

Proposal to introduce mandatory reporting of medical device adverse events by healthcare facilities

Final Impact Analysis

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Executive Summary

In Australia, the Therapeutic Goods Administration (TGA) is responsible for monitoring the safety and performance of therapeutic goods. This includes identifying and addressing emerging issues with the safety and performance of medical devices. Multiple inquiries and reviews have identified the need for strengthened post-market monitoring of medical devices to improve the TGA's capability to detect issues in the Australian market and provide timely information to consumers, health professionals and medical device sponsors and manufacturers.

This regulatory impact analysis describes the introduction of mandatory reporting requirements for adverse events involving medical devices. This impact analysis (IA) details and analyses a range of potential options to address the public health problem - the underreporting of medical device adverse events, which affects the TGA's ability to identify emerging safety and performance issues early. This impact analysis provides comprehensive answers to the seven questions posed by the Office of Impact Analysis (OIA). From the analysis of options prepared through the development of the impact statement, an effective and balanced option emerges. This impact analysis describes the context, the options, the benefits and costs associated with each option, and the implementation for the proposed option.

The public health problem

The 2017-2018 Senate Inquiry into transvaginal mesh implants and related matters highlighted the need for rapid information sharing between health providers and regulators about medical device safety and efficacy. A lack of reports had restricted the TGA's ability to take timely action to safeguard patients. The TGA introduced measures to improve information sharing, including streamlined processes for electronic reporting of information by device manufacturers, sponsors, health professionals and consumers, and measures to strengthen post-market risk assessment. However, two issues remain outstanding:

1. Mandatory adverse event reporting requirements exist only for device manufacturers and sponsors.
2. Longer term device failures may have serious clinical impacts well after device implantation and may present in a different healthcare setting.

In conjunction with these prevailing concerns, the TGA and stakeholders are concerned that the current underreporting of medical device adverse events by involved parties does not support the early identification of emerging safety and performance issues. In 2020, the TGA received approximately 6,000 medical device adverse event reports, of which, nearly 89% of reports were made by medical device sponsors. It is evident to the TGA that although reported numbers have been increasing, a significant number of medical device adverse events remain unreported (see Table 3 for reporting trends over the last 10 calendar years).

To address this underreporting, the TGA committed to:

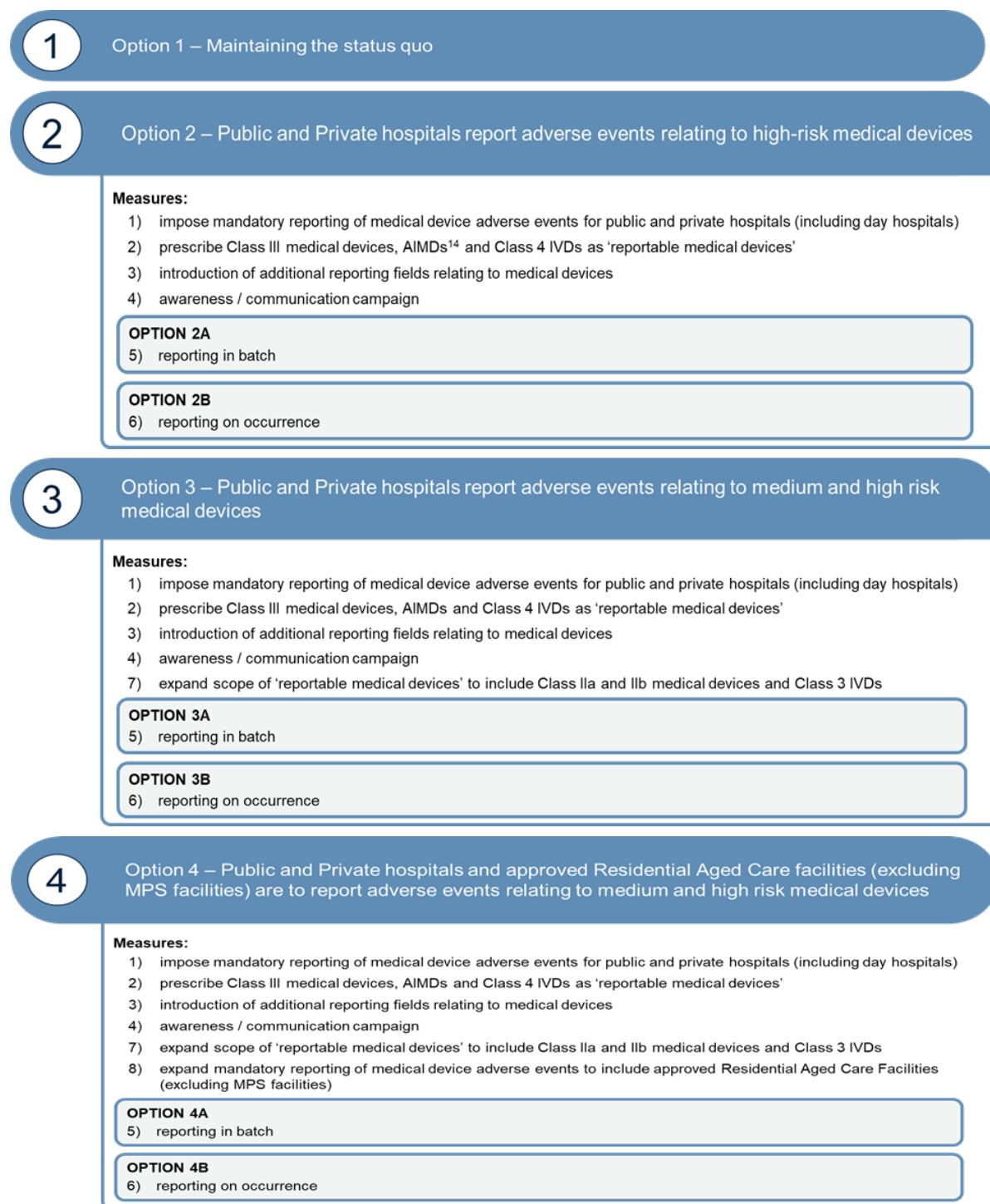
- Undertaking public consultation with key Australian stakeholders, including representatives from each state and territory departments of health, the Australian Commission on Safety and Quality in Health Care (the Commission), a range of healthcare organisations and some Organisation for Economic Co-operation and Development (OECD) health regulators. This consultation was completed in October 2021.
- Publishing a discussion paper on *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia*, to gauge stakeholder appetite for mandatory reporting of medical device related adverse events by healthcare facilities and gather information relating to circumstances that may impact the introduction of a mandatory reporting scheme.
- Working with the Commission to incorporate mandatory reporting within existing frameworks for hospital quality assurance and accreditation processes to minimise any additional regulatory burden.

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- Drafting and implementation of the *Therapeutic Goods Amendment (2022 Measures No. 1)* which received Royal Assent on 21 March 2023.

Options considered

The development of this Impact Analysis considered the options described in Figure 1. Progressive options have been developed based upon scalability in addressing identified gaps, achieving policy objectives, and balancing regulatory burden and costs.

Figure 1 - Policy options considered

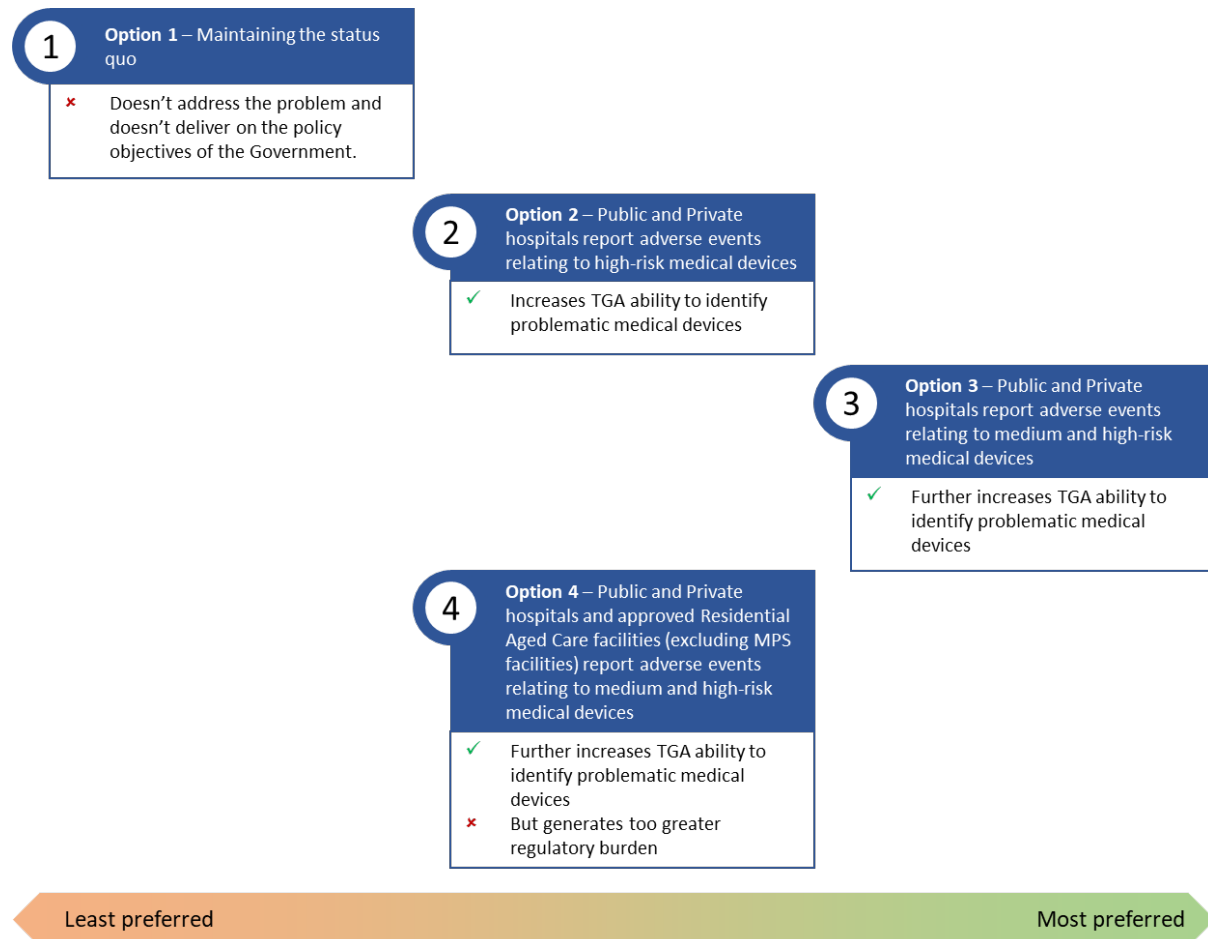


Analysis of options

Each of the above options were carefully analysed and a summary of the outcomes of this analysis is described in detail in [Question Six](#).

Based on the comprehensive assessment undertaken, **Option 3A** is currently considered¹ to provide the best balance between addressal of the policy objectives and regulatory burden placed on the reporting population; and is therefore the preferred option.

Figure 2 - Summary of options analysis



1. Option 1: Status Quo

- **Description:** Retain current voluntary reporting requirements for healthcare facilities.
- **Outcome:**
 - Fails to address underreporting or meet government objectives.
 - Fails to enact legislative requirements of the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023 (No. 10, 2023)* – Schedule 1
 - Leaves current gaps in adverse event reporting unaddressed.

¹ Further consideration of the preferred option will be undertaken in consultation with the steering committee comprised of representatives from states and territories governments and private health care.

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- **Net Benefit:** Nil. No improvement in safety signal detection, surveillance, or public health outcomes.
2. **Option 2: Public and private hospitals (including day hospitals) report adverse events relating to high-risk medical devices**
- **Description:** Require reporting of adverse events for high-risk medical devices (i.e., those classified as Class III, AIMDs and Class 4 IVDs). Two sub-options are proposed based on the reporting frequency. These are option 2A – reporting in batch and option 2B – reporting on occurrence.
 - **Cost per year for all private healthcare facilities combined over the ten-year default period:** \$1.19 million (option 2A) and \$1.20 million (option 2B). This equates to \$18,507 and \$18,662 per facility for options 2A and 2B respectively.
 - **Outcome:**
 - Improves detection of safety signals related to high-risk medical devices.
 - Limited scope restricts broader public health benefits.
 - **Net Benefit:** Moderate improvement in targeted areas but does not address broader underreporting issues.
3. **Option 3: Public and private hospitals (including day hospitals) report adverse events relating to medium and high-risk medical devices**
- **Description:** Builds upon option 2 by expanding mandatory reporting to include medium and high-risk medical devices (i.e., Class IIa, IIb and III, Class 3 and 4 IVDs, and AIMDs). Similar to option 2, there are two sub-options based on the reporting frequency. These are option 3A – reporting in batch and option 3B – reporting on occurrence.
 - **Cost per year for all private healthcare facilities combined over the ten-year default period:** \$1.62 million (option 3A) and \$1.67 million (option 3B). This equates to \$25,194 and \$25,972 per facility for options 3A and 3B respectively.
 - **Outcome:**
 - Addresses underreporting more comprehensively, covering a wider range of products.
 - Enhances the TGA's ability to detect safety signals and improve patient safety outcomes.
 - **Net Benefit:** Moderate-to-high improvement in safety detection and public health outcomes.
4. **Option 4: Public and private hospitals and approved Residential Aged Care facilities (excluding Multi-Purpose Services facilities) report adverse events relating to medium and high risk medical devices**
- **Description:** Expand mandatory reporting to include residential aged care facilities (excluding multi-purpose services facilities). There are two sub-options based on the reporting frequency. These are option 4A – reporting in batch and option 4B – reporting on occurrence.
 - **Cost per year for all private healthcare facilities and residential aged care facilities (excluding Multi-Purpose Services facilities):** \$5.56 million (option 4A) and \$5.61 million (option 4B). This equates to \$16,936 and \$17,100 per facility for options 4A and 4B respectively.

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- **Outcome:**
 - Offers the most comprehensive coverage and potential public health benefits.
 - While the cost per facility decreases, the total number of facilities needing to upgrade compliance systems, train staff and integrate reporting mechanisms into their operations increases significantly.
 - **Net Benefit:** Maximised public health benefits but with significant implementation challenges.

Preferred option

Based on the comprehensive assessment undertaken, **Option 3A** is considered to provide the best balance between addressal of the policy objectives and regulatory burden placed on the reporting population; and is therefore the preferred option.

- **Key Benefits:**
 - Strikes a balance between comprehensive safety signal detection and manageable regulatory costs.
 - Enhances the TGA's ability to monitor and respond to safety issues effectively.
 - Aligns with feedback from consumers, healthcare practitioners, state and territory departments of health and a range of healthcare organisations to focus on areas of highest clinical risk while minimising unnecessary reporting burdens.
 - Addresses policy objectives by utilising batch reporting to minimise regulatory burden whilst providing timely data and earlier signal detection.
- **Net Benefit:**
 - Provides a significant improvement in public health outcomes through enhanced surveillance and early detection of safety issues.
 - Mitigates the risk of underreporting by focusing on high-risk medical device categories by allowing earlier signal detection at the point of care.
 - Option 3A will first introduce mandatory reporting of high-risk medical devices then transition broader to include medium-risk medical devices as appropriate systems are established.

Stakeholder consultations

Extensive consultations with a diverse range of stakeholders informed the development of the preferred option and the proposed implementation strategy.

- **Stakeholders Consulted:**
 - Public and private hospitals, day hospitals, jurisdictions, specialist organisations such as the Australian Medical Association, Royal Australasian College of Medical Administrators, consumers and consumer groups, and medical device sponsors, manufacturers.
- **Engagement Timeline and Activities:**

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- **Public consultation (2021):** Broad support for a mandatory reporting scheme, with a willingness to align it with existing quality assurance frameworks to reduce regulatory burden.
 - ***Therapeutic Goods Act 1989* amendments (2023):** Mandated reporting by public and private hospitals, with supporting regulations planned for 2025.
 - **Roundtable Discussions (2023):** Focused on existing reporting mechanisms, implementation challenges, and stakeholder feedback.
 - **Interjurisdictional and IT Working Groups (2024):** Established to address ongoing implementation and technical requirements.

