Australian Government

Organ and Tissue Authority

Australian Vigilance & Surveillance System

ORGAN DONATION FOR TRANSPLANTATION

The Australian Vigilance and Surveillance System

2025 REPORT

Contents

1 Foreword

Organ donors, donor families, transplant recipients, and the Australian community trust that the organ donation and transplantation system is as safe and effective as possible. Ideally, all potential issues should be identified and corrected before they become actual failures in this complex system. 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 monitor trends and help inform national advice, recommendations, and guidelines.

The lives of 1,438 Australians were changed when they received an organ transplant in 2025. This was only possible thanks to the generosity of 557 deceased organ donors and their families who said yes to donation. In addition, there were 230 living kidney donations in Australia of which 53 were facilitated through the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program.

Organ donation and transplantation involves 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 continue to be improvements to clinical practices across the donation and transplantation system 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, identify issues and trends, and made recommendations to the appropriate governing committees with the aim of improving practices and access to transplantation. During the past year, this work has resulted in updates to key clinical practices and guidelines and the notification of trends to jurisdictions where recurring events were identified. In addition, regular communiques have been issued to the clinical sector that have highlighted important practices and learnings, as well as information from international publications considered relevant to safe donation and transplantation practice in Australia.

This report contains an analysis of 79 serious adverse event and/or reaction (SAER) notifications reported to the VSEAC. Events and reactions are rare – for context, there were 1,502 transplant procedures performed in 2025, with 34 of the SAER notifications directly related to donor or recipient processes, equating to 2.3% of all transplant procedures. The remaining 45 notifications related to broader system issues, specifically Australian Organ Donor Register (AODR) discrepancies. In this report, we collate information and trends to provide insights into the types of notifications received that have led to positive practice changes.

The total number of notifications received in 2025 has remained stable. When compared with 2024, this occurred alongside a higher number of transplants. This reflects the cumulative impact of earlier work to introduce new avenues for reporting, strengthened engagement across the sector, and improved identification of AODR related events. Building on this progress, we will undertake a review of the VSEAC framework starting in 2026, including working closely with Services Australia to reduce AODR-related errors.

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. The Organ and Tissue Authority and VSEAC continue to strongly encourage the reporting of actual or potential adverse events and reactions to increase knowledge that helps inform future advice. This will improve the safety and quality of donation and transplantation and enhance Australia's system.

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2 Background, update and reporting

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

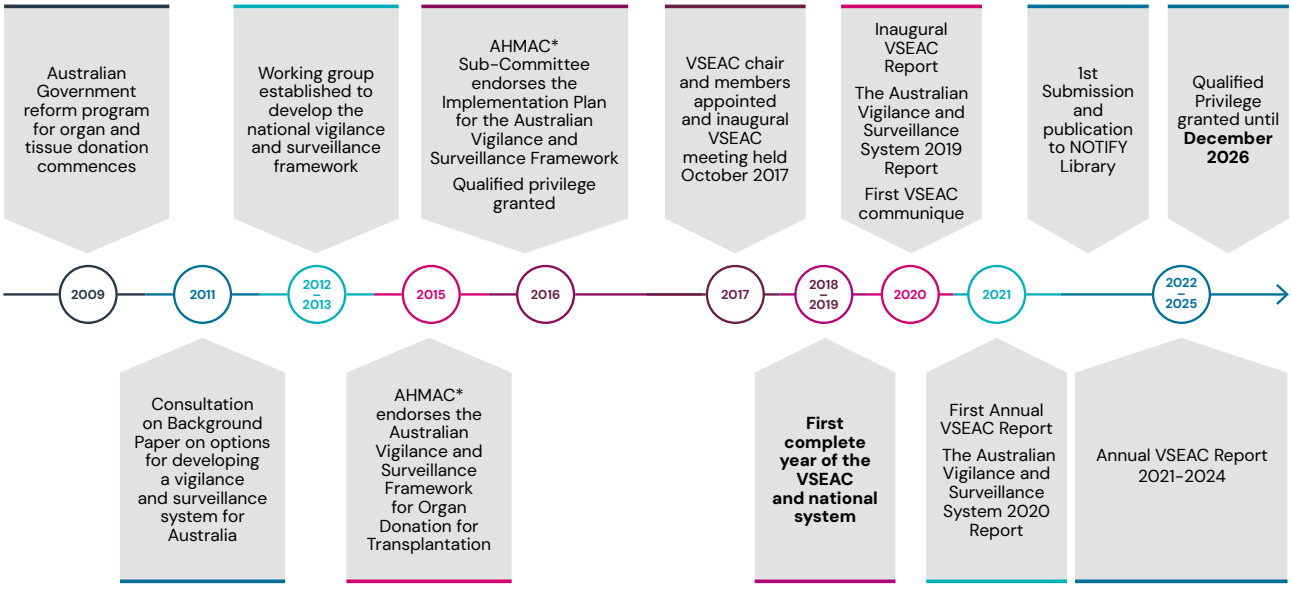
For organ donation and transplantation, vigilance and surveillance systems are established to maintain quality and safety throughout the process of:

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

Importantly we 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. A national monitoring system for detection, analysis and reporting provides an invaluable component of a feedback and improvement cycle. This leads to recommendations for practice improvements, an opportunity for shared learning, identification of long-term trends and ultimately a more effective and safer organ donation and 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 managing SAERs that occur within their jurisdiction.

*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.

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 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's (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.

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

The Australian Vigilance and Surveillance System has published 6 reports since 2020, collating all notifications received since 2012. This 2025 annual report covers all notifications received between 1 January and 31 December 2025. 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 as well as consideration towards improvement and prevention of recurrence.

2.2 VSEAC communiques

In addition to the annual report, the VSEAC regularly dispatches communiques. The purpose of the VSEAC 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. In 2025, the VSEAC issued 3 communiques to the donation and transplantation sectors, which encompassed the following themes:

- changes to donor blood group and human leukocyte antigen (HLA) type following bone marrow transplant or massive blood transfusion
- implications of incorrect patient information used for allocating organs
- importance of communication between donation and transplantation sectors
- unexplained death post-transplant
- missed opportunities for organ transplantation due to retrieval team unavailability, and
- importance of gaining accurate medical histories, particularly of malignant and infectious diseases.

2.3 Clinical guidelines

VSEAC provides advice and recommendations regarding the potential need for review of clinical guidelines and standard operating procedures, where inconsistencies in clinical practice are identified. Since its inception, notifications from the VSEAC have prompted several reviews and updates to the standard operating procedures and guidelines developed by The Transplantation Society of Australia & New Zealand (TSANZ), including updates to the infectious diseases content of the TSANZ Clinical Guidelines.

2.4 International reporting

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 submission to Project Notify at the time of review of the notification by the VSEAC committee. 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. One notification in 2025 was highlighted for consideration for submission to Project Notify and will be submitted in 2026 if all criteria are met.

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

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

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

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, and
- 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 with states and territories to help inform future national advice, recommendations, and guidelines. DonateLife agencies are required to notify SAERs to the Australian Vigilance and Surveillance System. Transplant units and Tissue Typing laboratories have been encouraged to report all SAERs through their local DonateLife agency. Notifications can also be submitted directly to the OTA Vigilance and Surveillance team or through the National OrganMatch Office.

3.1 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 ANZKX program, which is a living donation program supported by the OTA. The system encompasses all phases of the process from donation to transplantation, post-transplantation outcomes, 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 donor evaluation, organ offering and allocation, 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.

3.2 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]. The 2025 *European Directorate for the Quality of Medicines and Healthcare (EDQM) – 9th Edition Guide to the quality and safety of organs for transplantation (2025)* [5] referenced the same document (chapter 16). The VSEAC has not changed the current definitions for serious adverse events/ 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 2 categories:

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

3.3 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.

3.4 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 2025, with a mixture of face to face and virtual meetings. The VSEAC membership from 1 January 2025 to 31 December 2025 is outlined in **Appendix A**.

3.5 The VSEAC process

The Vigilance and Surveillance System process (as outlined in Figure 2) expanded its mechanisms for reporting of SAER notifications in 2024, and these mechanisms remain in effect in 2025. 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 within the DonateLife agency, the National OrganMatch Office, or by an individual directly to the OTA Vigilance and Surveillance team.

The SAER notification is initially reviewed and assessed by the OTA National Medical Director who 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 timelier 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 of, or involvement in an incident, prior to the consideration of each case.

