



**Australian Government**  
**Organ and Tissue Authority**



# **The Australian Vigilance and Surveillance System for Organ Donation and Transplantation 2021**

**2021 Report**  
June 2022

# Contents

|            |   |           |
|------------|---|-----------|
| <b>1</b>   | <b>Foreword</b>   | <b>1</b>  |
| <b>2</b>   | <b>Background, update and reporting</b>   | <b>2</b>  |
| <b>2.1</b> | 2020 Australian Vigilance and Surveillance System for Organ Donation and Transplantation Report | 4         |
| <b>2.2</b> | VSEAC quarterly communiques   | 4         |
| <b>2.3</b> | Clinical guidelines   | 4         |
| <b>2.4</b> | International reporting   | 4         |
| <b>3</b>   | <b>The Australian Vigilance and Surveillance System</b>   | <b>5</b>  |
| <b>3.1</b> | The Australian Vigilance and Surveillance System  | 5         |
| <b>3.2</b> | Scope of the national system  | 5         |
| <b>3.3</b> | Defining serious adverse events and reactions   | 6         |
| <b>3.4</b> | Commonwealth Qualified Privilege  | 6         |
| <b>3.5</b> | The Vigilance and Surveillance Expert Advisory Committee (VSEAC)                                | 6         |
| <b>3.7</b> | SAER notification database  | 7         |
| <b>4</b>   | <b>Overview of all reported serious adverse event and/or reaction notifications</b>             | <b>9</b>  |
| <b>5</b>   | <b>Analysis of serious adverse events and/or reaction notifications</b>                         | <b>12</b> |
| <b>5.1</b> | Analysis of SAER notification categories for 2021   | 12        |
| <b>5.2</b> | Overview of COVID-19 log notifications  | 15        |
|            | <b>Appendices</b>   | <b>16</b> |
| <b>A</b>   | VSEAC membership 2021   | 16        |
|            | <b>Reference List</b>   | <b>17</b> |

---

# 1 Foreword

**Transplant recipients, donors and their families, as well as the Australian community trust that the organ donation and transplantation system is as safe and effective as possible. Any potential or actual failures in our systems must therefore be identified, analysed and discussed so that actions can be taken to prevent recurrence, to keep our patients safe and to strive for the best possible outcomes.**

This year has seen ongoing challenges and impacts on the organ and tissue donation and transplantation system consequent to the COVID-19 pandemic. The pandemic has continued to put stress on our health and broader systems resulting in continued reductions in organ donation and transplantation activity compared with pre-pandemic years. As the pandemic has evolved there has been a requirement to adjust clinical practices both in the donation and transplantation sectors with the goal of keeping patients as safe as possible while optimising donation and transplantation opportunities.

Members of the Vigilance and Surveillance Expert Advisory Committee (VSEAC) are integral to the quality and safety cycle of the organ donation and transplantation system and have continued to play a vital role in sector's response to the pandemic.

The Vigilance and Surveillance system has matured since its inception with improvements to the submission process for notifications, the database holding notifications, and the provision of information and learnings to the clinical community through regular communiques.

In 2021 the Organ and Tissue Authority (OTA) and VSEAC strengthened national and international relationships through involvement in COVID-19 focused forums including the [COVID-19 Australian Transplantation and Donation Rapid Response Taskforce](#) and regular international information sharing meetings. VSEAC also identified the first suitable case for submission to

Project Notify, a publicly accessible, curated international database of adverse occurrences that seeks to improve safety and quality in donation and transplantation.

The 2021 annual Report contains an analysis of twenty-nine serious adverse event and/or reaction (SAER) notifications reported to VSEAC. This is an increase on the number of notifications received in 2020, which is expected as the system continues to mature. This small dataset does not allow for detailed reporting, whilst maintaining de-identification and confidentiality. The 2021 annual Report also reports on the notifications submitted via the COVID-19 log.

In 2021, the VSEAC also retained Commonwealth qualified privilege for another five years, following the original granting of qualified privilege in 2016. Qualified privilege is important in the functioning of VSEAC and for encouraging the submission of notifications by clinicians in the sector.