Implementation strategy

Implementation will follow an iterative, staged process to ensure healthcare facilities can adapt to the new reporting requirements effectively and allow sufficient time for state and territory governments and private health facilities to develop the appropriate systems to implement the mandatory reporting scheme. A 12-month voluntary transition period will be included, during which no compliance actions will be taken. This period will allow for IT system adjustments, stakeholder feedback, and identification of challenges to ensure a smooth transition to mandatory reporting. A staged implementation approach commencing with reporting of high-risk medical devices will allow for iterative system improvements to be managed ahead of each timeframe.

Introduction

This Impact Analysis presents the analysis of the proposal to introduce mandatory reporting requirements for adverse events involving medical devices to support improved end-user safety outcomes. It does so by using guidance provided by the Office of Impact Analysis within the Department of Prime Minister and Cabinet. The first section of the document describes in detail the context and background of medical devices, the drivers for the proposal and an overview of the current reporting framework and its implementation. The subsequent sections of the document are used to answer the Office of Impact Analysis's 'seven questions'.

Answering the central questions saw the development of four options for consideration (including 2 sub-options). Each option (and sub-option) is carefully analysed, and the relevant benefits and impacts are detailed. This analysis is supported through wide engagement with stakeholders and the thorough analysis of data from Australian and overseas sources. The background and detail of this analysis is contained in attached annexes and enclosures.

Background

In June 2011 an independent panel tasked with reviewing the transparency of the Therapeutic Goods Administration released their final report.² Recommendation 19 stated that, 'The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system' with Recommendation 21 stating that, 'The TGA work with State and Territory government stakeholders, and other relevant agencies, to improve the management of adverse event reporting in support of consumer safety'.³

In late 2016, the Australian Government responded to the March 2015 independent *Review of Medicines and Medical Devices Regulation*⁴ following extensive consultation with stakeholders. Agreed recommendations relating to medical devices included more comprehensive and active post-market monitoring of devices approved for use in the Australian marketplace with more timely analysis of hospital information, the introduction of electronic reporting for adverse event information, and enhanced collaboration with overseas regulators to improve the sharing of information relating to the ongoing safety and performance of medical devices.

The 2017/18 Senate Inquiry⁵ into the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Inquiry) investigated medical devices that were developed in the late 1990s for the treatment of stress urinary incontinence. The inquiry highlighted that with rapid technological changes, the number, range and complexity of medical devices will increase over time. This means that this will have a greater impact upon the TGA's capacity to detect problems in the Australian market and its ability to provide timely information regarding medical devices to consumers and healthcare professionals, thus emphasising the need for improvements in safeguarding patient safety through enhanced post-market monitoring. Recommendation 1 of the Inquiry (see call-out box below) noted the vital role of adverse event reporting in post-market surveillance and recommended

² Panel to Review the Transparency of the Therapeutic Goods Administration, 'Review to improve the transparency of the Therapeutic Goods Administration: Final Report', available at <https://www.tga.gov.au/sites/default/files/review-tga-transparency-1101-final-report.pdf>

³ Ibid., p.6.

⁴ See Sansom, Delaat and Horvath, 'Review of Medicines and Medical Devices Regulation: Report on the regulatory framework for medicines and medical devices', March 2015, available at [independent review - review of medicines and medical devices regulation - stage one report_0.pdf \(pmc.gov.au\)](https://www.pmc.gov.au/independent-review-review-of-medicines-and-medical-devices-regulation-stage-one-report-0.pdf). These matters were detailed under Recommendations 22 and 27.

⁵ The Senate Inquiry and an associated public awareness campaign led to a spike in reporting to the TGA by patients and then in later years by healthcare professionals of medical device-related adverse events, some many years after the event initially occurred. Therapeutic Goods Administration, *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia: Discussion Paper*, October 2021, p.7, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

the implementation of mandatory reporting of adverse events by medical practitioners.

Recommendation 1 from the 2017/18 Senate Inquiry into the Number of women in Australia who have had transvaginal mesh implants and related matters

Noting the vital role of adverse reporting in post-market surveillance, the committee recommends that the Australian Government, in consultation with the states and territories and the Medical Board of Australia, review the current system of reporting adverse events to the Therapeutic Goods Administration to:

- implement mandatory reporting of adverse events by medical practitioners
- provide guidance on what constitutes an adverse event for use by consumers, medical practitioners and device sponsors
- improve awareness of the reporting system
- examine options to simplify the reporting process.⁶

While the Government supported this recommendation in principle, it was noted that it posed policy and implementation issues that needed further consideration.⁷ To inform this consideration, the TGA consulted with other Australian Government agencies, State and Territory representatives and key stakeholders internationally to explore the range of issues and approaches to mandatory reporting of medical device adverse events.

Feedback⁸ indicated that most adverse events involving medical devices would likely occur, and be recorded, in public and private hospitals at the time of presentation or admission, and that in most instances these hospitals already record some information about medical device adverse events but may not provide it to relevant State or Territory health departments and/or the Commission and/or the TGA. Additionally, the experience of select overseas regulators (principally Canada and the USA) found that mandating reporting responsibilities for organisations rather than individual health practitioners:

- reduced the overall level of reporting burden placed upon individual health professionals
- provided greater flexibility for health services to allocate resources required for adverse event reporting

⁶ The Senate, Community Affairs Reference Committee, report title, 'Number of women in Australia who have had transvaginal mesh implants and related matters', dated March 2018, available at:

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/~media/Committees/clac_ctte/MeshImplants/report.pdf

⁷ Government response, report title, 'Australian Government response to the Senate Community Affairs References Committee report', tabled 10 October 2018, available at: <https://www.aph.gov.au/DocumentStore.ashx?id=ee63e51d-dccc-40c1-9475-cac214d0b3bf>

⁸ Therapeutic Goods Administration, *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia: Discussion Paper*, October 2021, p.6, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

- increased the potential quality of adverse event reports to the regulator⁹, particularly information relating to specific medical devices that may otherwise be unavailable to individual healthcare professionals at the time of incident notification that enabled more reliable monitoring and enforcement by regulators, and
- was more consistent with the responsibilities of device manufacturers for the reporting of adverse events.

The Government directed the TGA undertake further consultation in relation to mandatory reporting by healthcare facilities rather than directly by medical practitioners.¹⁰

In 2019 the Australian Government endorsed *An Action Plan for Medical Devices: Improving Australia's medical device regulatory framework*.¹¹ The plan noted that many incidents involving medical devices adverse events are not currently reported by private or public hospitals or by individual healthcare professionals. The plan also noted that recent incidents involving medical devices (such as transvaginal mesh) have highlighted the need to access more complete data on adverse events and to rapidly share information about emerging safety issues to address threats more promptly to patient safety and to take quicker action. The plan committed the TGA to consult publicly on whether it should be mandatory for healthcare facilities to report adverse events for medical devices to the TGA.¹² The TGA was also requested by Government to progress development of an implementation strategy in collaboration with the Commission and other stakeholders to leverage existing adverse event reporting and healthcare facility accreditation frameworks.

A public discussion paper, *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia*, was released for feedback in October 2021. Almost three quarters of respondents were in favour of introducing mandatory reporting of medical device adverse events by healthcare facilities in Australia. Some respondents felt such reporting was long overdue and that without it, the current underreporting complicated the early identification of emerging safety and performance issues with medical devices.¹³

Stakeholder feedback was considered together with other data and government priorities, which resulted in the drafting of legislation, the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022*, to support mandatory reporting of medical device adverse events by Australian public hospitals, private hospitals, and any other healthcare facilities (as prescribed by regulations). The Bill was signed into law on 21 March 2023.

⁹ The TGA notes in the discussion paper that several European countries have staff in each healthcare facility who are responsible for coordinating and submitting medical device-related incident reports to the national regulator. This was considered by these regulators as one of the most significant facilitators of effective reporting. Therapeutic Goods Administration, *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia: Discussion Paper*, October 2021, p.19, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

¹⁰ Parliament of the Commonwealth of Australia, Explanatory Memorandum to 'Therapeutic Goods Amendment (2022 Measures No.1) Bill 2022', p.15, available at https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fems%2Fr6953_ems_78535267-8570-4fb8-a407-dd0cc687373c%22

¹¹ Therapeutic Goods Administration, *An Action Plan for Medical Devices: Improving Australia's medical device regulatory framework*, April 2019, available at <https://www.tga.gov.au/sites/default/files/2022-08/action-plan-medical-devices.pdf>

¹² The plan also committed the TGA to consult publicly on options for removing some reporting exemptions of adverse events by industry to facilitate more timely and improved reporting.

¹³ Therapeutic Goods Administration, 'Discussion paper on potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia', viewed 29 January 2024, available at <https://www.tga.gov.au/resources/consultation/discussion-paper-potential-mandatory-reporting-medical-device-adverse-events-healthcare-facilities-australia>

What is a medical device?

Medical devices are defined in Section 41BD of the *Therapeutic Goods Act 1989*. Medical devices include a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, x-ray equipment, joint replacement devices, pacemakers and breast implants. They differ from medicines as they generally have a physical or mechanical effect on the body or are used to measure (or monitor) the body and its functions. Medical devices are classified depending on the level of risk they pose (as detailed in the table below).

Table 1. Medical device classification¹⁴

Classification(s)	Definition	Risk	Examples
<i>Class I</i>	<ul style="list-style-type: none">Intended use for basic medical functions.Not intended for use in supporting or sustaining human life or diagnosis, cure, mitigation, treatment or prevention of disease.	Low	<ul style="list-style-type: none">Surgical retractorsTongue depressors
<i>Class I - supplied sterile</i>	<ul style="list-style-type: none">Sterile on the point of sale.Intended for single use only.	Low to Medium	<ul style="list-style-type: none">Sterile surgical gloves
<i>Class I - with a measuring function</i>	<ul style="list-style-type: none">Intended for basic measuring activities.	Low to Medium	<ul style="list-style-type: none">Medicine cup with specific units of measurement
<i>Class IIa</i>	<ul style="list-style-type: none">Intended to support or sustain human life.Used in diagnosis, cure, mitigation, treatment or prevention of a disease.	Low to Medium	<ul style="list-style-type: none">Dental drills; ultrasound machines; hearing aids
<i>Class IIb</i>	<ul style="list-style-type: none">Intended to support or sustain human life.Used in diagnosis, cure, mitigation, treatment or prevention of a disease.	Medium to High	<ul style="list-style-type: none">Surgical lasersDiagnostic X-rayCardiac monitors
<i>Class III</i>	<ul style="list-style-type: none">Intended to support or sustain human life.Used in diagnosis, cure, mitigation, treatment or prevention of a disease.Typically include implantable devices.	High	<ul style="list-style-type: none">Prosthetic heart valvesAbsorbable surgical suturesHip prostheses (for example, replacement of hip joint)

Included in Options 3A, 3B, 4A and 4B

¹⁴ TGA, Medical devices overview, available at:

<https://www.tga.gov.au/products/medical-devices/medical-devices-overview>

Classification(s)	Definition	Risk	Examples
AIMDs ¹⁵	<ul style="list-style-type: none"> An active implantable medical device. An implantable accessory to an active implantable medical device. Used to control, monitor, or directly influence, the performance of an active implantable medical device. 	High	<ul style="list-style-type: none"> Implantable defibrillator

Included in Options 2A, 2B, 3A, 3B, 4A and 4B

Table 2 - In vitro diagnostic (IVD) medical device classification

Classification(s)	Definition	Risk	Examples
Class 1 IVDs	<ul style="list-style-type: none"> No public health risk or low personal risk 	Low	<ul style="list-style-type: none"> Sample collection container Microbiological culture media
Class 2 IVDs	<ul style="list-style-type: none"> Low public health risk or moderate personal risk 	Low	<ul style="list-style-type: none"> Pregnancy and fertility self-testing kits Cholesterol test
Class 3 IVDs	<ul style="list-style-type: none"> Moderate public health risk or high personal risk 	Moderate	<ul style="list-style-type: none"> Tests to detect a sexually transmitted disease (e.g., chlamydia, gonorrhoea) Human genetic tests
Class 4 IVDs	<ul style="list-style-type: none"> High public health risk 	High	<ul style="list-style-type: none"> Blood donor screening tests for HIV Test for Ebola

Included in Options 3A, 3B, 4A and 4B

Included in Options 2A, 2B, 3A, 3B, 4A and 4B

What is an adverse event?

An adverse event is an occurrence *involving a medical device* that meets any of the following criteria¹⁶:

- death of a patient, healthcare provider, user or other person
- a serious injury or serious deterioration to a patient, healthcare provider, user or other person, including;
 - a life-threatening illness or injury
 - permanent impairment of a body function
 - permanent damage to a body structure
 - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

A 'near adverse event' (also known as a 'near-miss') is an occurrence involving a medical device that might have led to a death or serious injury if, for example, the timely intervention of a healthcare practitioner is the only reason a death or serious injury did not occur. For an event to be defined as a

¹⁵ AIMDs, from 25 November 2021, were required to be reclassified from Class AIMD to Class III.

¹⁶ TGA, reporting adverse events overview, available at: <https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events>

near adverse event, it is sufficient that an event associated with the device occurred and that if the event occurred again, it might lead to death or serious injury.

For the purposes of the proposed mandatory reporting of adverse events relating to medical devices, Section 41JM of the *Therapeutic Goods Act 1989* details the requirement for the chief executive officer (CEO) of a healthcare facility to report adverse events involving reportable medical devices if:

- a reportable medical device is used in the facility; and the use of the device has resulted in the death, or a serious deterioration in the health, of a person while the device is used in the facility
- a reportable medical device is not used in the facility because of the intervention of a person in the facility; and the use of the device, if the device were used, would result in, or would be likely to result in, the death, or a serious deterioration in the health, of a person
- a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person; and the use of a reportable medical device has resulted in the serious deterioration in the health of the person¹⁷.

Medical devices post-market monitoring

Post-market monitoring, including the collection and analysis of adverse event data, is critical to undertaking compliance actions, including suspension and cancellation of Australian Register of Therapeutic Goods (ARTG) entries, recalls, and the imposition of civil penalty or criminal proceedings for non-compliance¹⁸.

The sought outcome for the TGA's post-market monitoring and vigilance activities is to improve the health and safety of patients and users by reducing the likelihood of adverse events occurring.

An important consideration is that there needs to be only *reasonable grounds to suspect involvement of a medical device failure or deterioration in effectiveness* for the reporting of an adverse events (or near-miss)¹⁹. An adverse event is not always caused by the therapeutic goods itself; it could arise from incorrect use or other circumstances, such as two properly functioning devices that do not operate as intended when used in combination. The reporter does not need to conduct a full (rather than interim) investigation to demonstrate causality between the medical device and the adverse event as this will most likely introduce delays of reporting and such investigation are more appropriately conducted by the device sponsor.

Through adverse event reporting, the TGA can monitor medical device use, performance in the real world and identify trends that may indicate emerging safety and performance issues. This facilitates taking appropriate regulatory action to address these issues in a timely fashion.

Database of Adverse Event Notifications – Medical Devices

The Database of Adverse Event Notifications (DAEN) - medical devices, contains information and reports of adverse events that the TGA has received in relation to medical devices used in Australia since July 2012. The publicly accessible search facility does not include reports submitted in the previous three months. This is to allow the TGA time to review and assess new reports submitted. Furthermore, as the DAEN does not contain all known safety information about a particular medical device, users are cautioned against making assessment about the safety of a medical device based on the information in the database.