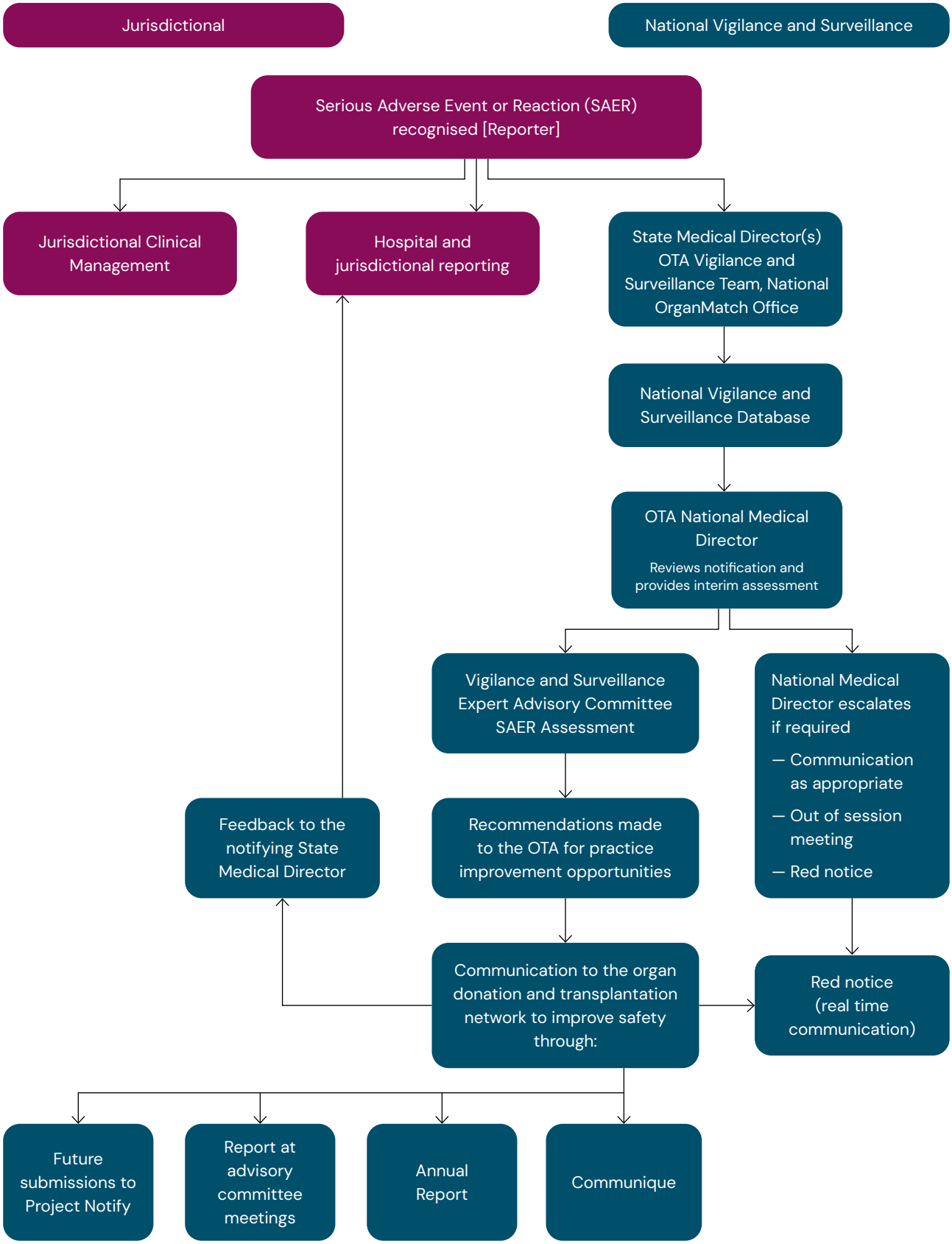
3.6 SAER notification database

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 associated literature reviews, Notify Library searches, and correspondence is stored with each SAER notification.

In 2025, planning began to review the VSEAC framework and streamline VSEAC processes. The review is scheduled to commence in 2026. This work will build on earlier enhancements to the portal used for online submission of SAER notifications, supporting the long-term aim of storing and editing submissions and related correspondence in a centralised system.

The role of VSEAC is to monitor trends of serious adverse events and reactions. Identifying trends helps VSEAC make recommendations for improved clinical practice to make organ donation and transplantation safer for all Australians.

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

The National Donation Program continued to see an increase in the number of deceased organ donors in 2025. There was a 6% increase in deceased organ donors in 2025 compared to 2024 and the highest number of deceased donors on record. This resulted in an 8% increase in the number of organ transplant recipients compared to 2024.