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

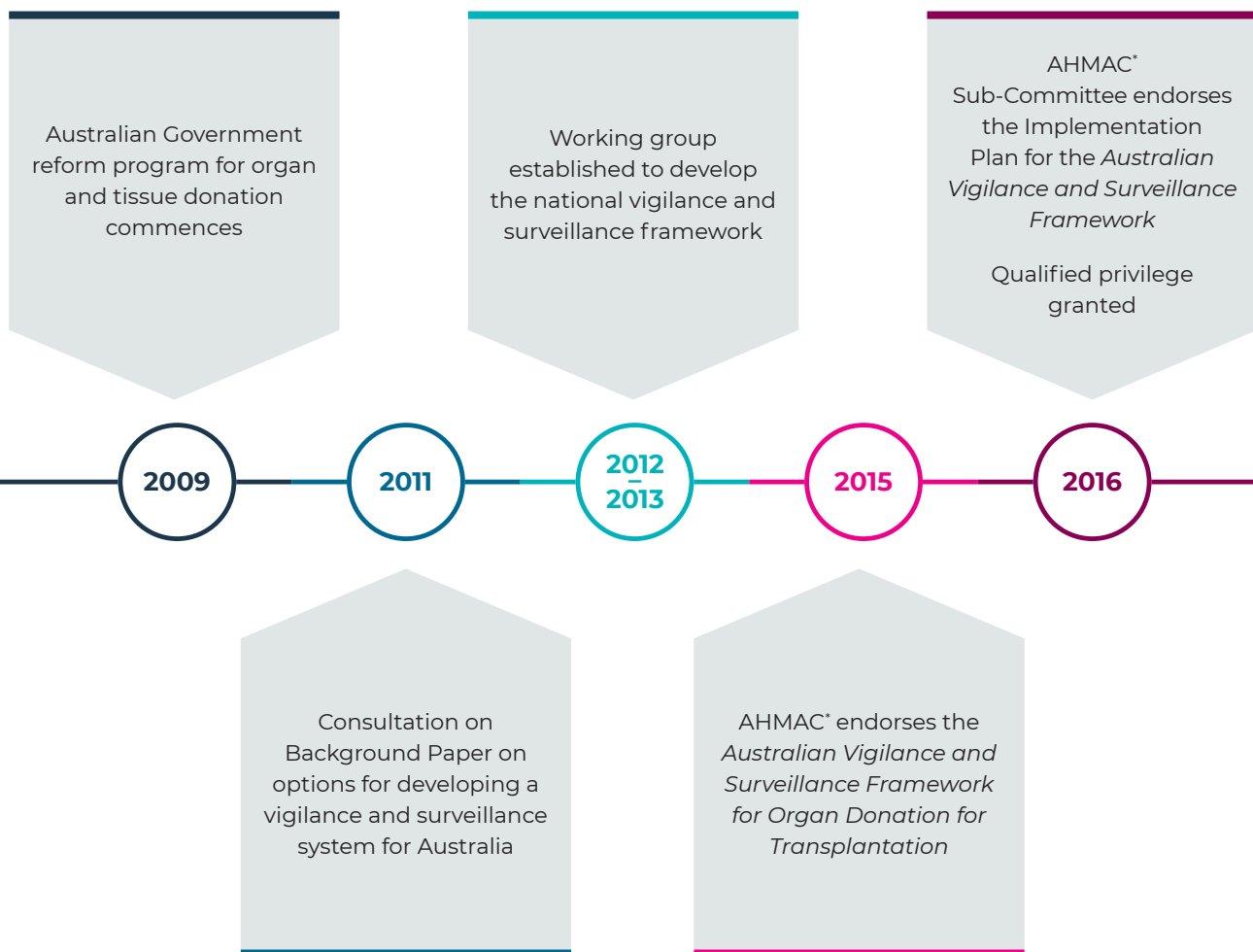
Organ and Tissue Authority

## 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 safeguard a better quality and safety in organs donated and used for transplantation. Importantly these systems aim to review and avoid reoccurrence of serious adverse events and/or reactions (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 full picture and identify any 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.

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



Throughout the development and implementation phases, states and territories were and continue

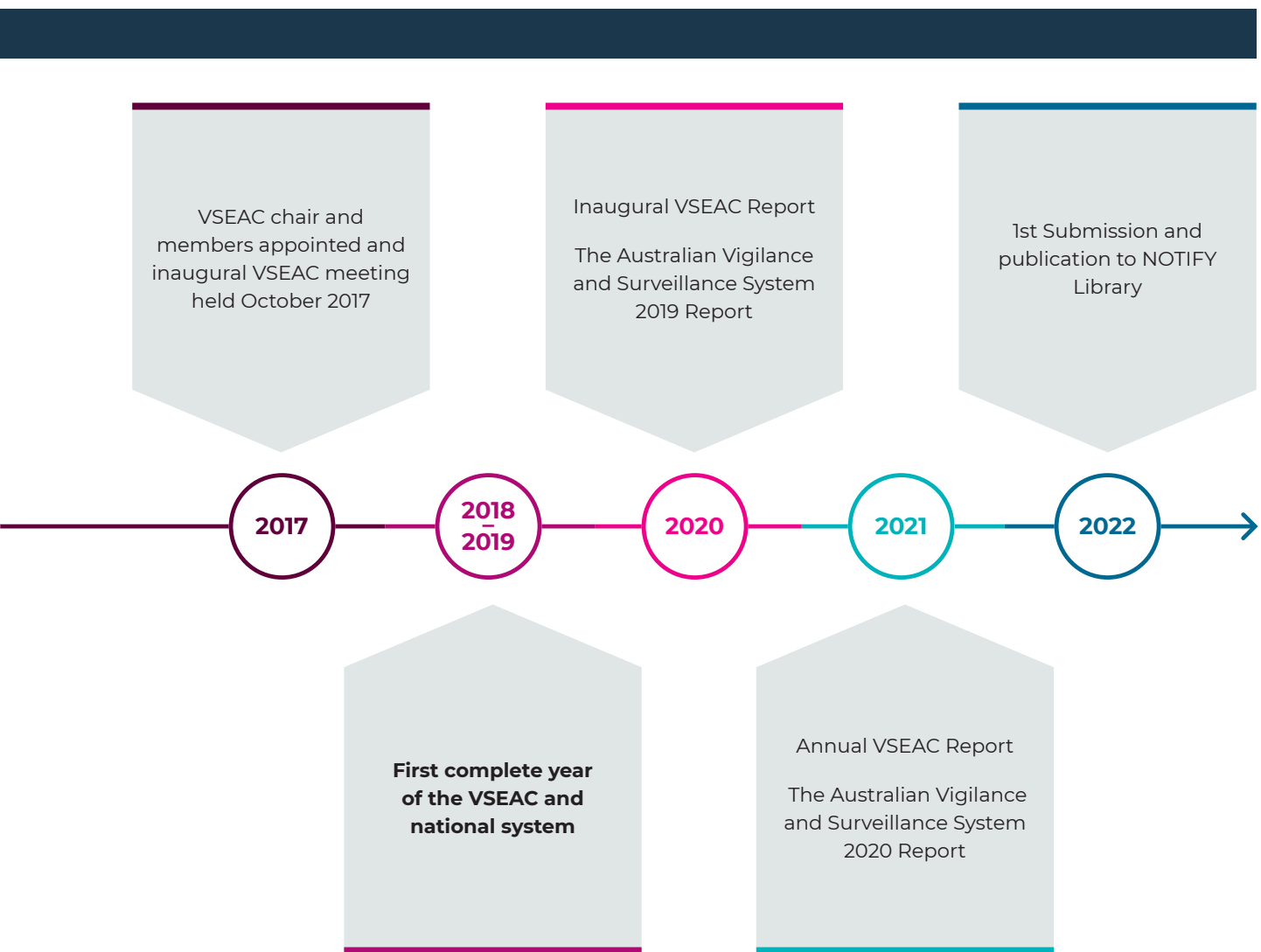
\*Australian Health Ministers Advisory Committee (AHMAC)

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 contribute to the improvement in clinical practice to further enhance patient safety.

Internationally 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'<sup>(1)</sup>. This is aligned with the OTA's strategy to enhance the safety of organ donation and transplantation in Australia.<sup>(2)</sup>

A brief history at Figure 1 (below) illustrates how the Australian vigilance and surveillance has matured over time.



to be responsible for management of individual SAERs that occur within their jurisdiction.

## 2.1 2020 Australian Vigilance and Surveillance System for Organ Donation and Transplantation Report

In July 2021, VSEAC released the second annual Report<sup>(3)</sup> on the Australian vigilance and surveillance system, for notifications received from 1 January to 31 December 2020 and also included insights into the impacts of COVID-19 on the organ donation and transplantation sector. The inaugural Vigilance and Surveillance report was released in 2020.