¹⁷ Parliament of the Commonwealth of Australia, 'Therapeutic Goods Amendment (2022 Measures No.1) Bill 2023', p.4-5, available at <https://www.legislation.gov.au/C2023A00010/asmade/2023-03-21/text/original/pdf>

¹⁸ TGA, Postmarket monitoring, available at: <https://www.tga.gov.au/postmarket-monitoring>

¹⁹ TGA, reporting adverse events overview, 'which events should I report?', available at: <https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events>

Users can execute a text query (for example, trade name, sponsor, device descriptor etc., and specify a date range for returned records (see figure below). Relatively little information is provided in the returned reports, with the likely key field of interest for users being the 'event description'.

Figure 3 - DAEN – medical devices search interface²⁰

Search the DAEN - medical devices

You must select one or more medical devices and a date range.

1. Select medical devices [\[Further information about selecting a medical device\]](#)

Enter a trade name, manufacturer, sponsor, GMDN term (device descriptor e.g., 'hip', 'pump') or an ARTG number.

2. Select date range [\[Further information about the date range\]](#)

From

July ▼

▼

To

October ▼

▼

Reports from the last three months have not been included in the database. [Why?](#)

☒ **Show advanced search options** [\[Further information about advanced search options\]](#)

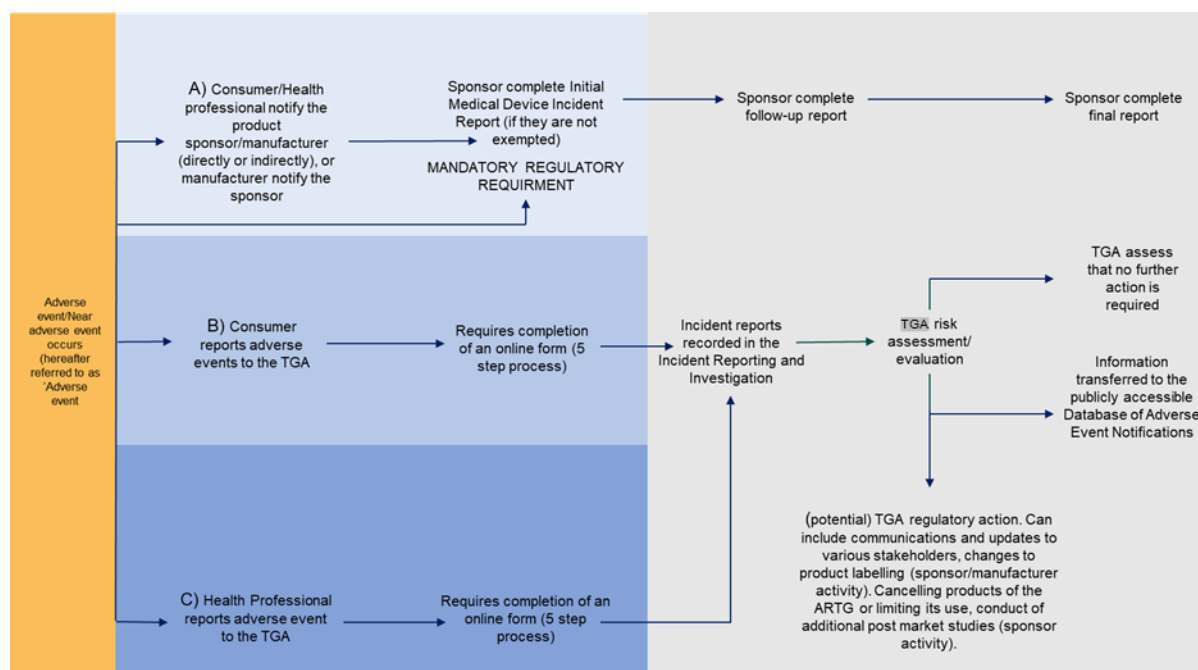
²⁰ TGA, Database of Adverse Event Notifications (DAEN) – medical devices, available at: <https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx>

Reporting medical device adverse events

Process overview – current state

The figure below summarises the current process for mandatory and voluntary reporting of adverse events.

Figure 4 - Current process for medical device adverse event reporting



Sponsor responsibilities

It is an automatic condition of inclusion under Regulation 5.7 of the *Therapeutic Goods (Medical Devices) Regulations 2002* that sponsors of medical devices report adverse events or near adverse events²¹ to the TGA Incident Reporting and Investigation Scheme (IRIS).²² IRIS reports include information about the adverse event and the medical device, and other information such as how the adverse event was treated. Adverse event reports submitted via the TGA website automatically flow through to the IRIS database.

Consumers or health professionals can notify the product sponsor (and/or manufacturer) of the adverse event directly, or, if the adverse event occurred in a healthcare facility, indirectly via the facility's product/quality manager who will then notify the device sponsor. Manufacturers may also become aware of an adverse event (which has occurred in Australia) related to one of their devices. In this case the manufacturer must notify the device sponsor.

²¹ Only adverse events that occur in Australia are required to be reported to the TGA. Adverse events that occur overseas for devices supplied in Australia do not need to be reported to the TGA, but records of these events should be available if requested. There are 8 exemption rules for the reporting of adverse events, such as a deficiency of a new device is found prior to its use. If the sponsor/manufacture believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented.

²² For the first three years of inclusion in the ARTG, sponsors of high-risk medical devices (an implantable Class IIb device, a Class 4 in vitro diagnostic device and Class III device) must submit annual reports demonstrating that the devices continue to meet the Essential Principles for safety and performance and that the manufacturer's post-market surveillance system can identify any safety or performance issues of signals associated with the device as early as possible. This report is to include the number of adverse events and incident reports in Australia and worldwide. See <https://www.tga.gov.au/resources/resource/guidance/annual-reports>.

Initial adverse event reports are required to be submitted in accordance with the below legislated timeframes²³ (unless they believe that an exemption rule can be applied):

- within 2 days of becoming aware of an issue of serious public health threat or concern that will require prompt action to reduce the hazard
- within 10 days of becoming aware of a death or serious injury
- within 30 days of becoming aware of an event that might have led to serious injury or death.

Additional information is to be provided as it becomes available. Updates on the status of any internal manufacturing investigations are expected to be provided to the TGA at regular intervals (defined as no less than every 30 days) with a final report provided within 120 days following the submission of the initial report. The final report will provide detailed information about the incident including details of the conduct and the outcome of the manufacturer's investigation of the incident.

Reports are submitted electronically via the Medical Device Incident Report (MDIR) application contained within the TGA Business Services (TBS) portal.

Other reporting of adverse events

State and territory health departments, hospitals, health professionals and consumers are also able to submit adverse event reports, though, unlike for sponsors and manufacturers, this reporting is entirely voluntary. Separate online forms have been created for the reporting of medical device incidents by consumers and by health professionals (see the figures below).

Figure 5 - Consumer Online Medical Device Incident Report Form²⁴

The screenshot shows the 'Users Medical Device Incident Report' form, specifically Step 1: About You. The form is part of the Australian Government Department of Health Therapeutic Goods Administration's system, Web Version: 2.1.6. The form is divided into five steps: Step 1: About You, Step 2: About the Incident, Step 3: Affected Person, Step 4: About the Device, and Step 5: Finish and Submit. The current step, Step 1, requires the user to provide their name and at least one contact method. The form includes fields for Title, First Name, and Surname, all of which are required. There is a dropdown menu for 'What is the preferred contact method?' with 'Email' selected. Below this are fields for Phone and Email, both of which are required. A question asks 'Would you like to provide additional contact information?' with 'No' selected. The form also includes a section for 'Please confirm your contact and privacy instructions' with two questions: 'Are you happy for the device company to know your identity, and for your contact information to be provided to the device company so that they can contact you about this incident?' and 'Who should the TGA contact for more information regarding this incident?'. Both questions have dropdown menus. At the bottom, there is a question 'Are you reporting this incident on behalf of someone else (the initial reporter)?' with 'No' selected. A 'Next Step >' button is located at the bottom right of the form.

²³Parliament of the Commonwealth of Australia, 'Therapeutic Goods (Medical Devices) Regulations 2002', page 46, available at: <https://www.legislation.gov.au/F2002B00237/2024-07-01/2024-07-01/text/original/pdf>

²⁴ TGA, Users Medical Device Incident Report, available at: <https://apps.tga.gov.au/prod/MDIR/UDIR03.aspx?mode=CON&sid=1709071381>

Risk assessment

TGA staff undertake risk-based assessments of the IRIS reports to determine the appropriate investigation required²⁵. Serious adverse events are prioritised for investigation. The assessments and investigations can result in a number of different outcomes.

No regulatory action required: If the TGA determines the adverse event is not of significant concern to public health, (e.g., if the incident is isolated, or appropriate preventative measures are in place to reduce the risk of further adverse events), no regulatory action is taken. Rather, these incidents are entered into IRIS and assessed as part of a broader trend analysis. Should there be an increase in reports for certain device categories, further investigation may be undertaken.

Regulatory action required: If it is determined the adverse event is a significant risk to public health (e.g., there are a large number of reports or the impact is significant), further investigation will be undertaken and may result in regulatory action. This may include communicating with various stakeholders, enforcing product information changes, limiting the use of the device, conducting additional post-market studies, or cancelling the product from the ARTG.

There are four distinct recall actions available to sponsors, as detailed below:

- **Recall.** Conducted to remove therapeutic goods permanently from the market or from use when there are deficiencies or potential deficiencies in safety, quality, efficacy, performance or presentation.
- **Product defect correction.** Undertaken to correct a specific or potential deficiency and includes repair, modification, adjustment, or re-labelling of a therapeutic good. Corrections involving a product's expiry date or updates or changes to any accessories, operating instructions or software. The corrective action may take place at the user's premises or any other agreed location. In some instances, the product can continue to be used if there is robust mitigation in place until a permanent correction has been implemented.
- **Hazard alert.** A hazard alert is issued for an implanted therapeutic good with a deficiency or potential deficiency relating to its safety, quality, or performance, because implanted goods (medical devices or biologicals or medicines) cannot be recalled. The hazard alert will typically contain precautionary information issued to healthcare professionals about issues or deficiencies relating to an implanted therapeutic good and advice about the ongoing management of affected patients. There may or may not be advice to consumers in the event the hazard alert is published on the TGA Website. A hazard alert may also be issued in conjunction with a recall notice for affected products that have not yet been implanted.
- **Product defect alert.** Allows the informed, continued use of defective but critical therapeutic goods, raises awareness of the issue and describes the precautionary actions that clinicians or patients may take to mitigate any associated risk. A product defect alert may later be followed by a recall once unaffected or alternative products become available. It is often the case that a product defect alert is utilised where there is no alternative product available at the time and/or for which a recall action will result in a significant interruption of patient treatment or a medicine shortage, either of which would likely present greater adverse clinical sequelae than the defect itself.

Most recall actions are voluntarily initiated by the sponsor once they become aware of a problem. The sponsor has responsibility for the recovery and disposal of the goods or completion of the agreed corrective action. If necessary, the TGA does have legislative powers to mandate the recall of therapeutic goods under Section 41K of the *Therapeutic Goods Act 1989*, namely:

The Secretary can require action to recall medical devices, or to inform the public about medical devices, that do not comply with requirements or cannot lawfully be supplied.

²⁵ TGA, Post market monitoring, 'responding to signals', available at <https://www.tga.gov.au/postmarket-monitoring>

The table below details the outcomes of medical device incident reports received over the last five financial years (n=37,540). Of the reports received less than 5% (4.29%) were investigated, of which for over two-thirds (70.33%) there was no other outcome. Of those investigations that did result in a specific outcome, the highest outcomes relate to product corrections ($\approx 4\%$) and product recalls ($\approx 3\%$). Approximately 1% of outcomes resulted in products being having their ARTG entry cancelled or suspended.

Table 3 - Medical devices incident report outcomes (2019 Quarter 1 to 2023 Quarter 3) ²⁶

Incident Report Outcome*	2019-2023	% of Outcomes
Reviewed, for Trending Purposes Only	1,240	70.33%
Active Investigations	120	6.81%
Field Safety Corrective Action Product correction	70	3.97%
Referral to other TGA Process	66	3.74%
Field Safety Corrective Action Product recall	53	3.01%
Manufacturing process improvements	40	2.27%
Other	40	2.27%
Field Safety Corrective Action Safety alert	19	1.08%
Instructions for use amended	18	1.02%
Field Safety Corrective Action Product alert	16	0.91%
Change to design	14	0.79%
User Education	14	0.79%
Quality system process improvements	11	0.62%
Product Cancelled from ARTG	10	0.57%
Product Suspended from ARTG	9	0.51%
TGA Publication	7	0.40%
Product enhancement/improvement notice	5	0.28%
Company Warned	4	0.23%
Not device related	4	0.23%
Field Safety Corrective Action Hazard alert	2	0.11%
Maintenance carried out by the hospital	1	0.06%
Total	1,763	100%

* Outcomes are not mutually exclusive

Legislative framework

At the Australian Government level, therapeutic goods (a subset of which are medical devices) are regulated under the *Therapeutic Goods Act 1989* and associated regulations. The *Therapeutic Goods Act 1989* was amended by the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*, to introduce a framework for the mandatory reporting of adverse events involving medical devices, principally by hospitals. Subsection 41JM(2) relates to incidents *where use of a reportable medical device* has resulted in a death, or a serious deterioration in the health of a person when the device is used in the facility. Subsection 41JM(3) relates to a 'near-miss', where, except for the intervention of a person in the facility (such as a healthcare practitioner) the *use of the reportable medical device* would have resulted in, or be likely to have resulted in, the death, or a serious deterioration in the health of a person at that facility. Subsection 41JM(4) applies if a health practitioner provides

²⁶ TGA, Annual Performance Statistics Reports (various titles), available at: <https://www.tga.gov.au/about-tga/corporate-information/tga-plans-reports/annual-performance-statistics-reports>

treatment to a person in the facility for a serious deterioration in the health of a person arising from the *use of a reportable medical device*. This clause is intended to capture situations where a person presents at a healthcare facility because of ill-health and the health practitioner identifies that the person may be experiencing an adverse event associated with the use of a medical device. This would include where the reportable medical device was used at home and the user presents at the healthcare facility after experiencing an adverse event. This provision may also apply where a person was treated using a medical device at a healthcare facility in the past and a person presents at a healthcare facility with poor health which is then determined to have associated with the prior use of a reportable medical device.

The Australian Government's regulatory roles include overseeing the safety and quality of therapeutic goods, while the state and territory governments license or register private hospitals and have legislation for the operation of public hospitals. As such, the chief executive officer (however described) of a healthcare facility was specifically identified in the *Therapeutic Goods Act 1989* as being responsible²⁷ for the provision of reports concerning medical device adverse events for reportable medical devices²⁸ to the Secretary of the Australian Government Department of Health, Disability and Ageing.²⁹ However, to reduce the likelihood of duplicate reporting,³⁰ the provision of the report to the Secretary is not required if the CEO has reported the relevant matters to either the CEO of the Commission or to the head of the relevant state/territory health department.³¹

Impact Analysis

In July 2022, the then Office of Best Practice Regulation (OBPR) and the Department of Health, Disability and Ageing agreed that while the proposed amendments to the *Therapeutic Goods Act 1989* to support the option of strengthening the mandatory reporting framework were able to proceed, a Regulatory Impact Statement (RIS) must be prepared in advance of the supporting regulations being registered. Furthermore, it was agreed that an early assessment RIS be prepared to inform the policy decision with respect to the relevant bill. Accordingly, on 3 November 2022 an Early Assessment RIS was submitted to the OIA to support the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022*. This document provided early information to the OBPR on some of the likely regulatory impacts of introducing the measure, with it being agreed that a complete and final RIS was to be prepared and reviewed prior to the amended regulations being tabled and additional consultation would be undertaken to support the development of the final RIS (Final IA).

²⁷ This civil penalty provision is consistent with similar legislative healthcare reporting obligations. For example, the maximum civil penalty aligns with subsection 10A(5) of the Australian Immunisation Register Act 2015 and subsection 13(2) of the National Cancer Screening Register Act 2016, which both impose a maximum penalty of 30 penalty units where a person fails to comply with reporting obligations.