In 2025, there were 79 notifications received, which were classified by notification type and category. Events and reactions remain rare. For context, there were 1,502 transplant procedures performed in 2025, with 34 of the SAER notifications directly related to donor or recipient processes - this equates to 2.33% of all transplant procedures. The remaining 45 notifications related to broader system issues.

Table 1 is a breakdown of the 79 notifications received in 2025, classified according to the types and categories used by the vigilance and surveillance system.

Table 1 SAER notifications that occurred and were reviewed in 2025

Notification type (total 79 notifications)		
Serious adverse reaction	3	4%
Serious adverse event	31	39%
Serious adverse events – broader system	45	57%
Notification category (total 79 notifications)		
Donation	59	75%
Retrieval	7	9%
Transplantation	12	15%
Laboratory	1	1%

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 2025 (79) remained similar to 2024 (76). This is considered likely due to strong awareness of the role and value of the vigilance and surveillance system, which continues to support steady submission rates.

Figure 3 shows the 79 SAER notifications submitted to and assessed by VSEAC during 2025, and whether they were reactions or events (individual specific or broader system).

Serious adverse events are rare compared to the number of donation and transplantation events.

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 2025

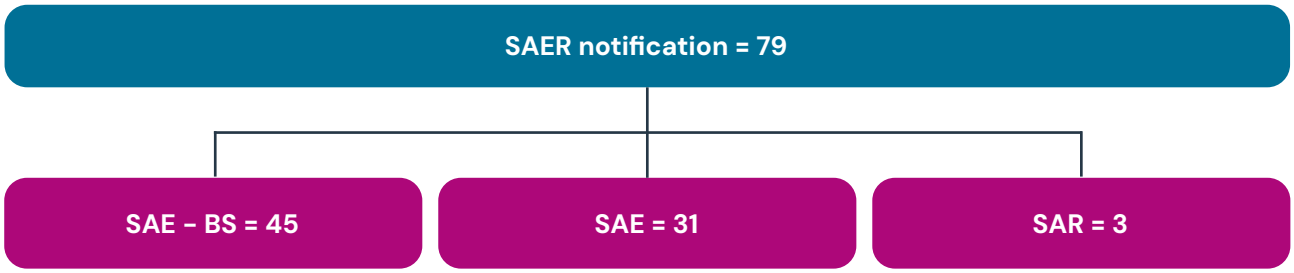


Table 2 demonstrates a decrease in the proportion of individual-specific SAER notifications relative to overall transplant procedures, from 3.6% in 2024 to 2.33% in 2025. The volume of notifications received in 2025 remained largely unchanged from 2024, with 79 notifications compared to 76 in the previous year. Three notifications in 2025 were serious adverse reactions involving possible transmission of donor derived diseases, including infection, malignancy or other diseases.

SAER: Serious adverse event and/or reaction.