In 2021, there were 29 notifications which were classified by notification type and notification category:

| Notification type                      |    |     |
|--|----|-----|
| Serious adverse reaction               | 3  | 10% |
| Serious adverse event                  | 8  | 28% |
| Serious adverse event – broader system | 18 | 62% |
| Notification category                  |    |     |
| Donation                               | 14 | 48% |
| Retrieval                              | 8  | 28% |
| Transplantation                        | 7  | 24% |



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

## 2.2 VSEAC quarterly communiques

In addition to the annual Report, VSEAC regularly communicates learnings in the form of sharing reported de-identified cases with associated commentary to the donation and transplant sector through quarterly communiques. The purpose of the VSEAC quarterly communiques is to raise awareness of current recommended clinical practices and convey new issues, risks and recommendations so as to enhance patient safety and donation and transplantation outcomes.

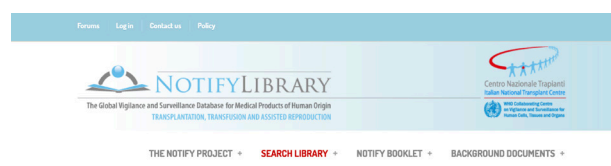
## 2.3 Clinical guidelines

A number of SAER notifications prompted a review of current standard operating procedures and guidelines. Both the National Standard Operating Procedure: Organ Allocation, Organ Rotation, Urgent Listing<sup>(4)</sup> and the TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors<sup>(5)</sup> were updated as a result of SAER notifications. Of note, this Guideline has been updated to include information relevant of the COVID-19 pandemic including donor screening and use of organs from donors at risk of or with COVID-19 infection.

## 2.4 International reporting

The VSEAC is committed to contributing to the international Notify Library<sup>(6)</sup> database when Australian SAERs meet the criteria for submission.

The VSEAC has 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. As part of VSEAC review of each SAER notification, it is determined whether the occurrence should be considered for Project Notify submission. In 2021, one notification met all criteria and was submitted to Project Notify. The submission was accepted and has been published on the Notify Library website in May 2022.



## 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 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 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 national and international 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 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 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 by providing 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, with the exception of 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 a 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 occurrences may also facilitate opportunities for process improvement, so the scope was broadened beyond possible donor to recipient disease transmission. These types of notifications are derived from international systems in both Europe and the US and are intended to include events that have consequences beyond the individual and have broad significance because of 'shared practices, services and supplies' [EDQM, Event (C) – pg 350].<sup>(8)</sup>

These process system issues, are termed 'serious adverse event – broader system (SAE-BS), which are then considered at a national level to identify where improvements could occur in the system to improve 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 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)'*<sup>(7)</sup>. In 2018 the *'European Directorate for the Quality of Medicines and Healthcare (EDQM) – 7th Edition Guide to the quality and safety of organs for transplantation (2018)'*<sup>(8)</sup>, in chapter 15 and appendix 19, referenced the same document. 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 to 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 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'.

VSEAC have further broken down an SAE into two categories:

- ▶ SAE – individual specific (SAE)
- ▶ 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 five-year period. A renewal was applied for in 2021 and another five-year period of Qualified Privilege was granted, taking effect on 14 December 2021.

### 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. In 2021, the VSEAC membership was reviewed with some change of members. The VSEAC membership between 1 January 2021 to 31 December 2021 is as outlined in Appendix A.

During 2021 VSEAC formally met three times. Due to COVID-19 restrictions these were all held via videoconferencing and matters were also progressed out of session and through email correspondence.



### **3.6 The Vigilance and Surveillance System process**

The Vigilance and Surveillance System process (as outlined in Figure 2 overleaf) remained unchanged throughout 2021 despite the challenges of the COVID-19 pandemic. The figure outlines the pathway that is followed when an adverse event or reaction occurs. It demonstrates that hospitals and states and territories are responsible for the immediate and ongoing clinical management of the incident and that concurrently the SAER notification is submitted to the Australian Vigilance and Surveillance System by the State Medical Director of the DonateLife Agency.

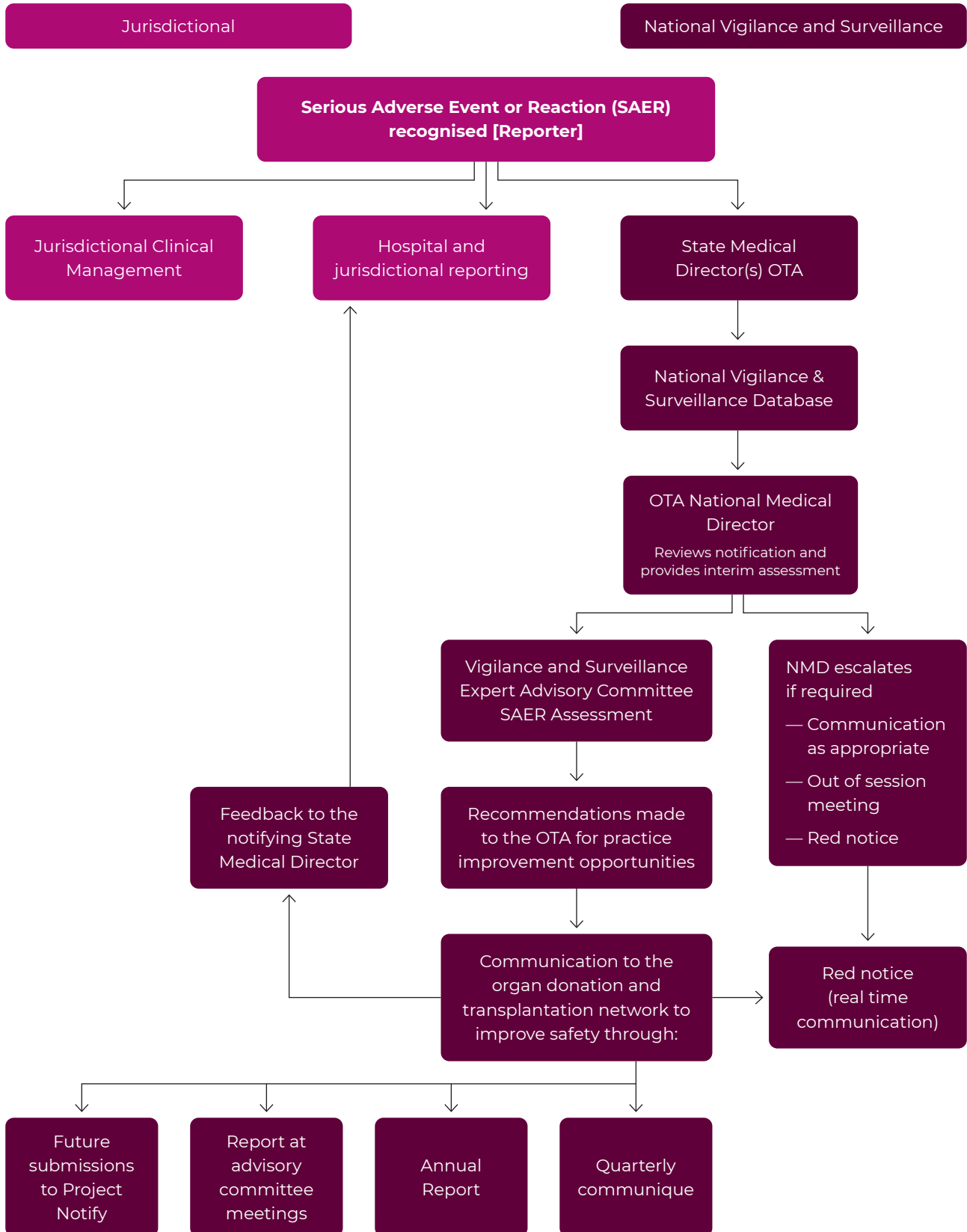
The SAER notification is initially reviewed by the OTA National Medical Director who assesses the notification and determines if any immediate actions are required. The notification is then reviewed by the VSEAC at the next meeting or out of session if a more timely response is required. SAER notifications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