²⁸ A 'reportable medical device' is defined in subsection 3(1) of the TG Act as a medical device of a kind prescribed by regulations. This is not intended to encompass all medical devices and provides the provision to limit the burden of the new reporting requirements on hospitals by excluding some classes of medical devices from reporting requirements. Medical devices could also be removed from the list of prescribed reportable medical devices.

²⁹ The prescribed civil penalty for the non-provision of medical device adverse event report is 30 penalty units (currently (January 2023) \$6,660) (s.41JM(8) of the TG Act).

³⁰ Health practitioners have indicated that they already have a heavy reporting burden including to internal incident management systems, professional associations, registries and coroners. Therapeutic Goods Administration, '2020 Insite Review Plan and Report, p.2.

³¹ Provision is made in the legislation (s.41JM(7) of the TG Act) for other persons to be named in the regulations for the purpose of receiving reports on medical devices adverse events.

Question One: What is the problem you are trying to solve?

Two key issues continue to limit the capacity of the TGA to identify and act upon market signals that indicate potential or emerging issues about the safety and effectiveness of medical devices³². These are:

- In Australia, mandatory adverse event reporting requirements have only existed for device manufacturers and sponsors.

Longer term device problems, such as those that have been a recent focus of public attention (for example, urogynaecological mesh, metal-on-metal hip devices, textured breast implants) are more likely to have serious clinical impacts some years after the device implantation, rather than identified as an immediate adverse event. These may present in a different healthcare setting to the original procedure. Adverse events that arise years after device implantation may not be immediately linked to the medical device, as the causal connection may not be apparent without thorough investigation. Patients may present at a healthcare facility multiple times or experience delayed complications before a link to the original medical device is identified, increasing disease burden and healthcare costs. Additionally, over time, patient records related to the original procedure may become inaccessible or incomplete, especially if the patient transitions to a different healthcare facility. This loss of continuity can make it challenging to establish a causative link between the medical device and an adverse event. The lack of systematic reporting requirements for healthcare facilities means that even when adverse events are recorded in hospital incident management systems, they are often not communicated to the TGA or sponsors or manufacturers for further investigation in a consistent manner. These factors create a significant blind spot for the TGA where critical safety signals may remain undetected, delaying responses to emerging risks and increasing the potential for further patient harm.

The medical device adverse event reporting requirement for healthcare facilities has remained voluntary for many years without any sustained change or improvements in reporting data, even with increased efforts and the introduction of education awareness initiatives. The existing voluntary reporting system frequently results in critical gaps in the data received by the TGA, including incomplete details about adverse events, the medical devices involved, and their impact on patient health. These data deficiencies create significant uncertainty in understanding the true extent and nature of adverse events, making it challenging to accurately assess the costs and benefits of regulatory interventions. Under-reporting delays the detection of emerging safety issues with medical devices, prolonging patient exposure to potential risks before appropriate regulatory actions can be taken. This uncertainty in the timing and frequency of adverse events complicates cost-benefit analysis, as the potential benefits of early intervention and harm reduction remain under-represented in projections. It was not until the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters* that revealed that earlier signal detection could have prevented or addressed these issues sooner which prompted the Government to introduce mandatory reporting of medical device adverse events by healthcare facilities.

A recent investigation of spinal cord stimulators (SCS) found that 2,605 adverse events were reported to the TGA over the past 10-years during 2014-2024. This prompted the TGA to request adverse event data from manufacturers and sponsors, revealing that many sponsors and manufacturers have been relying on or interpreting the medical device adverse event exemption rules to exclude many

³² TGA *Potential for mandatory reporting of medical device adverse events by healthcare facilities: discussion paper*, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

adverse events related to SCS from being reported. The TGA is undertaking a review of the exemption rules to ensure that such incidents are reported promptly, supporting improved monitoring and timely intervention. Additional requirements will also be imposed on sponsors and manufacturers, such as improving information regarding the indications and contraindications for use and providing information about the expected lifespan of the device.³³ Other regulators such as the U.S. FDA acknowledge the data limitations, and underreporting made it difficult to determine whether a device directly caused an injury or death.

With over 1,400,000 medical devices currently approved for use in Australia, stronger post-market monitoring of the safety and operation of medical devices is required to access critical data on adverse events and rapidly share information relating to emerging safety issues.³⁴

The volume of registered medical devices on the ARTG has increased consistently overtime (e.g., an 11% increase over the last 5 years³⁵) and is likely to continue to grow. Over this same period, a range of technological advancements have led to the introduction of more complex medical devices. This increase in volume and complexity of registered medical devices introduces new risks and challenges related to product design, usage and regulation which may contribute to a higher likelihood of medical device adverse events.

While healthcare facilities, health professionals and consumers are strongly encouraged to report adverse events, currently, this is done voluntarily. A breakdown of reports (Figure 6 below) received over the previous five calendar years (2019-23) shows that reports are predominantly (around 88%) submitted by sponsors and manufacturers, with the remaining 11% sourced from healthcare professionals and patients/consumers.

A further breakdown of reports during this same period (Figure 7) shows the average percentage of medical device adverse event reports from public and private hospitals is 5% and 6% respectively, whereas day surgeries make up only 1% of adverse event reports submitted to the TGA. The facility type was unable to be determined for approximately 8% of reports. Furthermore, no reports were received from other facility types including rehabilitation centres, pharmacies, diagnostic facilities, ambulance services and aged care facilities.

³³ TGA, Post-market review of spinal cord stimulation (SCS) devices, available at: <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/post-market-review-spinal-cord-stimulation-scs-devices>

³⁴ TGA, *Potential for mandatory reporting of medical device adverse events by healthcare facilities: discussion paper*, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

³⁵ Department of Health, Aged Care and Sport, *The New Frontier – Delivering better health for all Australians*, available at: <https://www.health.gov.au/sites/default/files/2023-11/inquiry-into-approval-processes-for-new-drugs-and-novel-medical-technologies-in-australia.pdf>

Figure 6 - Breakdown by source of medical device incident reports (1 January 2019 – 31 December 2023)³⁶

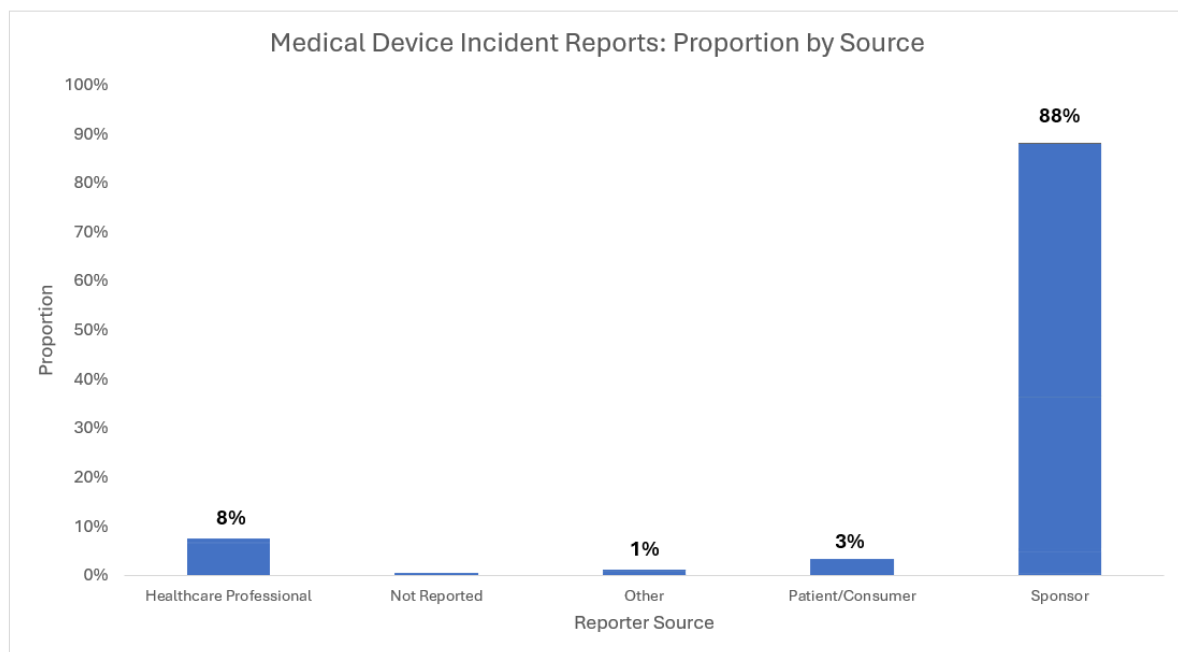
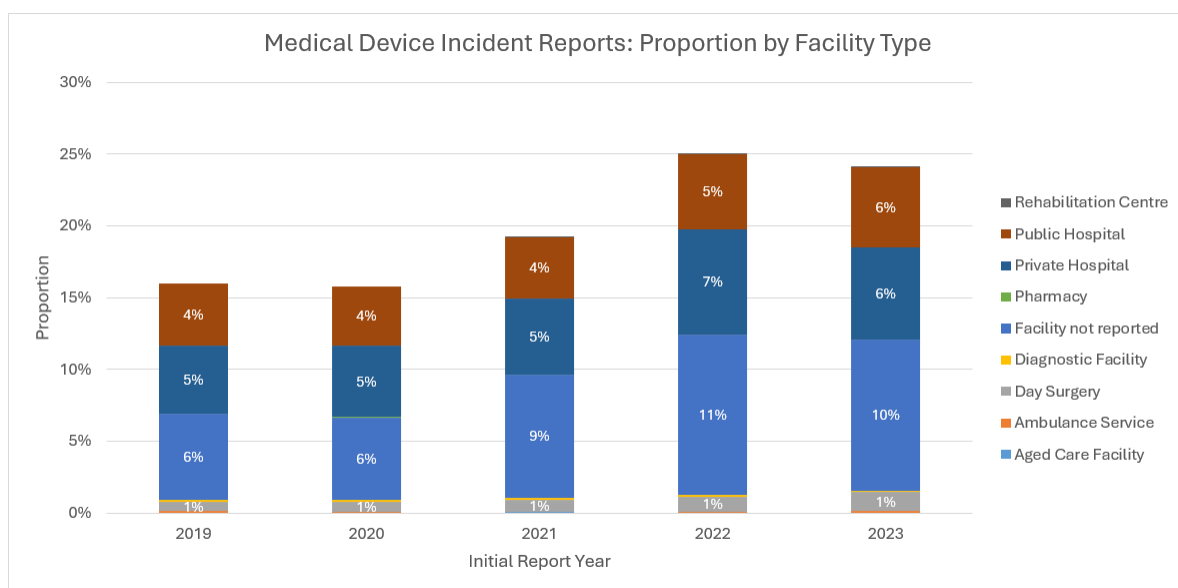


Figure 7 - Breakdown of medical device incident reports: proportion by facility type (1 January 2019 – 31 December 2023)³⁶



In 2014/15 the IRIS InSite program was initiated to improve awareness amongst healthcare professionals about the TGA's responsibilities in managing reports of adverse events and complaints associated with medical devices. The program aimed to raise awareness of the critical role clinical staff play in assisting the TGA take appropriate regulatory action to ensure the continued safety of medical devices supplied in Australia.³⁷ The program was initiated to address the significant under-reporting of adverse events by healthcare professionals, stating at the time "While difficult to quantify, the TGA may only be receiving 5% of reportable medical device adverse events".³⁸ Without a clear

³⁶ Source: TGA IRIS data (2019 - 2023)

³⁷ Specifically, the IRIS Insite Program sought to develop and deliver effective education programs targeted at health professionals in the hospital environment in relation to medical devices adverse event reporting.

³⁸ Therapeutic Goods Administration, '2020 Insite Review Plan and Report, p.1.

understanding of the full scope of adverse events, it is difficult to assess the true extent of risks associated with medical devices. This incomplete picture may lead to an underestimation of the potential harm to patients, delaying the identification of critical safety signals and earlier health interventions to provide patients with necessary care and potentially avoid future harm to other patients using the medical device who may be as yet unaffected. The decision to discontinue the IRIS InSite program was made in 2020 following a review of the program which demonstrated minimal changes to the embedded reporting practices and a very small and unsustained increase in reporting incidents to the TGA.

The Government has established clinical quality registries as a tool that can be used by the community, clinicians, hospital administrators and governments to monitor the safety and performance of some of the high risk implantable medical devices, however, use of these registries is voluntary with varying levels of data entry.³⁹ Health service organisations are responsible for reporting to the clinical quality registries. The reports are collected and managed by registry data custodians, which includes state and territory health departments, health service administrators and clinicians. Examples include the Australian Breast Device Registry (1997), Australian Orthopaedic Association National Joint Replacement Registry (2002), Australian Pelvic Floor Procedures Registry (2019). However, data completeness and accuracy, limited scope and delayed reporting, are limitations that impact the effectiveness of registry data.

Evidence of underreporting was further highlighted in the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters*, where the following statistics were outlined:

- the first adverse event relating to transvaginal mesh was reported to the TGA in 2006. It was 7 years post implantation before the first adverse event relating to mesh devices was reported to the TGA
- by the end of 2015, there were 12 patients with adverse events identified
- by 29 May 2017, the TGA had received a total of 226 adverse event reports (covering 249 patients)
- by 3 January 2018, the TGA had received 327 adverse event reports (covering 349 patients)
- by 3 August 2017, 2,400 women had provided accounts to the Health Issues Centre (HIC) describing adverse complications.⁴⁰

As detailed, there is a significant discrepancy between the number of impacted patients and the volume of adverse events reported to the TGA.

There have been other notable examples of medical device adverse event under reporting, including reports of adverse events related to textured breast implants and metal-on-metal hip prostheses. These examples illustrate the challenges inherent in ensuring timely and comprehensive reporting of medical device adverse events. The current reliance on voluntary reporting by healthcare professionals and consumers has created gaps in timely data availability, which can delay the identification of safety signals. Submissions as well as the recommendations that came out of the Senate Inquiry were aligned that more needed to be done to facilitate the reporting of adverse events, particularly by patients and medical practitioners.

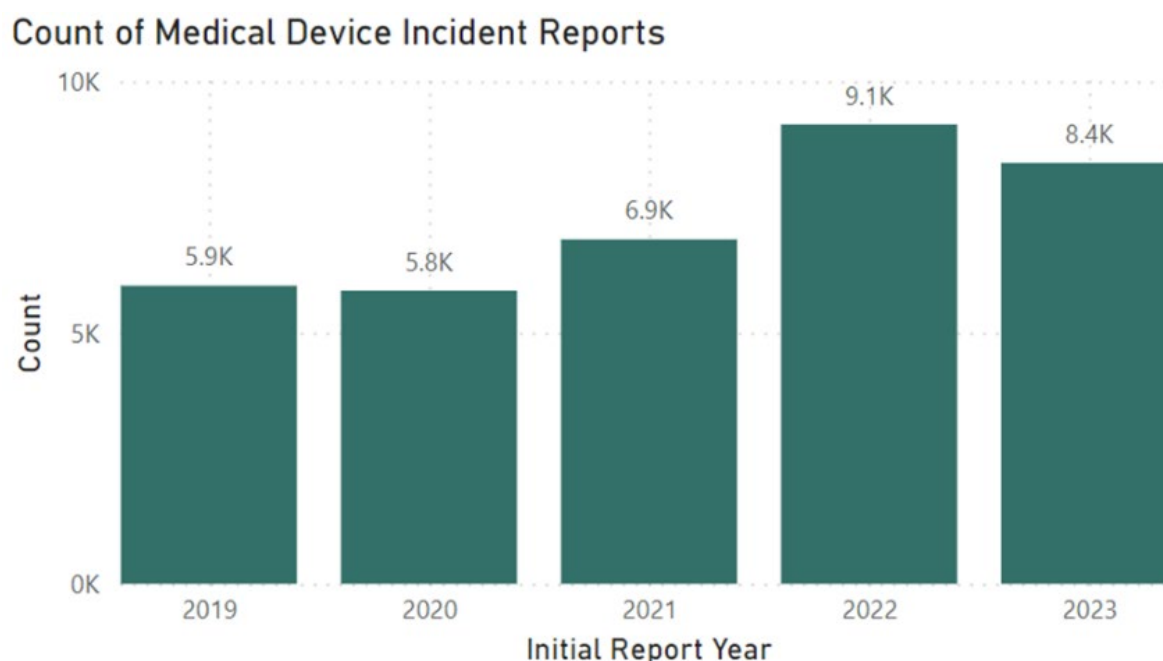
Since the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters*, the TGA has implemented a range of strategies to increase reporting of medical device adverse events, and while the number of reported medical device incidents has steadily increased over the past years, as shown in *Figure 8. Volume of device incident reports received*, it is evident that a significant number are not reported to the TGA. This may be because patients or health professionals are unaware that

³⁹ <https://www.health.gov.au/our-work/national-clinical-quality-registry-program>

⁴⁰ https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report

they can report incidents directly to the TGA; or do not want to take the time to do so; or, the incidents are reported to other parties, such as hospitals, who may/may not report the incident to the TGA, sponsor, or manufacturer of the device. During consultations there was general acknowledgement from both public and private healthcare facilities about inconsistencies in their reporting practices. The reasons cited included: lack of awareness, time constraints, complexity in identifying medical device related adverse events and inconsistent systems and processes across facilities. Healthcare staff have also cited the significant time pressures and resource constraints they often face, making it challenging to prioritise incident reporting amidst clinical responsibilities. This underreporting has resulted in increased risk to the health and wellbeing of patients, and delays in regulatory action for devices that may pose a threat.