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 - 2016 to 2025

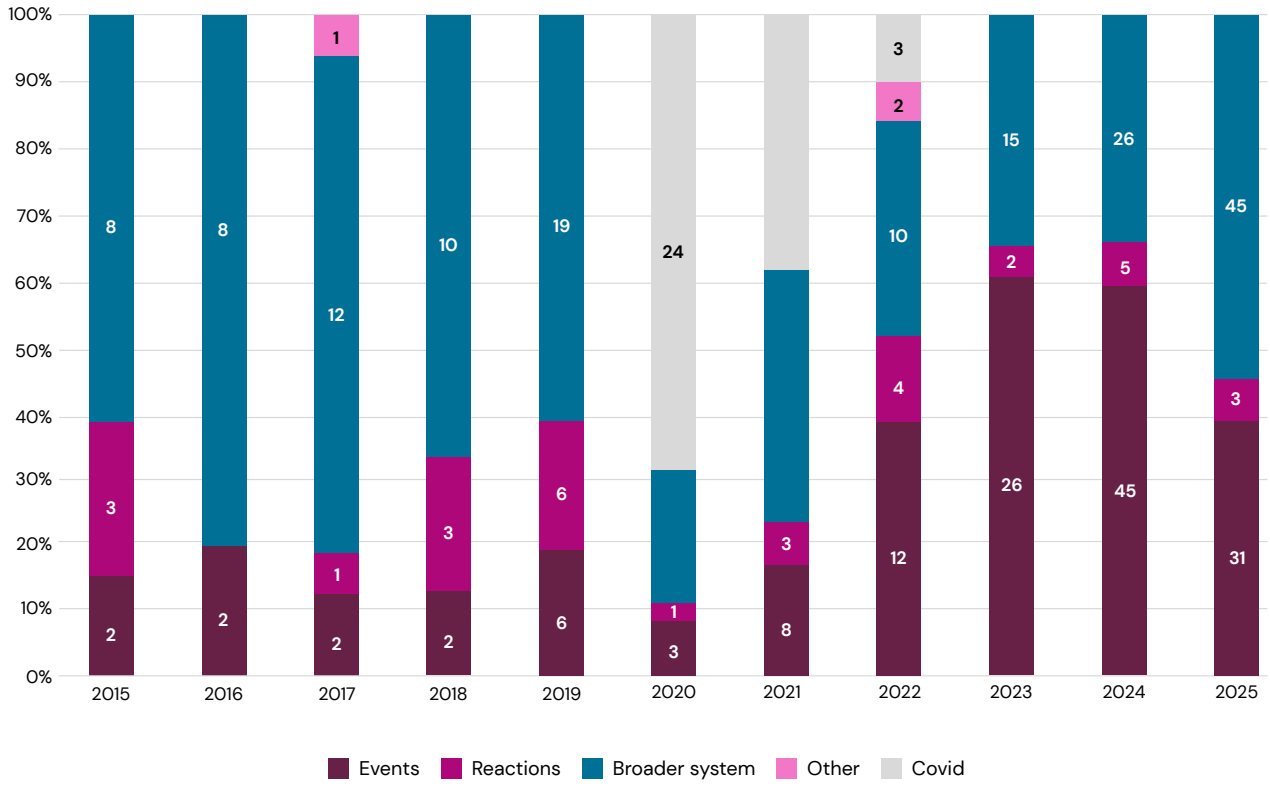
		VSEAC established								
Year	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Deceased organ donors	503	510	554	548	463	421	454	513	527	557
Transplant recipients	1,447	1,400	1,544	1,444	1,270	1,174	1,224	1,396	1328	1438
Transplant procedures	1,508	1,467	1,618	1,501	1,334	1,227	1,281	1,458	1387	1502
SAER notifications	2	3	5	12	4	13	14	28	50	34
SAE-BS notifications	8	13	11	16	7	20	10	15	26	45
Proportion of SAER notifications relative to transplant procedures	0.13%	0.20%	0.31%	0.80%	0.30%	1.06%	1.09%	1.92%	3.6%	2.33%

Figure 4 shows a comparison of the total 2025 incidents compared to SAER notifications in prior years, breaking down SAER notifications into the reported categories:

For 2025 the number in each category is as follows:

- Serious adverse event
  - individual specific = 31
- Serious adverse event
  - broader system = 45
- Serious adverse reaction = 3
- Other = 0

Figure 4 SAER notifications by category from 2016 to 2025



5 Analysis of serious adverse events and/or reaction notifications

SAER notifications are analysed and categorised 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 79 SAER notifications reviewed by VSEAC in 2025.

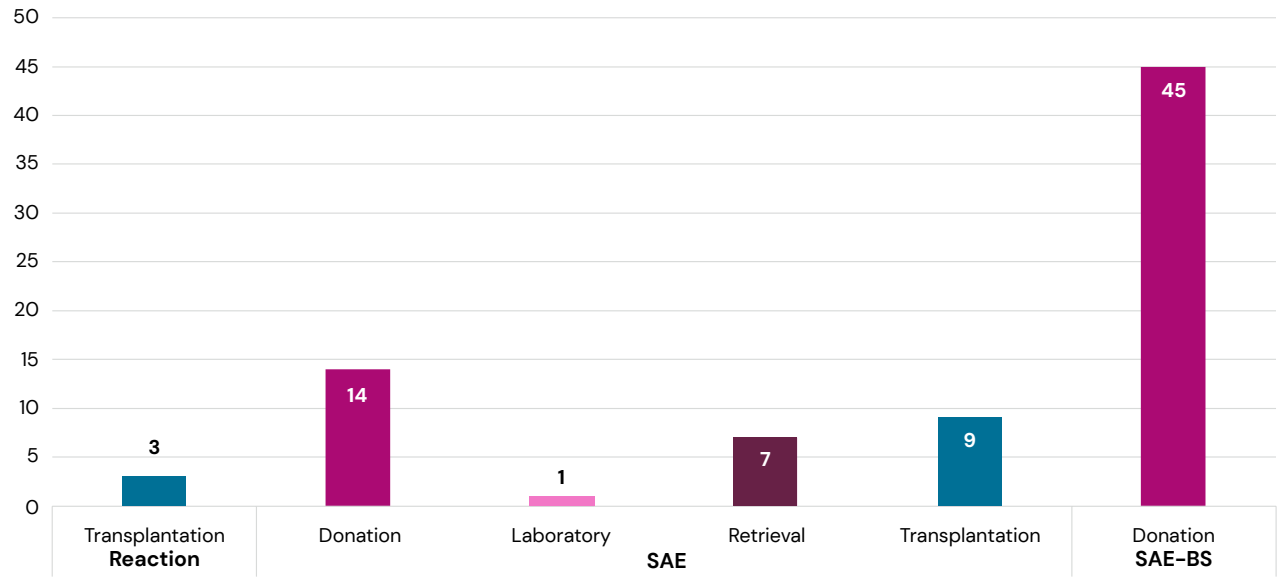
Figure 5 shows the 2025 notifications according to the 3 notification types (serious adverse event, serious adverse reaction and broader system issue) and the categories of donation, retrieval, transplantation and laboratory.