### **3.7 SAER notification database**

The SAER notification database is managed by the OTA and 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, actions, and outcomes. In addition, any literature reviews, Notify Library searches, and correspondence is also stored with each SAER notification.

In 2021, a portal to facilitate online submission of SAER notifications, expanded its operations with the aim of moving to submission of all notifications and associated correspondence through this mechanism in the near future.

**Figure 2** Communication pathway for SAER notifications



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

In 2021, donation and transplantation activity in Australia declined slightly from 2020. There was a 7% decrease in the number of people receiving a transplant and a 9% decrease in the number of donors compared to 2020<sup>(9)</sup>. The number of SAER notifications reported to VSEAC was higher as compared to the prior year (29 SAER notifications in 2021 compared with 12 SAER notifications in 2020). This shows the Vigilance and Surveillance system has become embedded as routine practice, strengthening the quality and safety of organ donation and transplantation processes.

The COVID-19 pandemic has impacted the program, following a decade of growth in donation and transplantation in Australia with the introduction of the national program in 2009. The combined impact over the two years has resulted in a 23% reduction in organ donors and a 19% reduction in transplant recipients compared to 2019<sup>(9)</sup>. This is consistent with the experience of other countries such as the UK and Canada<sup>(10)</sup>. DonateLife Agencies have worked with transplant teams throughout the period to navigate the challenges facing hospitals, clinicians and logistics impacting the national program, including COVID-19 restrictions, flight reductions, and border closures.

VSEAC normally considers issues that have impact on the broader system (SAE-BS), where practice improvements could be made. It was agreed, to continue to report COVID-19 issues on a separate log to capture ongoing impacts of COVID-19 on the organ donation and transplantation system, as they are COVID-19 specific. These are reported by the national DonateLife Agency Managers in each state and territory. The COVID-19 log of incidents was only reviewed by VSEAC when deemed necessary. In 2021, there were 18 COVID-19 log notifications, which will be addressed later in the report, none of which required review by VSEAC.

As can be seen in Figure 3 overleaf, there were 29 SAER notifications submitted and assessed by VSEAC during 2021. The 29 notifications included notifications of broader system issues.

The number of SAER notifications (29) relative to overall donation and transplant activity (transplant procedures) remains small, although increased from previous years, see Table 1 at 0.90%.



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

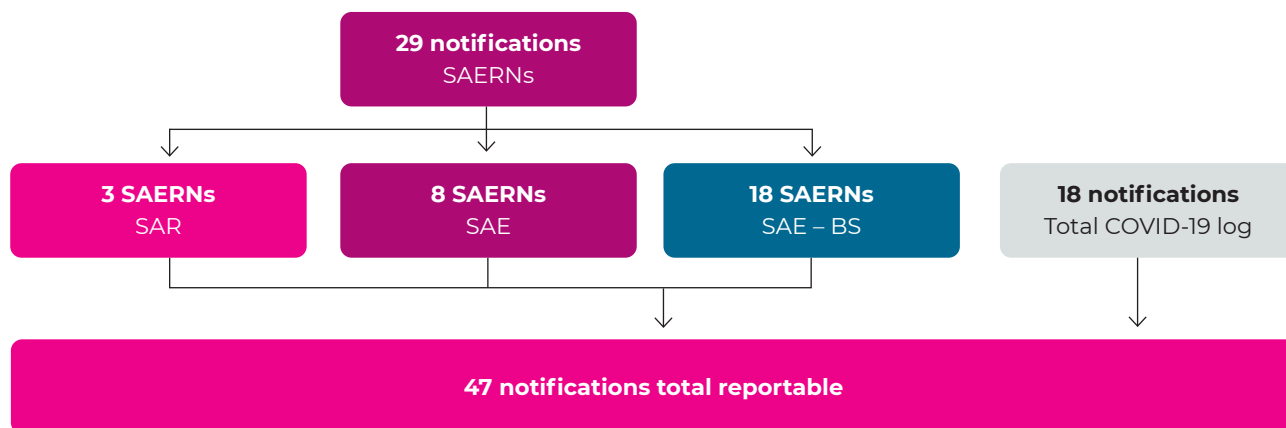
Figure 4 (overleaf), shows a comparison of the total 2021 incidents compared to SAER notifications in prior years, breaking down SAER notifications into three broad categories. For 2021 the number in each category is as follows:

| Notification category                   |    |
|---|----|
| Serious adverse reaction                | 3  |
| Serious adverse event                   | 8  |
| Serious adverse events – Broader system | 18 |