Figure 8 - Volume of medical device incident reports received⁴¹



Currently, voluntary reporting from healthcare facilities and consumers creates an information sharing gap between the consumer (patient), the medical practitioner/service (hospital/healthcare facility), and industry (the manufacturer and sponsor). Patients present to healthcare facilities to express concerns associated with medical devices, but the lack of feedback and follow-up mechanisms is contributing to a possible disconnect between incident reporting and addressing the identified issues.

The identification of medical device adverse events may occur earlier if reporting was required by multiple sources. Timely reporting enables industry and healthcare facilities to take corrective actions sooner, such as monitoring, implant removal, or discontinuing defective devices, enhancing patient safety. Early detection of issues reduces the need for extensive treatments and helps identify devices with safety or performance issues, thereby lowering healthcare costs and improving overall healthcare outcomes. A robust reporting framework ensures faster identification and resolution of safety issues, reducing harm to patients. By ensuring comprehensive and timely reporting, adverse events can be addressed at an earlier stage, reducing the need for complex and costly treatments. For example, early removal of a defective implant may prevent secondary complications that require hospitalisation.

Impacted Stakeholders

The underreporting of adverse events related to medical devices has broad implications on those responsible for medical device manufacturing, testing, utilisation and regulation. Below outlines the key stakeholder groups and how they are impacted.

⁴¹ TGA, Annual Performance Statistics Reports, available at:

<https://www.tga.gov.au/about-tga/corporate-information/tga-plans-reports/annual-performance-statistics-reports>

Government

The Australian Government (i.e., the TGA), as the regulator, faces significant challenges to identify and mitigate risks effectively due to the consistent underreporting of adverse events related to medical devices. Incomplete data hampers effective regulation and can cause diminished public trust. This lack of comprehensive reporting also hampers the TGA's monitoring and compliance responsibilities relating to:

- timely signal detection
- identification of rarer events and emerging issues
- timely investigation and regulatory response actions to address safety concerns
- provision of safety information to healthcare providers, medical device sponsors and manufacturers, and the general public.

Sponsors & Manufacturers

Manufacturers and sponsors of medical devices are affected by the underreporting of adverse events. There is currently no specific data available to quantify how many manufacturers or sponsors are impacted by the under reporting of medical device adverse events by facilities, and there is no available evidence to suggest that particular cohorts of sponsors or manufacturers may be disproportionately impacted. However, the lack of early signal detection creates broad impacts that span various types of devices and stakeholders. Additional challenges are faced by manufacturers and sponsors in the lack of visibility of where their medical devices are used once distributed. This creates significant challenges in tracing devices or implants back to specific patients or healthcare facilities in the event of safety concerns or recalls. Patients, meanwhile, may not always return to the original place of supply or implantation for follow-up care, further complicating efforts to monitor and address adverse events effectively. The limited feedback loop prevents manufacturers and sponsors from identifying and addressing emerging safety issues, hindering product safety improvements. Additionally, the lack of transparency can damage their market reputation, leading to more severe regulatory actions and increased risks of litigation. Litigation can result in significant financial costs, reputational damage and heightened regulatory scrutiny concerns.⁴² These consequences may delay innovation and create hesitancy amongst clinicians, healthcare facilities, and consumers in adopting newer technologies, which result in increased burden of disease at greater cost to the health care system.

Healthcare Facilities

Healthcare facilities also suffer from the impacts of underreporting medical device adverse events. Patient safety is compromised as unsafe devices continue to be used, and clinicians are left making misinformed decisions due to incomplete data. This situation poses challenges in meeting accreditation and compliance standards, and ultimately leads to a loss of trust from patients who expect prioritised safety and transparency.

Consideration for smaller healthcare facilities

During consultations, the TGA has identified that smaller private and day hospitals may lack the IT systems or infrastructure found in larger public or private facilities. To address this, multiple reporting channels will be incorporated (e.g., email, web portal) allowing reports in accessible formats such as excel or CSV files. This approach minimises the need for costly technology upgrades, ensuring equitable participation. An approach of continuous improvement would be taken to further streamline and support data provision over time.

⁴² A key example being the Johnson & Johnson's class action suits, resulting in a \$300 million settlement.

The Community

The general public, particularly patients, may face unknown health risks due to the underreporting of adverse events. Continued use of unsafe devices can lead to complications, with patients making healthcare decisions based on incomplete information. This not only increases healthcare costs but also erodes public trust in the healthcare system, as people lose confidence in its ability to protect their safety.

Distributional impacts

Based on currently available data related to medical device adverse events, it is challenging to determine whether the mandatory reporting scheme will cause any distributional impacts related to demographics, socioeconomic status or organisational factors. As the scheme focuses on improving safety for all patients with medical devices, no direct gender specific impacts can be identified beyond those already acknowledged relating to health equity. Additionally, it is acknowledged that the proposal was a recommendation from a report on medical events that affected women, and current data is insufficient to show that adverse medical events affect women at a higher rate compared to the total population. Over time as the reporting requirement is established, consideration should be given to identifying opportunities for analysis of data trends that could be conducted in order to identify any disproportionate impacts on certain cohorts.

The scheme is aimed at institutional compliance, with no individual focus given to reporting by specific roles or individuals, other than the legislative requirement to report being the responsibility of the chief executive officer (however described). Therefore, no disproportionate workforce impacts are currently identified.

The TGA will ensure that multiple reporting channels, such as the existing voluntary online forms, email, and phone, remain available for consumers and other stakeholders who wish to report directly. Throughout the implementation of the scheme the TGA will develop further guidance and communication materials to enhance awareness and support healthcare professionals in interrogating adverse events to gather additional details. While the current adverse event data does not provide sufficient granularity, as more consistent and comprehensive data becomes available over time, it may become possible to analyse and assess any potential distributional impacts of the scheme in the future.

Question Two: Why is government action needed?

Strengthening patient safety

Implementing mandatory reporting would allow more systematic data collection and analysis of medical devices related adverse events, enabling rapid identification of issues and timely interventions. It would support information sharing and assist in ensuring that health professionals receive timely updates on patient safety risks, improving patient safety.

As noted, the TGA is Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods (e.g., medicines, medical devices and biologicals). A primary function within the monitoring of products is Post Market Event Monitoring. This area's focus is to improve the health and safety of patients, healthcare professionals, users and others by reducing the likelihood of adverse events occurring and being repeated.

A key input for this function is adverse event reporting. Adverse event reporting allows the TGA to monitor medical device use, monitor their performance in the real world and identify trends that may indicate emerging safety and/or performance issues. These activities allow the TGA to take appropriate regulatory action to address these issues, thereby reducing the impact on the public.

As noted, there is range of evidence pointing to the fact there is significant underreporting of medical device adverse events.⁴³ This is impacting the TGA's ability to effectively identify and act upon signals that indicate potential or emerging issues in relation to medical devices. Prior government initiatives have seen limited improvements and thus further government action is required. It is proposed that through increased regulatory intervention, TGA's capability to identify, locate and act upon market signals that indicate potential or emerging issues about the safety of effectiveness of medical devices will be uplifted.

Education approaches have not worked

To address recommendations raised in the 2011 review, Therapeutic Goods Administration, *Final Report of the Review Panel and TGA reforms, A Blueprint for Australia's Future*, the IRIS InSite program (the Program) was initiated. Targeted at healthcare professionals, the Program sought to improve their understanding of the TGA's responsibilities in managing reports of adverse events and complaints relating to medical devices to ensure the continued safety of patients, medical professionals and medical devices used in Australia.

However, this attempt to increase voluntary medical device adverse event reporting through educational/awareness initiatives saw limited improvements. Upon review (2020 InSite Review Plan and Report), the InSite Program showed limited evidence of sustained improvements to the quantity and quality of medical device adverse event reporting. From 2015 to 2019, there was an initial increase in the number of reports from the facilities involved in the pilot program, rising from 139 reports in 2015 to a peak of 239 in 2018. However, after the initial increase, the following year decreased, with 194 reports in 2019). Following the completion of the InSite pilot program in 2020, from 2020 to 2024, the number of reports continued to decrease with a total of 303 reports from healthcare facilities averaging only 60 reports per year further adding to limitations of the

⁴³ The Senate, Community Affairs Reference Committee report titled, 'Number of women in Australia who have had transvaginal mesh implants and related matters', outlined the significant underreporting in relation to Urogynaecological Mesh products. In the report, it was outlined that as of 3 January 2018, only 327 reports had been lodged, covering 349 patients. Upon examination the Health Issues Centre (HIC) reported that as of 3 August 2017, 2,400 women had provided personal accounts to the HIC describing adverse events.

educational/awareness initiative. It is also worth noting that the number of medical device adverse event reports across Australia (for those not taking part in the pilot program) also continued to increase over this period. This increase in reporting external to the program makes it unclear whether the limited improvements identified in the pilot program was a result of the IRIS InSite program, or macro trends in reporting nationally.

Limitations of overseas reporting for signal detection

The TGA actively collaborates with overseas regulators through its participation in initiatives like the International Medical Device Regulators Forum (IMDRF) and International Medical Device Safety Updates Forum. These platforms enable comparable regulatory agencies worldwide to share data, insights and safety signals, fostering a collaborative environment for improving global medical device safety. The information from overseas regulators can be useful for general signal detection by providing early indications of potential safety concerns or emerging issues related to medical devices. Data from global sources may help identify broader trends, such as increased performance issues or adverse events associated with a particular category of devices.

While these collaborations are crucial for global regulatory harmonisation, the TGA's ability to act solely on overseas data is limited by its regulatory jurisdiction. The TGA does not have the authority to directly act on events occurring outside Australia. Any regulatory actions in Australia must be supported by domestic data or evidence and align with the *Therapeutic Goods Act 1989*. Overseas reports also reflect different healthcare systems, patient populations, and regulatory frameworks, which may not align with Australian conditions. Medical device models supplied in overseas markets may vary significantly in design, manufacturing, or intended use. As a result, the performance and safety profiles of products can differ across regions. Therefore, the data from other jurisdictions cannot directly inform the regulatory action within Australia and can be used only as a supplementary source to enhance the TGA's signal detection capabilities.

Streamlined reporting tools

The Senate Inquiry highlighted that many women who experienced adverse outcomes related to mesh implants faced significant reporting barriers. These challenges included a lack of awareness of reporting mechanisms and difficulty navigating complex reporting systems. In response to these issues, the TGA released the *Action Plan for Medical Devices in 2019*. A core focus of the action plan was to enhance the accessibility and usability of adverse event reporting mechanisms. This commitment led to the development of simplified online reporting forms for health professionals and consumers in 2019 to encourage completion and make reporting of adverse events more user friendly, while also reducing the administrative burden for healthcare providers and consumers. These systems were designed to encourage higher reporting rates by making the process accessible. While these tools improved the ease of submitting reports, they did not address the fundamental issue of under reporting and lack of timely signals. Without an obligation to report, stakeholders did not engage systematically. The voluntary approach led to inconsistent reporting undermining the efforts to build a comprehensive dataset for signal detection and regulatory action.⁴⁴

Regulatory tools available to intervene

The *Therapeutic Goods Act 1989* provides the legislative basis for the regulation of therapeutic goods in Australia. More specifically, the Act prescribes mandatory reporting of adverse events involving

⁴⁴ Figure 6 - Data on adverse event reports by source 2019-2023

medical devices. The *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2023* provides a framework for the mandatory reporting of medical device adverse events by healthcare facilities (principally public and private hospitals) in specified circumstance (e.g., where the use of a reportable device in a hospital has resulted in a person's death or serious health deterioration), to enhance patient safety and improve the safe use of medical devices.

The Government/TGA's Objectives

The objectives of the Government's actions are to:

- enhance patient safety and improve the safe use of medical devices by introducing a framework for the mandatory reporting of adverse events involving medical devices, principally by hospitals⁴⁵.

Government intentions

The aim of the legislation and associated regulations is to enhance the capacity of the TGA to:

- more rapidly identify and respond to significant issues associated with medical devices that impact upon the quality of care and life experienced by Australian consumers
- more systematically identify emerging signals that could indicate potential risks to the quality of care or quality of life experienced by Australians
- undertake more timely and comprehensive analysis and information-sharing of information between governments and healthcare organisations
- minimise the ongoing burden of data collection placed upon individual healthcare facilities by requiring a minimal amount of information to support further follow-up by the regulator or product sponsors.
- provision of more timely information to healthcare providers about possible risks to patient and professional safety.

In addition, the information could be used to actively compare adverse event reports received by health professionals or healthcare facilities with those reported by device manufacturers to monitor compliance with reporting requirements, and to ascertain and address potential gaps in reporting by different stakeholders.⁴⁶

What would success look like?

Overall, success of government intervention would see:

1. increased volume of reported medical device adverse events by healthcare facilities over a given period – A higher volume of reported incidents would indicate that health care facilities are actively identifying and documenting adverse events.
2. timelier signal detection of medical device adverse events as they occur – A well-functioning mandatory reporting system complemented by robust data analytics, will enable healthcare facilities and the TGA to identify signals of potential issues more quickly. This allows for

⁴⁵ Parliament of the Commonwealth of Australia, *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022 Explanatory Memorandum*, available at: https://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bld=r6953

⁴⁶ TGA, Potential for mandatory reporting of medical device adverse events by healthcare facilities: discussion paper, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-devic/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

appropriate interventions and rapid corrective actions, which reduces the impact of adverse events.

3. improved identification of rarer events and potential emerging issues across the country – A comprehensive reporting system would enable nationwide surveillance. Data from diverse healthcare settings and regions can be captured, increasing the likelihood of detecting rare events. Identifying rarer events and emerging issues is important for understanding the full scope of risks associated with medical devices.
4. earlier regulatory responses to address safety concerns – Earlier detection of issues with medical devices through the mandatory reporting scheme would allow the TGA and health care facilities to take timely action, such as issue warnings, updating guidelines or recall actions on unsafe devices.
5. more frequent provision of information to healthcare facilities regarding alerts to patient and professional safety – Regular and timely information will help healthcare facilities stay informed about safety and performance issues, take appropriate actions and promote continuous improvement in safety protocols and reporting practices.
6. proactively identify and mitigate risks associated with medical devices – Proactive risk management ensures patient safety and maintains trust in medical devices and healthcare systems.
7. improved data quality enabling meaningful trend identification and analysis – Standardising data collection methods and definitions ensures consistency and comparability of reported data. Analytical capabilities and data validation processes would be enhanced.