5.1 Analysis of SAER notification categories for 2025

The SAER notifications can be categorised according to whether they relate to donation, retrieval, or transplantation. For 2025, the 79 notifications were categorised as:

Notification category		
Donation	59	75%
Retrieval	7	9%
Transplantation	12	15%
Laboratory	1	1%

Figure 5 SAER notifications by classification and category

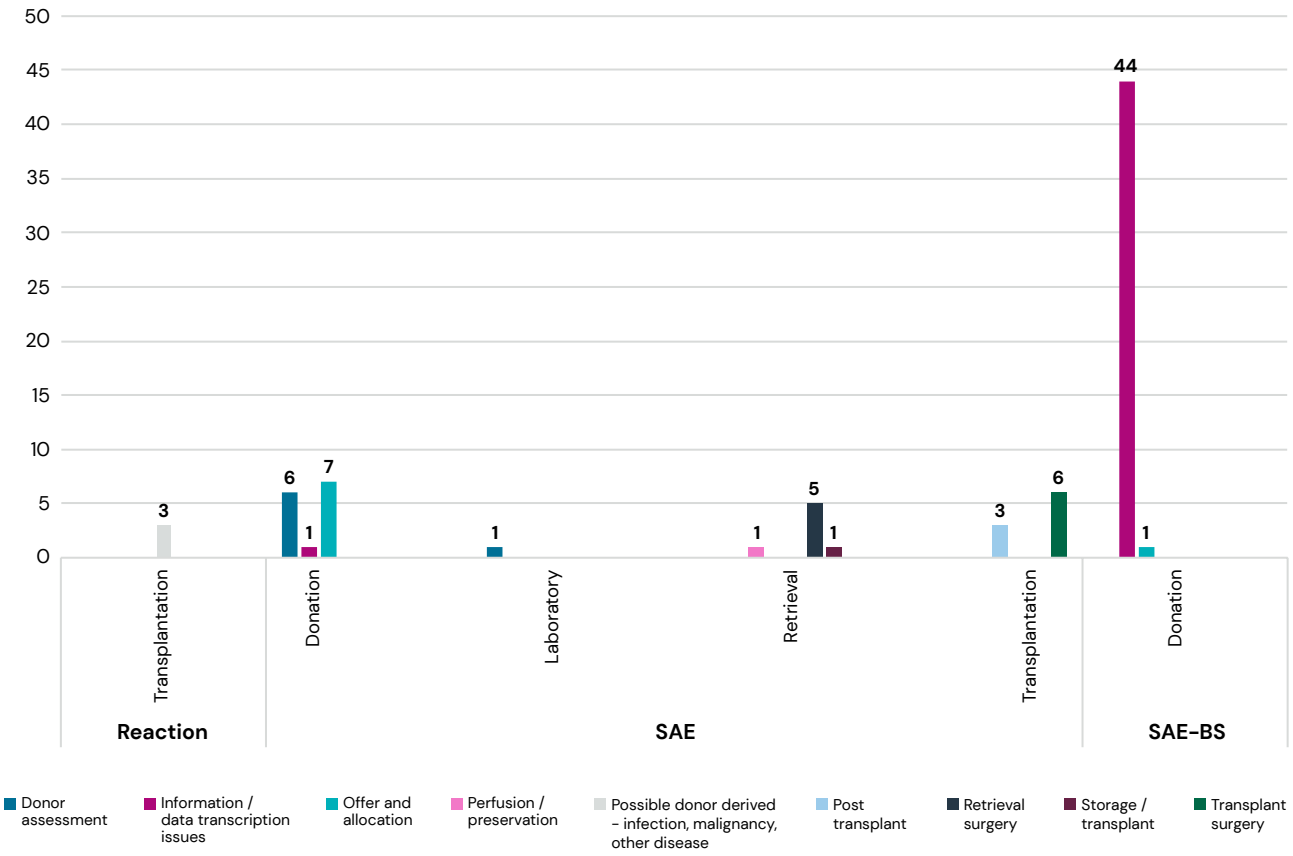


Notifications can be further classified into the following sub-categories:

- 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
- malignancy or other diseases.

Figure 6 shows the number of notifications in each sub-category in 2025. In 2025, the information/data transcription sub-category had the most notifications (45), followed by offer and allocation (8) and donor assessment (7).

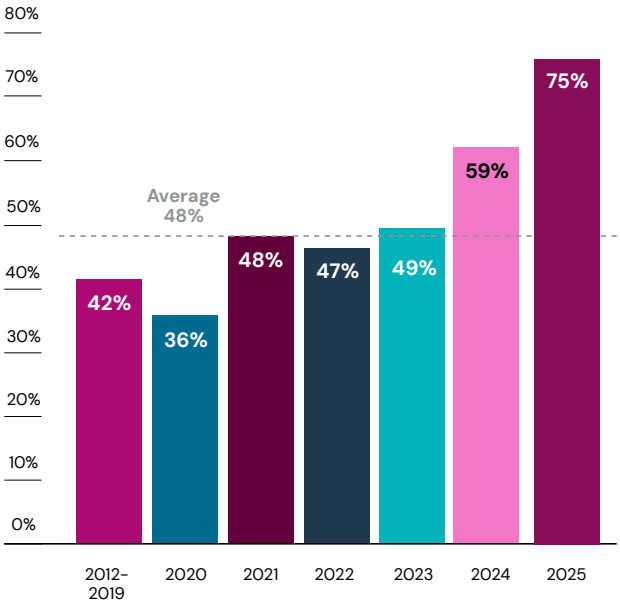
Figure 6 SAER notifications by sub-category in 2025



5.1.1 SAER notifications relating to donation

SAER notifications relating to the donation category accounted for 75% of the total number of notifications received in 2025. This was 16% higher than 2024 data and 27% higher than the average of all SAER notifications relating to the donation category from 1 January 2012 to 31 December 2025 (48%).