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 2021**

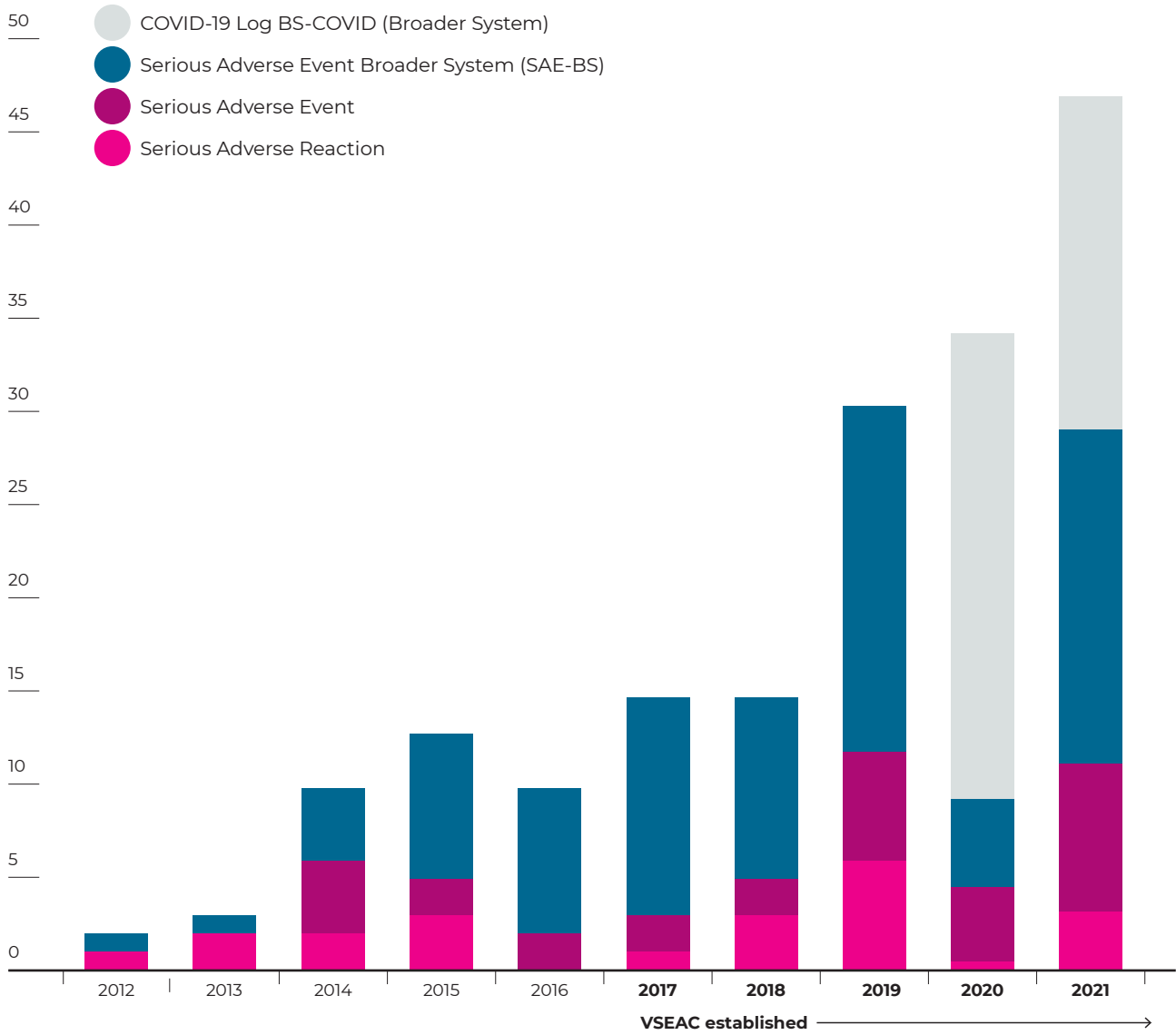


**Table 1 SAER notifications in context of deceased organ donors, transplant procedures and transplant recipients: 2012 to 2021**

| Year  | 2012  | 2013  | 2014  | 2015  | 2016  | VSEAC established |       |       |        |       |
|---|-------|-------|-------|-------|-------|-------------------|-------|-------|--------|-------|
|   |       |       |       |       |       | 2017              | 2018  | 2019  | 2020   | 2021  |
| Deceased Organ Donors                                 | 354   | 391   | 378   | 435   | 503   | 510               | 554   | 548   | 463    | 421   |
| Transplant Recipients                                 | 1,049 | 1,121 | 1,107 | 1,239 | 1,447 | 1,400             | 1,544 | 1,444 | 1,270  | 1,174 |
| Transplant Procedures*                                | 1,100 | 1,163 | 1,164 | 1,301 | 1,508 | 1,467             | 1,618 | 1,501 | 1,334  | 1,227 |
| SAERN Patient Specific**                              | 1     | 2     | 6     | 5     | 2     | 3                 | 5     | 12    | 4      | 11    |
| SAEN Broader System                                   | 1     | 1     | 4     | 8     | 8     | 13                | 11    | 16    | 7      | 18    |
| Proportion SAERN** relative to transplant procedures* | 0.09% | 0.17% | 0.52% | 0.38% | 0.13% | 0.20%             | 0.31% | 0.80% | 0.30%# | 0.90% |

\*Note, the 2020 percentage has been adjusted from the prior annual report to include only patient specific SAERNS.

**Figure 4 SAER notifications by year: 2012 to 2021**



## 5 Analysis of serious adverse events and/or reaction notifications

The incidents reported via the SAER notification process and reviewed by VSEAC have sufficient granular detail to enable analysis and categorisation according to the part of the donation and transplantation continuum they relate to, and also their impact. The following sections provide detailed information about the 29 SAER notifications reviewed by VSEAC in 2021.

### 5.1 Analysis of SAER notification categories for 2021

The SAER notifications can also be categorised according to whether they relate to donation, retrieval, or transplantation (Figure 5). For 2021, out of the 29 notifications, there were:

| Notification category |    |
|-----------------------|----|
| Donation              | 14 |
| Retrieval             | 8  |
| Transplantation       | 7  |

Figure 6 opposite shows the notifications according to the three types of notifications (serious adverse event, serious adverse reaction, or broader system) 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 was encouraged.