The following section (Question 3) will outline each policy option considered and indicate the level to which they address these success criteria.

Question Three: What policy options are you considering?

Policy Options

The four regulatory options proposed in this IA are:

Option 1: Maintaining the status quo

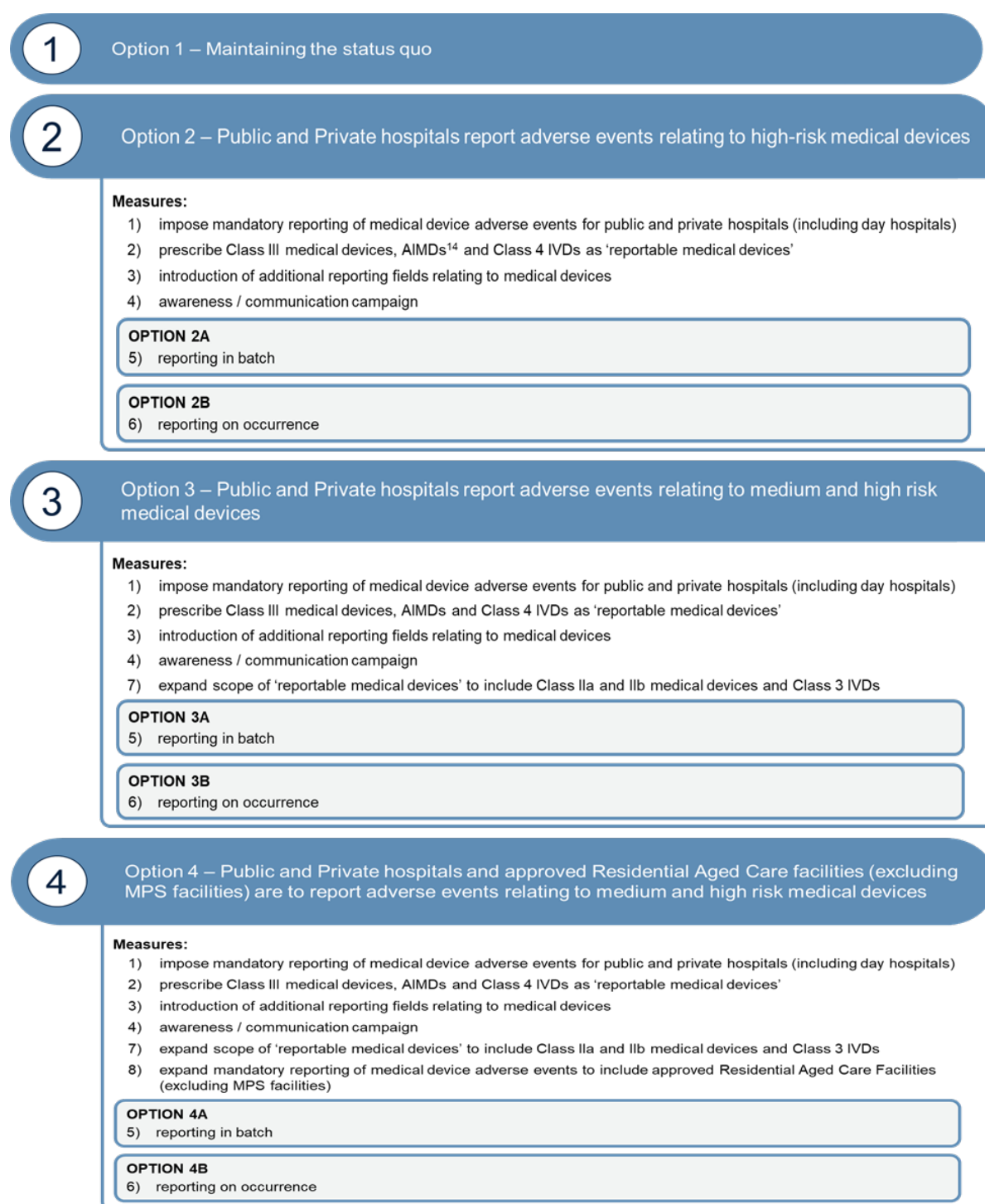
Option 2: Public and Private hospitals report adverse events relating to high-risk medical devices

Option 3: Public and Private hospitals report adverse events relating to medium and high-risk medical devices

Option 4: Public and Private hospitals and approved Residential Aged Care facilities (excluding Multi-Purpose Services (MPS) facilities) report adverse events relating to medium and high-risk medical devices

The problem, its root cause, prior regulatory interventions and the objective of the regulatory response suggests that there are four potential policy options. A progressive approach has been taken to the development of these policy options, with Option 1 posing the least regulatory burden, through to Option 4 which poses the most significant. Similarly, the structure of this section mirrors this progressive approach, with each section building upon the last.

Figure 9. Policy options considered



The commencement of the provisions outlined in the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2023* is expected to be implemented in March 2025. However, under Option 1 - Maintaining the status quo:

- the amendments to the *Therapeutic Goods Act 1989* would not be implemented; and thus
- there is no requirement for healthcare facilities to report adverse events relating to medical devices.

In effect, this would see medical device adverse event reporting continue to occur largely in line with current reporting requirements and mechanisms. Medical device adverse event reporting would continue to be mandatory for medical device manufacturers and sponsors, with the addition of healthcare facilities, and voluntary for medical practitioners and medical device consumers. However, with no mechanism to give effect to the amended legislation, and no revised procedures and systems to support the new reporting requirements, the onus would be on the individual healthcare facilities to report incidents via the pathways already in place. Namely, the Consumer Online Medical Device Incident Report Form (shown at Figure 5) and the Users Medical Device Incident Reporting platform for healthcare professionals.

While difficult to quantify, it is thought that the TGA may only be receiving 5% of reportable medical device adverse events. Maintaining the status quo would see medical device adverse events continue to be significantly underreported, propagating the current challenges in identifying, mitigating and responding to potential patient safety issues relating to medical devices. This, in turn, could continue to propagate the current reporting trends, volumes and demographics (i.e., medical device adverse event reporting in 2020 comprised of 89% medical device sponsors and manufacturers; 8% healthcare professionals; 1% patients; 2% other).

Maintaining the status quo poses risks to the TGA's ability to comprehensively monitor and act upon emerging safety and performance issues of medical devices. While the current system provides some level of oversight, it remains insufficient for identifying and mitigating longer term device failures such as those that have been the focus of public attention (e.g., urogynaecological mesh, metal-on-metal hip prostheses, and textured breast implants) that may only become apparent after years of use. Failure to expand the scope of mandatory reporting scheme to health care facilities could result in missed opportunities to detect early warning signals, ultimately compromising patient safety. This limitation could lead to significant reputational risks regarding the TGA's effectiveness as a national regulator and its commitment to safeguarding public health, eroding trust and confidence in TGA's ability to protect public health.

The responses to the September 2021 discussion paper indicated there is limited support by consumers, industry and healthcare professionals for maintaining the status quo for the reporting of medical device adverse events (i.e., 73% (n=41) of total respondents (n=55) were in favour of mandatory reporting).⁴⁷

The status quo option provides the baseline for the determination of any changes to regulatory compliance costs for the other options being considered.

⁴⁷ TGA, Potential for mandatory reporting of medical device adverse events by healthcare facilities: discussion paper, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

Success Criteria

Option 1 does nothing to address the Government's objectives and will make no impact on the achievement of the success criteria.

The following table details the level to which the proposed option addresses the success criteria of government intervention. The ratings provided are qualitative and are relative to the other policy options proposed.

Table 4 - Success criteria

Success Criteria	Level of Addressal
1. increased volume of reported medical device adverse events by healthcare facilities	Low - does not address
2. timelier signal detection of medical device adverse events as they occur	Low - does not address
3. improved identification of rarer events and potential emerging issues across the country	Low - does not address
4. earlier regulatory responses to address safety concerns	Low - does not address
5. more frequent provision of information to healthcare facilities regarding possible threats to patient and professional safety	Low - does not address
6. proactively identify and mitigate risks associated with medical devices	Low - does not address
7. improved data quality enabling meaningful trend identification and analysis	Low - does not address

2

Option 2 – Public and Private hospitals report adverse events relating to high-risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign

OPTION 2A

- 5) reporting in batch

OPTION 2B

- 6) reporting on occurrence

Option 2 would see the implementation of mandatory medical device adverse event reporting for public and private hospitals (including day hospitals). This option proposes that reporting be mandatory for reportable medical devices deemed to be high-risk (i.e., those classified as Class III, AIMDs, and Class 4 IVDs). As is described in this section, two sub options are proposed regarding the frequency of reporting. These are:

- Option 2A – reporting in batch⁴⁸
- Option 2B – reporting on occurrence.

Measure 1 – Mandatory Reporting by Health Care Facilities

As noted, Option 2 (as well as the ensuing Options 3 and 4) sees the implementation, compliance monitoring and enforcement of amended legislation mandating reporting of medical device adverse events by healthcare facilities, namely public and private hospitals. This approach is guided by practice in other countries, such as the USA⁴⁹ and more recently, Canada⁵⁰, where it is mandatory for healthcare facilities to report side effects or adverse events that may be related to medical devices. In these cases, an organisation-focussed approach, rather than imposing requirements on individual medical practitioners / staff was considered to:

- reduce the overall level of reporting burden placed upon individual health professionals
- provide greater flexibility for health services to allocate resources required for adverse event reporting
- increase the potential quality of adverse event reports to the TGA, particularly information relating to specific medical devices that may otherwise be unavailable to individual healthcare professionals at the time of incident notification
- be more reliably monitored and able to be enforced by regulators, and more consistent with responsibilities of device manufacturers for the reporting of adverse events.

In consultation with key state and territory stakeholders, there was strong support for the introduction of mandatory reporting by all Australian healthcare facilities, including:

- specialist medical practices

⁴⁸Batch reporting does not preclude healthcare facilities reporting on-occurrence, if necessary.

⁴⁹ Food & Drug Administration, *Medical Device Reporting (MDR): How to Report Medical Device Problems*, available at:

<https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>

⁵⁰ Government of Canada, *Incident reporting for medical devices: Guidance document*, available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/meffect-canada/incident-reporting-medical-devices-guidance-2021.html>

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- public and private ambulance services
 - pharmacies
 - residential care providers
 - non-medical specialist cosmetic procedure centres
 - general practices
 - dental and orthodontic practices
 - community based health services such as district nursing services
 - chiropractic practices who conduct diagnostic imaging
 - allied health practices recognised and regulated by the Australian Health Practitioner Regulation Agency (AHPRA) such as physiotherapists, medical radiation practitioners, audiologists.⁵¹

While broad coverage of healthcare facilities would improve TGA's capability to detect, identify and respond to adverse events and potential emerging issues relating to the safety of medical devices, it would also impose significant regulatory burden. Option 2 proposes to introduce mandatory reporting of medical device adverse events to a targeted population - public and private hospitals (inclusive of day hospitals) accredited to the National Safety and Quality Health Service (NSQHS) Standards (1,329 hospitals, day procedure services and public dental practices accredited as at 2023).⁵² This population would provide significantly greater reporting coverage without imposing a disproportionate regulatory burden on the broader community. This is due to the target population's:

- organisational resources available for reporting purposes
- in line with their NSQHS Standards accreditation requirements, reporting systems and processes with the capability for further development will largely already be in place.

This was supported broadly across multiple consultation responses, including that from the Commission, who acknowledged that the systems and infrastructure of a larger health service organisation may be able to participate more readily in a mandatory reporting system. Additionally, they recognised that individual health practitioners, such as general practitioners, may find additional reporting burdensome.⁵³

Measure 2 – Prescribe medical devices considered to be of 'high-risk' as Reportable Medical Devices

As described in the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2023*:

'reportable medical device means a medical device of a kind prescribed by regulations made for the purposes of this definition'

Measure 2 proposes that the regulations would prescribe reportable medical devices as those that are currently (and in future) classified as high-risk. This includes Class III medical devices, AIMDs and Class 4 IVDs. This means that reporting of medical device adverse events would be mandatory for events (either near miss, serious injury or death) involving (or potentially involving) a Class III medical device, AIMD or Class 4 IVD. These categories comprise of medical devices that have been

⁵¹ <https://www.health.gov.au/topics/allied-health-care/who-can-provide>

⁵² <https://www.safetyandquality.gov.au/consumers/public-reporting-hospital-performance-nsqhs-standards>

⁵³ Evidence for this is based on 57 submissions to the discussion paper, covering consumers, industry, healthcare facilities and other interested parties. Specifically, submissions from the Australian Medical Association, Australian Private Hospitals Association, and the Australian Commission on Safety and Quality in Health Care, all indicated the relative burden the introduction of mandatory reporting would have on the potential healthcare facilities for inclusion.

determined to have a higher risk of potential harm, either to those the medical device is intending to help (i.e., patients), or those that may come into contact with it (e.g., medical practitioners).

These high-risk medical devices make up roughly 10% of medical devices registered on the ARTG. However, this same Class has been attributed to 49.5% of medical device adverse events reported over the last five calendar years (Q1 2019 to Q4 2023). In comparison, Class I devices, which are of low risk relative to Class III and make up 53.7% of medical devices currently registered, are attributed to 4.4% of medical device adverse events reported in the same period.⁵⁴

The intention of limiting the prescribed reportable medical devices to comprise solely of Class III medical devices, AIMDs and Class 4 IVDs, is twofold:

1. limit the regulatory burden imposed on the regulated community (i.e., public and private hospitals); and
2. maintain focus on medical devices that pose the highest potential risk to consumers, medical practitioners and the public.

Measure 3 – Addition of reporting fields relating to medical devices

Measure 3 proposes to introduce additional data fields to existing local incident management systems for the reporting population. An iterative approach has been taken in developing the information requirements of medical device adverse event reporting. As much as possible, to reduce the regulatory burden imposed on the regulated community, Measure 3 seeks to leverage extant public and private hospital reporting systems and data fields.

The following datasets (both existing and new) were identified in consultation with stakeholders. The new data fields would be critical in strengthening post-market medical device monitoring and improving patient safety, thereby uplifting the TGA's capability to identify and act upon market signals that indicate potential or emerging issues about the safety and effectiveness of medical devices.

Existing Data

Responses to the 2021 consultation paper highlighted the limited consistency across public and private hospitals in relation to the reporting systems in operation. Further, respondents explained that there is a patient-centric approach to reporting, and that data and information currently being collated is usually used for purposes other than adverse event reporting (that being, adverse events broadly – not specifically related to medical devices). This means that the data fields / information currently being collected has a limited focus on the medical devices in use. However, it was identified that some and/or all of the following data is being collected through current platforms:

- suspected involvement of a medical device
- brand/trade name of the medical device
- where the device came from (e.g., facility / health professional)
- current location of the medical device
- a free text field for other information, often including:
 - traceability information such as barcode/batch number/lot number
 - event details and the device's environment
 - if any other devices were involved
 - patient consequences and outcomes

⁵⁴ Data collected from the ARTG Search Visualisation Tool at: <https://compliance.health.gov.au/artg/>. The values cited refer to the number of medical devices registered for use in Australia, not the total number of medical devices currently in use in Australia.

-
- if device was returned
 - the healthcare provider that used the device
 - incident number or identifier (if applicable).

New Data

Beyond the data currently being collected across existing systems, Measure 3 would see the addition of a field relating to the classification of the incident. Specifically, whether it was a:

- death
- serious injury or deterioration in health or major harm
- treatment for a serious injury or deterioration in health related to a medical device⁵⁵, or
- prevention of a serious injury or deterioration in health (near miss).

⁵⁵ Noting that this could include serious injury or deterioration in health or major harm relating to a medical device or treatment that has occurred outside of the healthcare facility it presents at.