Figure 7 SAER notifications related to donation.



For 2025, these notifications included the following sub-categories:

5.1.1.1 Donor assessment

The notifications in this category relate to the potential donor assessment process that involves a comprehensive evaluation to determine suitability for organ donation. This entails a detailed consent process with the next of kin, an extensive medical history review, and additional medical tests and assessments. Donor assessment information is provided to transplant units who use this information in considering suitability for potential recipients.

There were 7 notifications in the donor assessment category related to individual-specific events, including complaints regarding the Australian Donation Risk Assessment Interview (AUS-DRAI), organs declined due to potential for transmission of donor derived disease and/or infection, donor medical issues not identified prior to retrieval of organs, and organs not utilised due to incorrect pathology reporting.

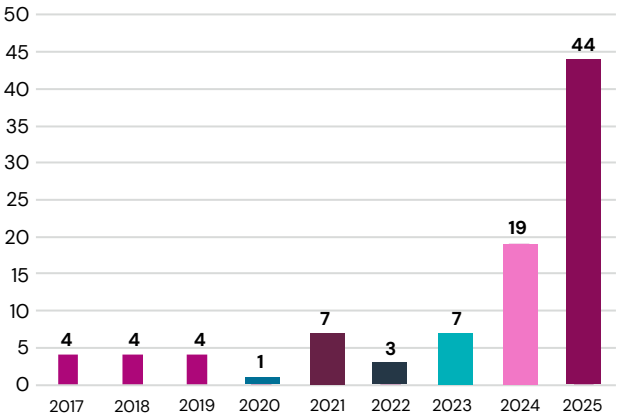
5.1.1.2 Offer and allocation

There were 8 notifications related to the offering and allocation of organs. These notifications were related to logistical issues and organ allocation processes, including tissue typing processes.