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

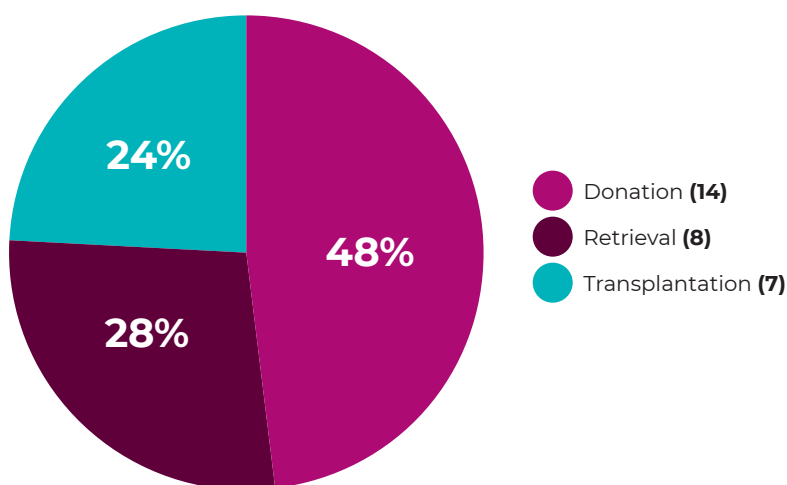
Figure 7 opposite shows the number of notifications in each sub-category in 2021. It shows the information/data transcription issues sub-category had the most notifications followed by retrieval surgery and possible donor derived infection.

A more in-depth overview of SAER notifications reviewed by the VSEAC by category, from 1 January 2021 to 31 December 2021, is further outlined next.

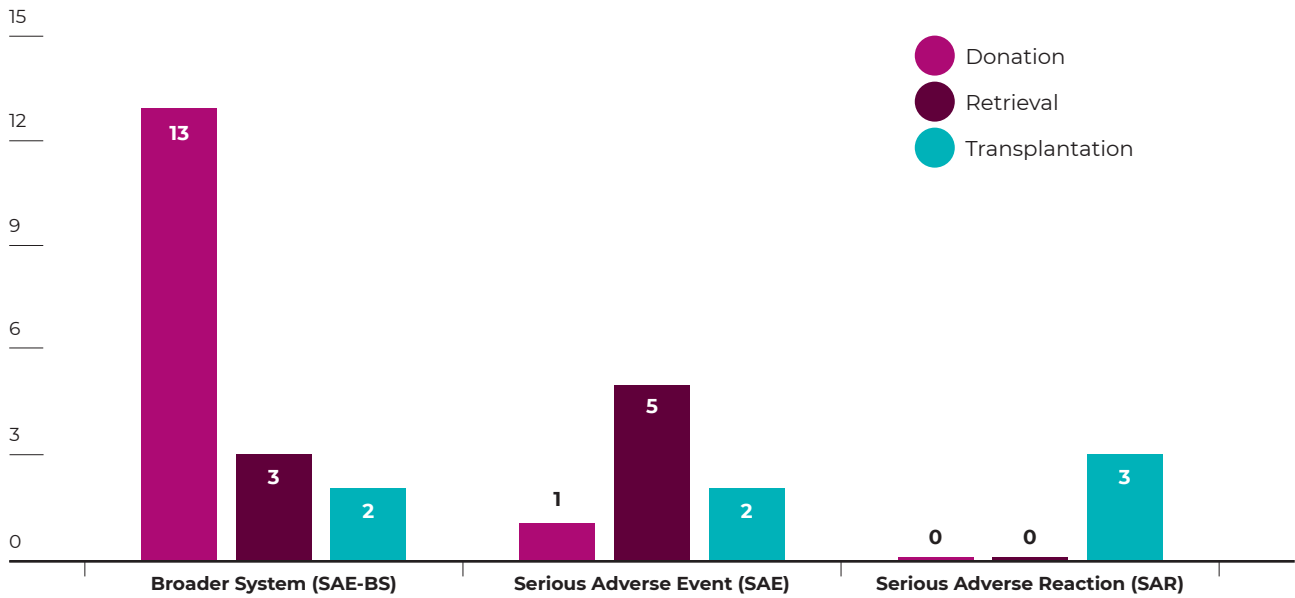


Notifications detailed here have been de-identified to ensure confidentiality.

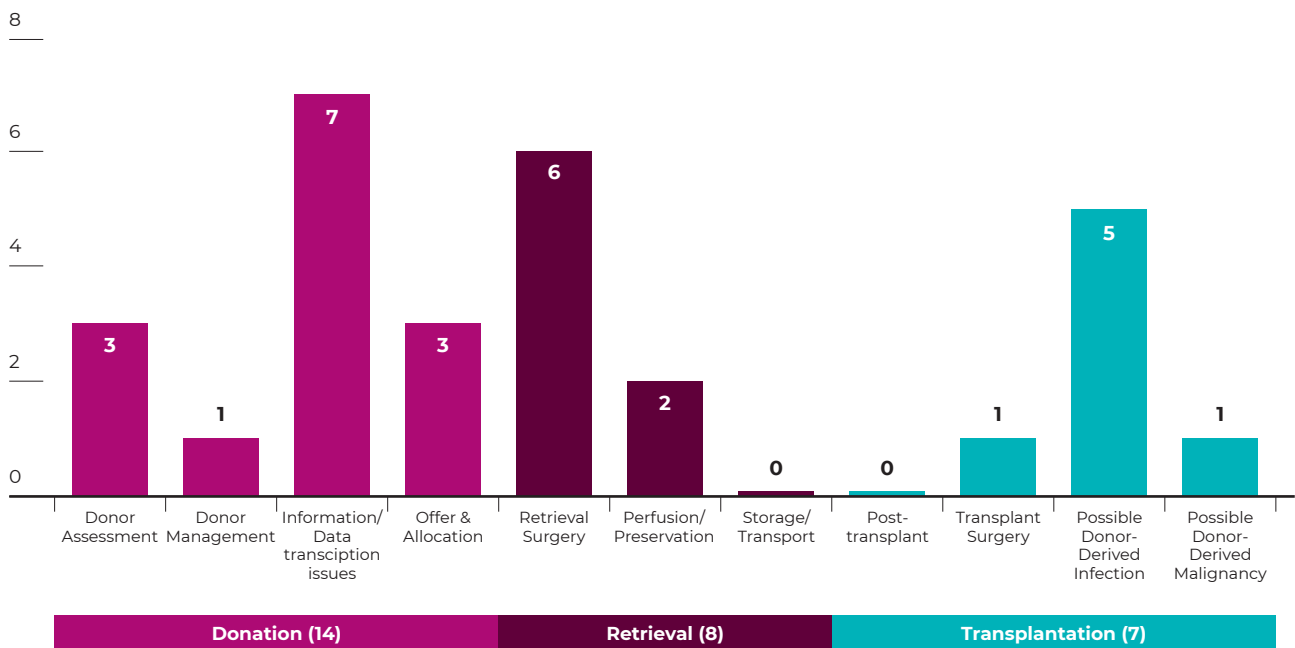
**Figure 5 SAER notifications by Donation, Retrieval and Transplantation categories in 2021**