A breakdown of the proposed data fields is outlined in the figure below.⁵⁶

Figure 10 - Possible data items for reporting to the TGA

FIELD	FORMAT	DEFINITION (TBC)	VALUES
1. State/Territory Name	String	METEOR	Select one option only AA[A]
2. Facility/Site Name	List	Declared Hospitals	Select one option only
3. Facility Identifier (auto generated)	String	METEOR	Hospital identifier XXXXX
4. Date/Time of Incident	Date	Date (day, month, year) and time (hours and minutes) of incident	DDMMYYYY:HHMM
5. De-identified Patient Details	String	Family name letters 2, 3, 5 Given name letters 2, 3 Date of birth (day, month, year) Sex (1-male, 2-female, 3- unknown)	SLK-581 XXXXXDDMMYYYN.
6. Incident Narrative*	Text	What happened? What was actions were taken?	Up to 100 words Up to 100 words
7. TGA incident classification*	List	Death Serious injury or deterioration in health or major harm Treatment for a serious injury or deterioration in health related to a medical device Prevention of a serious injury or deterioration in health (near miss)	Select all that apply
8. Device Description*	Text	Where was (is) device located? Describe type of device? Describe purpose of device?	Up to 20 words Up to 20 words Up to 100 words
9. Incident reported to state/Territory government	List	Yes No	Select one option only
10. Device Name*	Text	State device name if known	Up to 20 words
11. Unique Device Identifier (UDI) (when available)	Text	State the UDI if known	
12. Device manufacturer (if known)	Text	State device sponsor if known	Up to 20 words
13. Incident reported to device sponsor?	List	Yes No	Select one option only

*Mandatory fields as per the requirements in the Act

Systems

Key to the efficient transfer of medical device adverse event reports from healthcare facilities to the TGA are the underlying Incident Management Systems (IMS) used by public and private hospitals. The IMS' used across public and private hospitals varies, however through consultation with key stakeholders, the following was identified:

⁵⁶ The minimum data fields are subject to ongoing stakeholder discussions and agreements.

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- RiskMan is widely used across public hospitals in VIC, NSW, QLD, ACT and NT, however additional systems include:
 - Clinical Incident Management System (used in WA)
 - Safety (Reporting and) Learning System(s) (SLS/SRLS) (used in SA and TAS)
 - Incident Management System Plus (IMS+) (used in NSW)
 - Victorian Health Incident Management System
 - Around two thirds of private hospitals utilise the following IMS:
 - RiskMan
 - The Patient Safety Company (TPSC)
 - Events, Risk, Improvements, and Compliance (ERIC)

While the majority of facilities utilise a digital IMS, it must be noted that it is likely that many private hospitals would utilise a range of hard copy and/or electronic IMS that have not been identified in stakeholder consultation.

Measure 3 proposes the addition of data fields related to medical devices to ensure minimum data requirements for reporting are met. This would require upgrades and/or updates to local IMS', which could incur a significant cost to the healthcare facilities. Implementation of the regulations are likely to be iterative, and so far as is possible, would try to align with healthcare facilities' current system upgrade lifecycle (to maintain accreditation to the NSQHS Standards, healthcare facilities are required to regularly review their incident management systems⁵⁷).

Measure 4 – awareness / communication campaign

Measure 4 proposes the development and implementation of a comprehensive communication and awareness campaign targeted specifically at healthcare facilities, emphasising the importance of reporting medical device adverse events. Such a campaign would involve disseminating information through various channels within healthcare settings, including training sessions, informational materials, and digital platforms. The objective of this initiative would be to educate healthcare professionals about the significance of promptly reporting any adverse events associated with medical devices they encounter in their practice.

The TGA currently provides a range of online tools and resources to facilitate medical device adverse event reporting. The TGA has also published detailed guidance to support stakeholders in understanding reporting processes, which includes stepwise instructions and frequently asked questions.^{58,59} Building upon these existing resources, the TGA will publish comprehensive guidance and communication materials throughout the roll out of the mandatory reporting to ensure healthcare facilities have a clear understanding of the requirements in order to facilitate compliance.

Leveraging the learnings from prior communication campaigns (i.e., the InSite Program), a well-considered communication and awareness campaign would still serve as a crucial mechanism for fostering a culture of vigilance and accountability within healthcare facilities. This measure is expected to be planned and implemented in collaboration with the Commission, in line with the release of updates to the NSQHS Standards.⁶⁰ The Commission will be updating the NSQHS Standards to

⁵⁷ In line with action 1.11 g. from the NSQHS Standards, which requires accredited entities to "regularly review and act to improve the effectiveness of the incident management and investigation system".

⁵⁸ <https://www.tga.gov.au/resources/resource/reference-material/medical-device-incident-reporting-and-investigation-scheme-iris>

⁵⁹ <https://www.tga.gov.au/resources/resource/reference-material/reporting-adverse-events>

⁶⁰ Updating of the NSQHS Standards will occur on multiple occasions. Firstly, with an Advisory to the Second Edition of the Standards (in 2025), and later, with the release of the Third Edition of the Standards (predicted to be in 2027).

require the mandatory reporting of adverse events associated with medical devices and it has an established program focussed on communicating and educating health care professionals and health services on the requirements of the standards.

The TGA collaborates annually with medicines safety organisations and regulators worldwide to promote #MedSafetyWeek. #MedSafetyWeek promotes reporting of medicine side effects by consumers and health professionals. In the future, this event could be leveraged to design similar initiatives for medical devices. By raising awareness about the necessity of reporting medical device adverse events, healthcare providers can contribute to the early detection of potential safety issues, facilitating timely interventions and mitigating risks to patient health. Ultimately, the success of such a campaign hinges upon fostering a collaborative environment where healthcare facilities and professionals recognise their pivotal role in safeguarding patient well-being through active and transparent reporting practices.

In addition, the TGA has launched its sponsor directed medical devices vigilance program to further educate medical device sponsors on the importance of having established systems and procedures in place including for reporting adverse events received from all sources.

OPTION 2A

5) reporting in batch

Measure 5 – reporting in batch

Measure 5 proposes the reporting of medical device adverse events to be conducted in batch. In practice, this could occur monthly or every two months⁶¹, with each healthcare facility generating and submitting a summary of medical device adverse events for that period.

In consultation with stakeholders, it was expressed that the usage of an Application Programming Interface (API) to assist in the expedient transfer of data would be welcomed as a future option. Because of the range of capabilities, there will be capacity to transfer data to the TGA in multiple ways - portal/emails/attachments (current approach); individual reporting via webforms and API readiness as systems develop. Batch reporting does not, however, preclude the use of on occurrence reporting for significant or complex cases of adverse or suspected adverse events. It is recognised, and expected, that if there are rare events that pose serious harm on a broader scale (i.e., a 'public threat'), these events would be reported on occurrence and not held back to be reported as a batch. This applies for all options proposing batch reporting and would be at the discretion of the facility applying TGA guidance.

Additionally, the TGA anticipates that smaller facilities, those most likely to have immature local incident management systems, may opt to utilise existing mechanisms to report medical device adverse events (e.g., reporting via TGA's website).

OPTION 2B

6) reporting on occurrence

Measure 6 – reporting on occurrence

Measure 6 proposes that reporting is on an on-occurrence basis. Meaning upon identification of a medical device adverse event, healthcare services (i.e., public and private hospitals) would need to report each unique medical device adverse event within the relevant timeframe outlined in the regulations. Reporting timeframes would be based on the determined complexity/severity of the adverse event, following similar categorisations as to those currently imposed on medical device sponsors / manufacturers in relation to medical device adverse event reporting.⁶² These categories and current associated timeframes for sponsors/manufacturers are described in the table below.

⁶¹ Frequency of batch reporting is yet to be agreed upon by stakeholders. There is potential this could occur monthly or every two months.

⁶² Timeframes for reporting on occurrence are yet to be agreed upon by stakeholders.

Table 5 - Incident severity scale with associated timeframes for reporting

Severity	Current reporting timeframe for sponsors/manufacturers
Serious public health threat or concern	48 hours
Death or serious injury	10 days
Near misses that could have resulted in death or serious injury	30 days
All others	60 days

Success Criteria

Option 2A and 2B are estimated to address the success criteria to a moderate level. Compared to the status quo, it is anticipated that both Options 2A and 2B will provide timely signal detection as both covers high-risk medical devices (i.e., Class III medical devices, AIMDs and Class 4 IVDs), which are more likely to be associated with serious adverse events. Regardless of batch or on occurrence reporting, adverse events involving high-risk devices will be identified early and reported within the specified timeframes allowing for safety concerns to be addressed. Additionally, compared with the status quo, healthcare facilities will receive safety related information more frequently, enabling them to stay informed about potential risks and improve patient care. On occurrence reporting allows critical incidents, such as deaths or serious harm, to be flagged immediately. Batch reporting, although periodic, still provides more frequent updates compared to voluntary reporting, enabling earlier identification of trends.

It should be noted that the limited scope of medical device adverse events being captured (i.e. only high-risk devices including Class IIIs, AIMDs and Class 4 IVDs), which constitute only 9.8% of all medical devices included in the ARTG, will significantly limit the ability to obtain meaningful trend identification and analysis.

The following table details the level to which the proposed option addresses the success criteria of government intervention. The ratings provided are qualitative and are relative to the other policy options proposed.

Table 6 - Success criteria

Success Criteria	Level of Addressal
1. increased volume of reported medical device adverse events by healthcare facilities	moderate
2. timelier signal detection of medical device adverse events as they occur	moderate
3. improved identification of rarer events and potential emerging issues across the country	moderate
4. earlier regulatory responses to address safety concerns	moderate
5. more frequent provision of information to healthcare facilities regarding possible threats to patient and professional safety	moderate
6. proactively identify and mitigate risks associated with medical devices	moderate
7. improved data quality enabling meaningful trend identification and analysis	low

3

Option 3 – Public and Private hospitals report adverse events relating to medium and high risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign
- 7) expand scope of 'reportable medical devices' to include Class IIa and IIb medical devices and Class 3 IVDs

OPTION 3A

- 5) reporting in batch

OPTION 3B

- 6) reporting on occurrence

Option 3 would see the implementation of mandatory medical device adverse event reporting for the same population as Option 2 (i.e., public and private hospitals). However, it is proposed that the scope of reportable medical devices be expanded to include medical devices deemed to be medium to high risk (i.e., Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs)⁶³. Option 3 also proposes two sub options regarding the frequency of reporting. Those being:

- in batch
- on occurrence.

In summary, Option 3 would propose:

- healthcare facilities to include public and private hospitals
- reportable medical devices would include Class IIa, IIb and Class III medical devices, AIMDs and Class 4 IVDs
- reporting information would leverage, as far as is possible, existing systems and data collected to meet a minimum dataset requirement
- reporting frequency would be either on occurrence, or in batch monthly or every two months.

Measure 7 – expand scope of 'reportable medical devices' to include medium-risk medical devices

As noted, Option 3 would see the expansion of the scope of reportable medical devices. More specifically, Measure 7 proposes to include:

- Class IIa – low to medium risk level for potential harm
- Class IIb – medium to high risk level for potential harm
- Class 3 IVDs – moderate risk level for potential harm
- Class III – high risk level for potential harm
- AIMDs – high risk level for potential harm
- Class 4 IVDs – high risk level for potential harm.

While this expanded scope would increase the reporting burden placed on public and private hospitals, it would more comprehensively cover medical devices deemed to be of higher risk, which aligns with the policy objectives of the amended legislation. The addition of these two classes would

⁶³ Measures 1 – 5 have been addressed on pages 29 – 34.

see the coverage of registered medical device expand from 9.8% (i.e., Class III medical devices, AIMDs and Class 4 IVDs), to 43.4% (Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs). In relation to historic medical device adverse event reporting, this would increase coverage from 49.5% of reports in the last five calendar years, to 90.9%.

Success Criteria

Options 3A and 3B are estimated to address the success criteria to a moderate to high level. Similar to Option 2, the introduction of mandatory reporting regulations would increase the volume of reports and thus support the timelier detection of adverse events due to the expanded scope of medical devices to include medium to high-risk medical devices (i.e. Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs) which would ensure a wider range of medical devices are monitored.

A larger dataset from medium- and high- risk devices would improve the TGA's ability to detect, assess and respond to potential safety issues related to medical devices and more holistically achieve the objectives of Government (i.e., through the more comprehensive coverage of medical devices assessed as being of high potential risk to safety). Including medium to high risk devices allows for earlier identification and mitigation of issues before they escalate to more severe incidents, reducing long term harm and healthcare costs. The expanded coverage would also allow for more frequent provision of information to stakeholders. The inclusion of medium risk devices will generate a more substantial and continuous stream of adverse event reports, enabling the TGA to deliver tailored safety information and recommendations to health care facilities and industry based on specific risks associated with different device categories. The increased scope of reporting data will allow for better comparability, analytical capabilities, data validation processes thereby producing meaningful signals and trend analysis.

The following table details the level to which the proposed option addresses the success criteria of government intervention. The ratings provided are qualitative and are relative to the other policy options proposed.

Table 7 - Success criteria

Success Criteria	Level of Addressal
1. increased volume of reported medical device adverse events by healthcare facilities	moderate
2. timelier signal detection of medical device adverse events as they occur	high
3. improved identification of rarer events and potential emerging issues across the country	moderate
4. earlier regulatory responses to address safety concerns	high
5. more frequent provision of information with the inclusion of medium and high risk devices, enabling healthcare facilities to identify early signals and possible threats to patient and professional safety	high
6. proactively identify and mitigate risks associated with medical devices	high
7. improved data quality due to the inclusion of medium to high risk medical devices. This expanded scope allows for meaningful trend identification and analysis	moderate

4

Option 4 – Public and Private hospitals and approved Residential Aged Care facilities (excluding MPS facilities) are to report adverse events relating to medium and high risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign
- 7) expand scope of 'reportable medical devices' to include Class IIa and IIb medical devices and Class 3 IVDs
- 8) expand mandatory reporting of medical device adverse events to include approved Residential Aged Care Facilities (excluding MPS facilities)

OPTION 4A

- 5) reporting in batch

OPTION 4B

- 6) reporting on occurrence

Option 4 would build upon the previously described option 3 (i.e., public and private hospitals report adverse events relating to medium and high-risk medical devices), expanding the population to include approved residential aged care facilities (excluding MPS facilities).⁶⁴ Option 4 also proposes two sub options regarding the frequency of reporting. Those being:

- in batch
- on occurrence.

In summary, Option 4 would propose:

- healthcare facilities to include public and private hospitals, as well as approved residential aged care facilities (excluding MPS facilities)
- reportable medical devices would include Class IIa, IIb and Class III medical devices, AIMDs and Class 3 and 4 IVDs
- reporting information would use, as far as is possible, existing systems and data collected to meet a minimum dataset
- reporting frequency would be on occurrence or in batch monthly or every two months

Measure 8 – expand mandatory reporting of medical device adverse events to include approved Residential Aged Care Facilities

Measure 8 would see the inclusion of approved residential aged care facilities to those mandated to report medical device adverse events. It is proposed that this would include residential aged care facilities accredited by the Aged Care Quality and Safety Commission (ACQSC).

Aged care residents are more susceptible to adverse events due to their frailty and the complexity of their health conditions.⁶⁵ Complex medical devices and emerging technology can play a crucial role in elderly care, assisting with diagnosis, therapy, monitoring, and rehabilitation.⁶⁶ Effective management of these devices is essential to ensure high-quality patient care while minimising risks of adverse events. Ensuring that adverse events are reported can help better protect this high-risk group by identifying risks early and enabling timely corrective actions.

⁶⁴ Measures 1 – 5 and 7 have been addressed on pages 29 – 34 and 35 respectively.

⁶⁵ Andrew Georgiou, & Mikaela Jorgensen (2022). Incidence of adverse incidents in residential aged care. *Australian Health Review*, 46(4), 405-413.

⁶⁶ Balasubramanian, M., Brommeyer, M., Simmonds, L., Shafei, A. (2023). Integrated Care Models in Aged Care: The Role of Technology. In: Pfannstiel, M.A. (eds) *Human-Centered Service Design for Healthcare Transformation*. Springer, Cham.