5.1.1.3 Information/data transcription issues

In 2025, there were 45 notifications related to information/data transcription errors. Of these notifications, 44 were AODR discrepancies, representing only 2.8% of total AODR enquiries made by DonateLife staff. This indicates AODR discrepancies remain relatively infrequent despite accounting for a large proportion of notifications. All governments are focused on increasing registrations on the AODR. Families are much more likely to consent to organ donation when their family member was registered on the AODR.

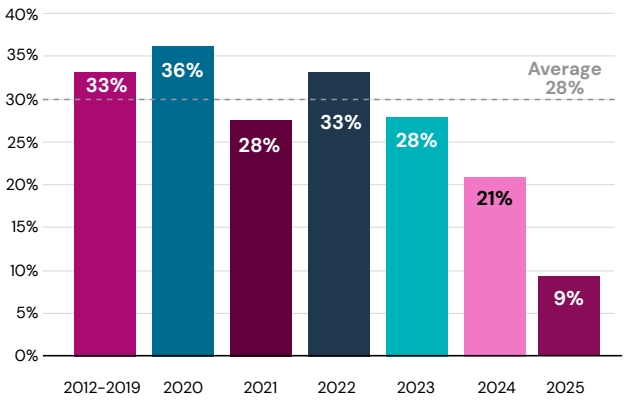
Figure 8 Australian Organ Donor Register (AODR) SAER notifications.



5.1.2 SAER notifications relating to retrieval

SAER notifications relating to the retrieval category made up 9% of the total number of notifications from 1 January 2025 to 31 December 2025 (Figure 9).

Figure 9 SAER notifications related to retrieval.



In 2025, these notifications included the following sub-categories:

5.1.2.1 Retrieval surgery

There were 5 notifications within the retrieval surgery category. These notifications related to any surgical retrieval challenges or organ injuries, including surgical technique, donor physiology or surgical retrieval team members and logistics.

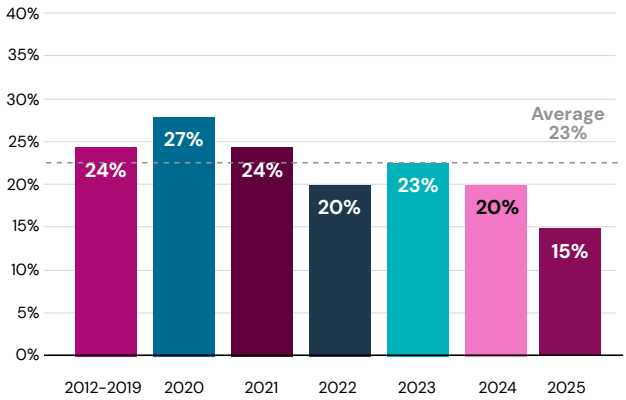
5.1.2.2 Perfusion and preservation

Notifications related to the perfusion and preservation of organs reduced from 3% in 2024 to 1% in 2025.

5.1.3 SAER notifications relating to transplantation

SAER notifications relating to the transplantation category accounted for 15% of the total number of notifications from 1 January 2025 to 31 December 2025 (Figure 10).

Figure 10 SAER notifications related to transplantation.



In 2025, 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 disease for 2025, encompassing infection, malignancy or other disease. In all 3 of the notifications an organ was transplanted, and the possible donor derived disease transmission was managed appropriately.

5.1.3.2 Transplant surgery

There were 6 notifications of issues that occurred or were identified during transplant surgery. These included changes to the recipient's medical condition and the condition of donated organs.

Appendix A
VSEAC membership 2025

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 2025 to 31 December 2025.

Position	Committee role (representative and expertise based)	Held by
Chair (OTA CEO appointed)	Editor in Chief Transplantation Journals, 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 Directors	Dr Elena Cavazzoni - NSW Dr Stewart Moodie - SA
Member	Donation Nurse Specialist	Ms Erin East
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 & New Zealand	Dr Handoo Rhee
Member	Australasian Donation and Transplant Coordinators Association representative	Ms Nicola Seifert
Member	Oncology expertise	Dr Brian Stein
Member	Physician representative, Transplantation Society of Australia & New Zealand	Prof Angela Webster
Member	Epidemiologist	A/Prof Germaine Wong
Member	Tissue typing and immunology expert	Ms Rhonda Holdsworth

Reference list

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