**Figure 6 SAER notifications by category and notification type in 2021**



**Figure 7 SAER notifications by sub-category in 2021**



### 5.1.1 SAER notifications relating to donation

SAER notifications relating to the donation category made up 48% of the total number of notifications from 1 January 2021 to 31 December 2021. These notifications include the following sub-categories:

#### Donor assessment

The work up of a potential donor involves gathering extensive health information, a detailed consent process with the next of kin that specifies each organ and/or tissue to be donated, further screening tests and assessments, and provision of this information to transplant units who have potential matched recipients.

There were three notifications in the donor assessment category. None of the notifications resulted in missed donation opportunities. One notification resulted in VSEAC review of the current advice in the TSANZ Clinical Guidelines for Organ Transplantation for Deceased Donors<sup>(5)</sup>, and determined that the advice was still current.

#### Donor management

There was one case in this category, where VSEAC noted that this was a rare occurrence and no action was required. VSEAC noted that this was a rare occurrence.

#### Information/transcription issues

In 2021, there were seven SAER notifications related to the discrepancies in results of checks of the Australian Organ Donor Register (AODR).

The VSEAC continue to rate these inconsistencies in searching the AODR seriously as family knowledge that their relative had registered to be a donor is critical to their decision making.



In 2020, 89% of families agreed to donation when their family member was registered to donate on the Australian Organ Donor Register (AODR).

#### Offer and allocation

There were three SAER notifications related to offering and allocation of organs.

These occurrences prompted review of the National Standard Operating Procedure: Organ Allocation, Organ Rotation, Urgent Listing<sup>(4)</sup> with adjustments made to improve clarity and consistency with information in the TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors<sup>(5)</sup> The development of the OrganMatch system may create further opportunities for improving the offer and allocation process.

### 5.1.2 SAER notifications relating to retrieval

SAER notifications relating to retrieval made up 28% of the total number of notifications from 1 January 2021 to 31 December 2021. These notifications include the following:

#### ► Retrieval surgery

There were six notifications in this category, three of these relating to a broader system focus pertaining to hospital or local level issues. Three notifications related to surgical retrieval challenges.

Each notification prompted local review of the relevant retrieval process.

#### ► Perfusion and preservation

Two notifications were received in relation to storage and transport of the donated organs. The organs were determined to have hypothermic damage.

These notifications have prompted a review of local and international storage and transportation processes.

### 5.1.3 SAER notifications relating to transplantation

SAER notifications relating to the transplantation comprised 24% of the total of notifications from 1 January 2021 to 31 December 2021. These notifications include the following sub-categories:

#### ► Transplant surgery

There was a notification of a kidney unable to be used due to recipient surgical issues, the kidney was unable to be reallocated.



► **Possible donor derived malignancy**

One notification related to a possible donor derived malignancy. The organ transplant recipients from the same donor have been informed and no further reports of donor-derived malignancies have been reported.

► **Possible donor derived infection or other disease**

Five notifications related to infectious or other disease transmission. There were three cases of donor-derived viral infection, with one case prompting a report to the Notify Library as it was a rare event and of interest to the international community.

There were two SAER notifications ranked as red impact, as a result of these, VSEAC undertook the following actions:

- Investigated the processes and cases involved to identify if any trends existed regarding organs arriving at the transplant hospitals with hypothermic damage. VSEAC recommended a review of the organ packaging process, including exploration of local and international organ packaging and transportation processes, which is currently being undertaken.
- The OTA was encouraged to continue the work with the relevant Australian Government portfolio agencies to resolve the 'Australian Organ Donor Register' issues experienced by the DonatLife Network.

## 5.2 Overview of COVID-19 log notifications

Throughout 2021, the OTA continued to record and monitor incidents that occurred as a result of COVID-19 issues. During 2021, there were 18 reported incidents, although 11/18 incidents were for 2020, but not reported until 2021. The COVID-19 log process, complements existing systems, including local reporting, action and the VSEAC SAER notification process.

The incidents received in 2021 have been grouped into three categories, with interstate courier/ flight issues being the predominate issue with 11 notifications made (Figure 10).

### 5.3.1 Interstate/ courier issues

The logistics associated with transportation of staff and organs across the country continued to be an issue until the domestic borders began to open up and consequently the improved availability of more domestic and commercial flights. Out of the 11 notifications in this category, 5 (45%) occurred during 2020, but were not reported until 2021.

### 5.3.2 Communication

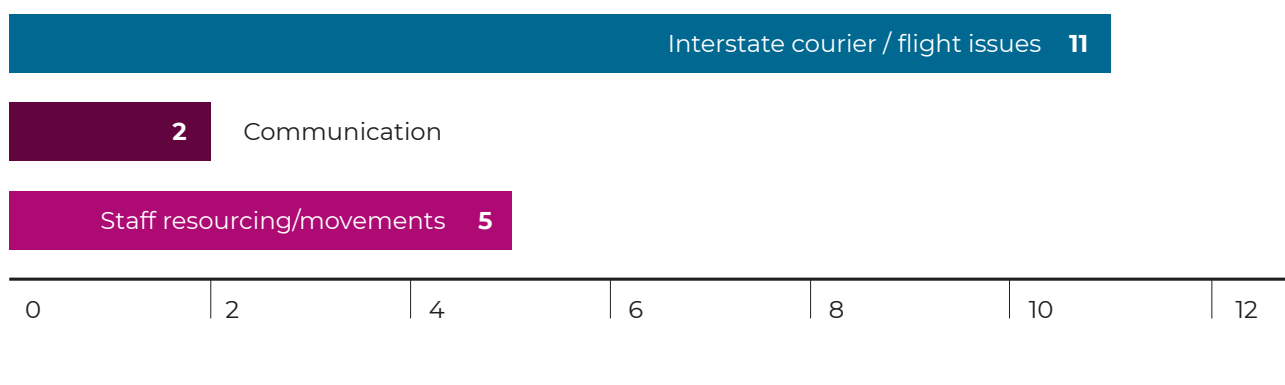
There were two notifications related to communication. Note, that both incidents occurred in 2020.

