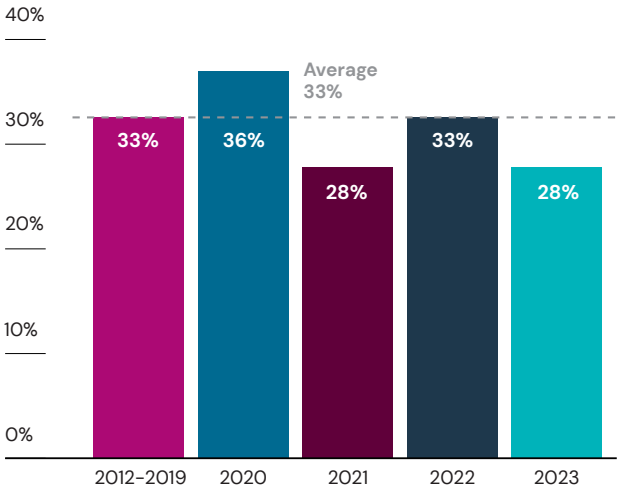
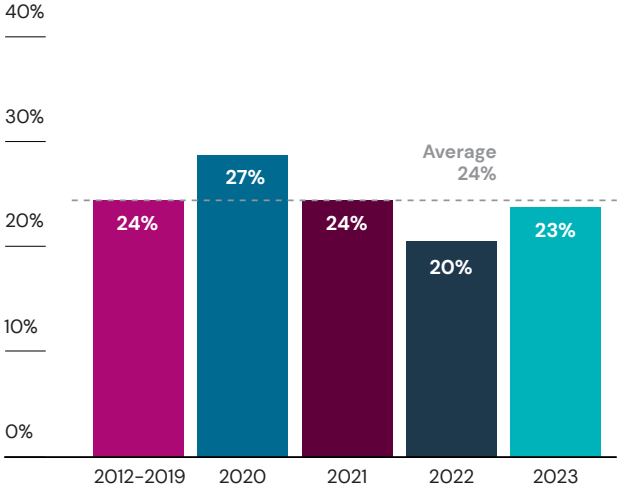


Figure 11 SAER notifications related to Transplantation.



For 2023, these notifications included the following sub-categories:

5.1.2.1 Retrieval surgery

There were 9 notifications within the retrieval surgery category. There were 7 notifications related to surgical retrieval challenges, including surgical technique and donor physiology. There were 2 notifications related to a broader system focus pertaining to hospital or local level issues.

5.1.2.2 Perfusion and Preservation

There was one notification in relation to perfusion and preservation of organs due to retrieval capacity constraints and logistics.

5.1.2.3 Storage and Transportation

There were 2 notifications relating to storage and transportation issues. Many donated organs are transported around the country using domestic flights. There are occasions when the timing of surgery, courier logistics and availability of flights create challenges for the donation and transplantation process.

5.1.3 SAER notifications relating to transplantation

SAER notifications relating to the transplantation category made up 23% of the total number of notifications from 1 January 2023 to 31 December 2023.

For 2023, these notifications included the following sub-categories:

5.1.3.1 Possible Donor Derived Infection or other disease

There were 3 notifications within the category of possible donor derived infection or other disease transmission. In all 3 notifications the organs were transplanted, and the possible donor derived infection or other disease transmission was managed appropriately.

5.1.3.2 Transplant surgery

There were 4 notifications related to issues occurring or identified during the transplant surgery relating to equipment malfunction, logistics relating to recipient availability or condition of the organ and the matching of donor to recipient size.

The role of the VSEAC is to monitor trends within serious adverse events and reactions. Identifying trends results in the VSEAC making recommendations for improved clinical practice in order to make organ donation and transplantation safer for all Australians.

Appendix A
VSEAC membership 2023

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 table below outlines all VSEAC members between 1 January 2023 to 31 December 2023.

Position	Committee role (representative and expertise based)	Held by
Chair (OTA CEO appointed)	Editor in Chief Transplantation Journal, Chairman Australian Bone Marrow Donor Registry	Prof Jeremy Chapman
Deputy Chair	National Medical Director, Organ and Tissue Authority	A/Prof Helen Opdam
Member	Infectious Disease Physician, Microbiologist	Dr Peter Boan
Member	DonateLife State Medical Director/s	Dr Elena Cavazzoni – NSW Dr Stewart Moodie - SA
Member	Donation Nurse Specialist, DonateLife Queensland	Ms Niamh Farrell
Member	Donation Nurse Specialist, DonateLife Victoria (commenced December 2023)	Ms Erin Bryen
Member	Communicable Diseases Network Australia representative	Dr Louise Flood
Member	Transplant Nurses Association representative	Ms Julie Pavlovic
Member	Senior Medical Virologist	Prof William Rawlinson
Member	Surgeon representative, Transplantation Society of Australia and New Zealand	Dr Handoo Rhee
Member	Australasian Donation and Transplant Coordinators Association representative	Mr Paul Robertson
Member	Australasian Donation and Transplant Coordinators Association representative (commenced December 2023)	Ms Nicola Seifert
Member	Oncology expertise	Dr Brian Stein
Member	Physician representative, Transplantation Society of Australia and New Zealand	Prof Angela Webster
Member	Epidemiologist	A/Prof Germaine Wong

Reference List

1 World Health Assembly, *Human organ and tissue transplantation (WHA 63.22),* 2010. Available: https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf. [Accessed April 2024].

2 Organ and Tissue Authority (OTA), *OTA Strategy 2022-2027,* 2022. Available: https://www.donatelife.gov.au/sites/default/files/2022-08/OTA%20Strategy%202022-2027.pdf. [Accessed April 2024].

3 World Health Organization, *NOTIFY Library - The global vigilance and surveillance database for medical products of human origin.* Available: https://www.notifylibrary.org/. [Accessed April 2024].

4 EU Public Health Programme, *Vigilance and Surveillance of Substances of Human Origin (SOHO V&S) Deliverable 8,* January 2013. Available: https://www.notifylibrary.org/sites/default/files/SOHO%20V&S%20Communication%20and%20Investigation%20Guidance.pdf. [Accessed April 2024].

5 The Commission of the European Communities, *Guide to the quality and safety of organs for transplantation*, December 2022. Available: https://www.edqm.eu/en/guide-quality-and-safety-of-organs-for-transplantation. [Accessed April 2024].

6 Australian Government Department of Health and Aged Care. Commonwealth Qualified Privilege Scheme. Available: https://www.health.gov.au/our-work/commonwealth-qualified-privilege-scheme. [Accessed February 25, 2024].