### 5.3.3 Staff resourcing/ movements

Three of the five incidents involved travelling retrieval teams.

With the opening up of borders and relaxation of COVID-19 rules, the number of incidents being reported as part of the COVID-19 log have been declining, as we learn to live and adapt to COVID-19.

Figure 10 COVID-19 Log categories



# Appendix A

## VSEAC membership 2021

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 VSEAC membership was reviewed in 2021, below lists all VSEAC members for 2021, between 1 January 2021 to 31 December 2021

| 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                    | Chief Executive Officer, Organ and Tissue Authority                                      | Ms Lucinda Barry (until Sept 2021)  |
| Member                    | Infectious Disease Physician, Microbiologist   | Dr Peter Boan   |
| Member                    | DonateLife State Medical Director/s  | Dr Rohit D'Costa VIC (Outgoing)<br>Dr Elena Cavazzoni – NSW (Incoming)<br>Dr Stewart Moodie – SA (Incoming) |
| Member                    | Donation Nurse Specialist, DonateLife Queensland   | Ms Niamh Farrell  |
| Member                    | Communicable Diseases Network Australia Representative                                   | A/Prof Paul Dugdale (Outgoing)<br>Dr Louise Flood (Incoming)  |
| Member                    | Transplant Nurses Association representative (NEW)                                       | Ms Julie Pavlovic (Incoming)  |
| Member                    | Infectious Disease Physician   | Prof Lindsay Grayson (Outgoing)   |
| Member                    | Senior Medical Virologist  | Prof William Rawlinson  |
| Member                    | Surgeon representative, Transplantation Society of Aust & NZ                             | Dr Mr Michael Fink (Outgoing)<br>Dr Handoo Rhee (Incoming)  |
| Member                    | Australasian Transplant Coordinators Association Representative                          | Mr Paul Robertson   |
| Member                    | Oncology expertise   | Dr Brian Stein  |
| Member                    | Physician representative, Transplantation Society of Aust& NZ                            | Prof Nicholas Shackel (Outgoing)<br>Prof Angela Webster (Incoming)  |
| Member                    | Epidemiologist   | Prof Germaine Wong  |

# Reference List

- 1 Sixty Third World Health Assembly. 2010. Human organ and tissue transplantation - Agenda item 11.21. [online] World Health Assembly. Resolution WHA63.22. Available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf) [Accessed 10 May 2022].
- 2 Organ and Tissue Authority, n.d. Strategic Plan 2020-21 To 2024-25 [online], Donatelife.gov.au, Available at: [https://www.donatelife.gov.au/sites/default/files/2022-02/OTA22%20424%20%20OTA\\_Strategic%20Plan\\_2021-22\\_Final%203%20Sep\\_for%20publication.pdf](https://www.donatelife.gov.au/sites/default/files/2022-02/OTA22%20424%20%20OTA_Strategic%20Plan_2021-22_Final%203%20Sep_for%20publication.pdf) [Accessed 10 May 2022].
- 3 Organ and Tissue Authority (OTA), n.d. *The Australian Vigilance and Surveillance System for Organ Donation for Transplantation – 2020 Public Report* [online], Donatelife.gov.au, Available at: [https://www.donatelife.gov.au/sites/default/files/202108/final\\_vseac\\_public\\_2020annualreport\\_08072021.pdf](https://www.donatelife.gov.au/sites/default/files/202108/final_vseac_public_2020annualreport_08072021.pdf) [Accessed 10 May 2022].
- 4 The Transplantation Society of Australia and New Zealand, Organ and Tissue Authority, Australian Transplant Coordinators Association, Oct 2021. *National Standard Operating Procedure: Organ Allocation, Organ Rotation, Urgent Listing*. [online], Version 3.0, atca.org.au, Available at <http://www.atca.org.au/files/National%20SOP%20Organ%20Allocation%20Organ%20Rotations%20and%20Urgent%20Listing%20Oct%202021.pdf> [Accessed 11 May 2022]
- 5 The Transplantation Society of Australia and New Zealand, May 2022. *Clinical Guidelines for Organ Transplantation from Deceased Donors (Clinical Guidelines)*, Version 1.9 [online] Available at: [https://tsanz.com.au/storage/documents/TSANZ\\_Clinical\\_Guidelines\\_Version-1.8\\_Final.pdf](https://tsanz.com.au/storage/documents/TSANZ_Clinical_Guidelines_Version-1.8_Final.pdf) [Accessed 23 May 2022].
- 6 Notify Library, n.d. The Notify Project | [www.Notifylibrary.Org](http://www.Notifylibrary.Org). [online], Notifylibrary.org. Available at: <https://www.notifylibrary.org/content/notify-project#:~:text=The%20Notify%20Library%20is%20a,on%20the%20use%20of%20MPHO>. [Accessed 10 May 2022].
- 7 SOHO V&S, 2013. *Guidance for Competent Authorities: Communication and Investigation of Serious Adverse Events and Reactions Associated With Human Tissues And Cells*. [online] Notifylibrary.org. Available at: <https://www.notifylibrary.org/sites/default/files/SOHO%20V&S%20Communication%20and%20Investigation%20Guidance.pdf> [Accessed 10 May 2022].
- 8 European Directorate for the Quality of Medicines (EDQM), 2018. *7th Edition - Guide to the quality and safety of Organs for transplantation* [online] EDQM.eu. Available at: <https://www.edqm.eu/en/news/new-release-7th-edition-guide-quality-and-safety-organs-transplantation> [Accessed 10 May 2022].
- 9 Organ and Tissue Authority, Feb 2022. *2021 Australian Donation and Transplantation Activity Report* [online], Donatelife.gov.au, Available at: [https://www.donatelife.gov.au/sites/default/files/2022-02/OTA\\_2021ActivityReport\\_Feb2022-Final.pdf](https://www.donatelife.gov.au/sites/default/files/2022-02/OTA_2021ActivityReport_Feb2022-Final.pdf) [Accessed 10 May 2022].
- 10 Global Observatory on Donation and Transplantation. Available at: <http://www.transplant-observatory.org/> [Accessed 22 May 2022].