This suggestion is in line with new regulations introduced internationally such as the U.S. FDA and has the potential to provide a more complete picture of adverse events.⁶⁷

As noted, this expanded scope of reporting population would provide TGA with a larger database to analyse, potentially increasing their capability to detect weak signals that indicate potential or emerging issues related to the safety and/or effectiveness of medical devices. This would improve TGA's ability to meet its objectives.

Accreditation by the ACQSC, similar to the accreditation for hospitals to the NSQHS standards, is key to implementation. Amendments to the existing standards would be critical in effective implementation of mandatory reporting for this population as they would prescribe the incident management and reporting requirements to facilitate mandatory reporting.⁶⁸

Future Expansion of Population

In consultation with stakeholders, the TGA looked into the viability of including healthcare facilities that were not declared as hospitals by the *Private Health Insurance Act 2007*. Through careful consideration with these stakeholders, it was determined that public and private hospitals (including day hospitals) and approved residential aged care facilities were the key facilities to be included as part of mandatory reporting. However, in future, mandatory reporting could be expanded to include other facilities, inclusive of:

- specialist medical practices
- public and private ambulance services
- pharmacies
- non-medical specialist cosmetic procedure centres
- general practices
- dental and orthodontic practices
- community based health services (e.g., district nursing services)
- chiropractic practices who conduct diagnostic imaging
- allied health practices.

Mandatory reporting by these facilities was generally well supported by the stakeholders engaged and may be taken forward by the TGA for consideration for future inclusion.

Success Criteria

Options 4A and 4B are estimated to most comprehensively address the success criteria, as well as achieving the Government's objectives from the introduction of new regulations. The expansion of reporting population to include approved Residential Aged Care facilities would further increase the volume of adverse event reporting and thus the TGA's ability to identify, assess and respond to emerging safety issues relating to medical devices.

Amendments to the existing Aged Care Quality Standards will be critical for the effective implementation of mandatory reporting for this population in the future. The existing incident management systems and reporting practices within residential aged care facilities have not yet been fully assessed. Further exclusive consultation is required to fully understand the systems, reporting practices and associated data requirements before proceeding with expanding mandatory reporting scheme to these facilities. The limitations of this option also relate to the typical class of medical

⁶⁷ [Medical Device Reporting \(MDR\): How to Report Medical Device Problems | FDA CFR - Code of Federal Regulations Title 21](#)

⁶⁸ As outlined by the ASQSC in their best practice guidance on effective incident management systems, accessible at: <https://www.agedcarequality.gov.au/sites/default/files/media/effective-ims-guidance-august-2021.pdf>

devices used within said facilities, and their relevance to the Government's objectives from new regulation (i.e., the medical devices used are typically of lower risk). As such, consideration must be given to the relative costs and benefits of expanding the scope.

The following table details the level to which the proposed option addresses the success criteria of government intervention. The ratings provided are qualitative and are relative to the other policy options proposed.

Table 8 - Success criteria

Success Criteria	Level of Addressal
1. increased volume of reported medical device adverse events by healthcare facilities	high
2. timelier signal detection of medical device adverse events as they occur	high
3. improved identification of rarer events and potential emerging issues across the country	high
4. earlier regulatory responses to address safety concerns	high
5. more frequent provision of information to healthcare facilities regarding possible threats to patient and professional safety	high
6. proactively identify and mitigate risks associated with medical devices	high
7. improved data quality enabling meaningful trend identification and analysis	high

Question Four: What is the likely net benefit of each option?

Benefits and Risks of Policy Options

Option 1 maintains the status quo. This option does not address the public health problem that has been identified and prevents the delivery of the Government's policy objectives.

Options 2A and 2B seek to mandate reporting of adverse events relating to high-risk medical devices by healthcare facilities. These options address the success criteria to a moderate level. The introduction of mandatory reporting requirements would increase the volume of reports and support the timelier detection of adverse events and potential medical device safety issues. However, Options 2A and 2B are limited by the scope of medical devices mandated to be reported on (i.e., only on high-risk medical devices).

Options 3A and 3B seek to mandate reporting of adverse events relating to medium and high-risk medical devices by healthcare facilities. These options are estimated to address the success criteria to a moderate to high level. The expanded scope would more comprehensively cover medical devices deemed to be of medium to high potential risk to safety.

Options 4A and 4B will see further expansion to the scope of regulation imposed on healthcare facilities through a broadening of the population mandated to report on medical device adverse events. These options, however, will pose the most significant regulatory burden.

This section outlines the benefits and costs for each of the four options proposed in this Impact Analysis.

Method of Analysis

A multi-criteria analysis (MCA) methodology was utilised to adequately analyse, assess, and recommend the most suitable policy option. In development of this Impact Analysis, Value of Statistical Life (VSL) analysis was considered for use. However, due to the limited data available (and the varying reliability of the data⁶⁹) it was decided not to be used in support of this Impact Analysis.

Multi-Criteria Analysis

Multi-criteria analysis is a decision-making methodology used to evaluate and compare different options based on multiple criteria or factors. It offers a structured approach to complex decision-making by breaking down each policy option into its constituent parts and systematically considering the various objectives, constraints, and preferences involved. MCA involves identifying relevant criteria, weighting their relative importance, and aggregating an assessment that facilitates the comparison and ranking of policy options.

For the purposes of this Impact Analysis, each policy option, sub-option, and constituent measures, were assessed and ranked relative to each other on the following criteria:

- **Achievement of Success Criteria:** the level to which the proposed option addresses the success criteria of government intervention (as outlined in Tables 4, 6, 7 and 8)

⁶⁹ A key example for why VSL has not been used in this instance is the data on reporting volumes post-implementation of new regulations in the US. In the 10 years post implementation the volume of reports increased almost 40-fold. In the same period, reported deaths increased by over 100-fold. It is likely new regulations improved the FDA's ability to detect, assess and respond to potential medical device safety issues. However, there was not only a large increase in reported deaths, but a significant increase in reported deaths relative to reports. Device data for the US accessible at: <https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files>

- **Benefits and Costs:** the aggregate relative benefits and costs across affected populations, specifically:
 - businesses e.g., public and private hospitals, aged care facilities, medical device sponsors and manufacturers
 - government e.g., TGA
 - general public
- **Regulatory Burden:** the total regulatory burden on the regulated community over 10 years, annualised.

Consultations with key state and territory stakeholders informed the weightings allocated to each criterion listed in the MCA. A 40% weighting was placed on the achievement of success criterion as a high value was placed on ensuring the policy option selected is facilitating achievement of positive health outcomes (e.g., timelier detection of weak signals), improved patient safety, and compliance with legislative requirements.

The regulatory burden criterion was also weighted highly at 40%. Minimising regulatory burden is critical for practical implementation of and compliance with the scheme. A high weighting aligns with discussions with stakeholders, that a large number of healthcare facilities in the regulated population have limited resources and are concerned about resourcing pressure through introduction of excessive reporting requirements.

A 20% weighting was applied to the overall benefit and cost across affected populations as it is deemed an important consideration but considered secondary to achieving success criteria. A lower weighting is considered appropriate because stakeholders recognised that initial costs may be high, but the longer-term benefits, such as improved healthcare outcomes, justify the investment.

The table below summarises the weighting of each criterion, and the relative ranking for each policy option and sub option against said criterion. These rankings are informed by an aggregation of both qualitative and qualitative data and have been averaged to provide an overall ranking of options. Option 3A has an overall ranking of 1 (i.e. preferred option) based on the MCA criteria. Further explanation across the different policy options and rankings can be found in Appendix A.

Table 9: MCA Criteria, Weightings and Rankings Across Policy Options

MCA Criteria	Weighting %	1	2A	2B	3A	3B	4A	4B
Achievement of Success Criteria	40%	7	6	5	4	3	2	1
Benefits and Cost	20%	7	5	6	1	4	2	3
Regulatory Burden	40%	1	2	3	4	5	6	7
Average Ranking		4.60	4.20	4.40	3.40	4.00	3.60	3.80
Overall Ranking		7	5	6	1	4	2	3

The Regulatory Burden Measurement

The Regulatory Burden Measurement Framework (the Framework) has been applied to each option outlined in the Impact Analysis (see [Appendix B](#)).

The Framework follows the guidelines provided by the Office of Impact Analysis⁷⁰. The regulatory burden measurements are calculated on a ten-year basis. Costs are presented on an average per year basis, with one-tenth of the initial start-up costs added to the expected ongoing annual regulatory burden costs to provide the annual average cost that is expected for the first ten years. A range of assumptions are used as model inputs. Many of the key assumptions are the same between measures.

The regulatory burden estimates depend upon publicly available data and external (third party) perspectives on how the proposed regulations would impact upon the potential reporting populations (i.e., public and private hospitals and approved residential aged care providers). The preferred option will have a \$1.66 million cost to public hospitals, as per Figure 12. These costs have been excluded from the RBE calculation in alignment with the IA Framework which states only costs to individuals, businesses and community organisations are included in the RBE.

Figure 11 - annualised average cost of new regulations on private stakeholder groups (from business as usual 10-year avg, \$million)

Stakeholder Type	Cost Type	Option 1	Option 2a	Option 2b	Option 3a	Option 3b	Option 4a	Option 4b
Business (private healthcare facilities, residential aged care facilities excluding MPS facilities))	Administrative Costs		0.46	0.47	0.89	0.94	1.86	1.91
	Substantive Compliance Costs		0.73	0.73	0.73	0.73	3.70	3.70
	Delay Costs		-	-	-	-	-	-
	Sub-total	-	1.19	1.20	1.61	1.67	5.56	5.61

Figure 12 - annualised average cost of new regulations on the public sector⁷¹ in \$million (excluded from Regulatory Burden Estimate (RBE))

Stakeholder Type	Cost Type	Option 1	Option 2a	Option 2b	Option 3a	Option 3b	Option 4a	Option 4b
Public Sector	Administrative Costs		0.44	0.44	0.88	0.88	0.88	0.88
	Substantive Compliance Costs		0.77	0.77	0.77	0.77	0.77	0.77
	Delay Costs		-	-	-	-	-	-
	Total	-	1.21	1.21	1.66	1.66	1.66	1.66

⁷⁰ OIA, Regulatory Burden Measurement Framework, accessible at: <https://oia.pmc.gov.au/sites/default/files/2024-02/regulatory-burden-measurement-framework.pdf>

⁷¹ Costs to public sector is comprised of the implementation costs for public hospitals. While excluded from the RBE, we have included the estimated costs to the public sector due to the significant number of public health facilities that will be impacted.

Option 1, maintenance of the status quo would see:

- the amendments to the *Therapeutic Goods Act 1989* are not implemented; and thus
- there is no requirement for healthcare facilities to report adverse events relating to medical devices.

Benefits

The benefits tied to maintaining the status quo would primarily relate to the lower regulatory impost on the reporting populations. Should the status quo be maintained, the TGA would not be able to enforce the legislation requiring healthcare facilities (in particular, public and private hospitals) to mandatorily report on medical device adverse events. Of the options proposed, this provides the lowest level of intervention, and thus the lowest cost on the regulated community.

Costs

As noted, Option 1 proposes that the amendments outlined in the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2023* are not implemented, thus imposing no requirements on healthcare facilities to report medical device adverse events. In addition, the system and process changes required to local incident management systems in healthcare facilities would not be developed, finalised or implemented. Without the regulations:

- medical device adverse events would continue to be underreported
- the TGA's capability to detect weak signals relating to medical devices that pose a potential health risk would likely be unchanged
- a repeat of significant public health incidents, similar to those experienced in the Urogynaecological Mesh case is possible.⁷²

Each of these issues would raise significant reputational risks for the TGA and broader Department of Health, Disability and Ageing, and its ability to effectively regulate medical device safety.

The proliferation of these issues would have obvious impacts on patient safety outcomes but would also have follow on effects on other businesses, for example, medical indemnity insurers. The lack of comprehensive reporting increases the likelihood of undiscovered issues leading to claims, which can result in:

- higher payouts and increased premiums
- greater financial risk due to the inability to accurately assess and price policies
- straining insurer resources and necessitate more stringent underwriting practices.

This option would come at a cost to Australian businesses, individuals and the community through on-going costs related to the failure to identify and quickly rectify issues with medical devices.

This option does not address the public health problem that has been identified and prevents the delivery of the Government's policy objectives to strengthen patient safety and post-market monitoring of medical devices.

⁷² In addition to the public health risk, these incidents also present a significant financial liability to businesses (e.g., the \$300 million Johnson & Johnson settlement)

2 Option 2 – Public and Private hospitals report adverse events relating to high-risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign

OPTION 2A

- 5) reporting in batch

OPTION 2B

- 6) reporting on occurrence

Option 2 seeks to mandate medical device adverse event reporting for healthcare facilities, inclusive of public and private hospitals. However, mandatory reporting is restricted to adverse events relating to devices deemed to be of high potential harm to public safety (i.e., those classified as Class III, AIMDs or Class 4 IVD medical devices)

Additionally, Option 2 presents two sub-options:

- Option 2A – reporting medical device adverse events in batch; and
- Option 2B – reporting medical device adverse events on occurrence.

Benefits

The key benefit of Option 2 (both 2A and 2B) is that they would support earlier identification of, and response to, emerging medical device issues. This would enable the TGA to:

- obtain a more rapid estimation of the frequency and severity of safety problems associated with particular medical devices
- understand whether a broader range of safety or performance events with specific medical devices have occurred (that may not be known or reported by medical device sponsors or manufacturers)
- detect rarer events / weaker signals based upon more complete reporting
- inform consumers and health professionals about emerging areas of concern to enable earlier action.

More broadly, they would:

- reduce impost of reporting for individual healthcare professionals
- support more informed procurement decisions made by healthcare facilities, professionals and consumers.

While benefits of the proposed regulatory changes are those relating to patient and medical practitioner safety, detecting these early signals are crucial in minimising the risk of medical device defects, which will in turn lower sponsors' and manufacturers' financial exposure to legal proceedings of faulty products. Therefore, the costs in rectification will be reduced across the lifecycle of a medical device. This benefit is explored in further detail through the case studies below and is further explained in Appendix A.

Case Study – Urogynaecological Mesh

Urogynaecological mesh is used to treat Stress Urinary Incontinence and Pelvic Organ Prolapse, by providing additional structural support to the surrounding organs. In most cases, this surgical procedure was successful, however many patients experienced an array of complications. Due to mesh migration and erosion, many women experienced differing levels of discomfort. Patients experienced an array of symptoms including nerve damage, painful sexual intercourse and chronic pain. The first reported event was in 2006 and by 2012, a class action was filed against Johnson & Johnson, and its subsidiary Ethicon, which resulted in a settlement sum of \$300 million. This is the largest settlement in a product liability class action in Australian history.

Case Study – Metal-on-metal Hip Prostheses

Metal-on-metal hip prostheses were developed as an alternative to traditional hip replacements, which typically use materials like ceramics or plastic, in order to be more durable. In the early 2000's, reports of implant failure, metallosis, pseudotumours and osteolysis began to emerge. Patients reported various degrees of pain in the hip, groin and/or thigh area. The same area was often inflamed, patients experience limited mobility and some reported loosening of the implant. Some experienced implant failure and required revision surgery, however the most severe cases included the diagnosis of metallosis which caused tissue damage, inflammation and pseudotumours. An Australian class action was launched in 2011 against pharmaceutical distributor Johnson & Johnson and manufacturer DePuy International Ltd, which included a 17-week trial in the Federal Court of Australia. In 2016, the Federal Court of Australia approved the settlement of the DePuy ASR Hip Implant Class Action for \$250 million plus interest and legal costs.

Costs

The success of these options would see an increase in the volume of medical device adverse event reports. This in turn, would likely result in an increased expenditure of resources in relation to undertaking the reporting, assessing incoming reports, as well as response activities.⁷³ These impacts will be felt across both healthcare facilities and medical device sponsors and manufacturers.

Businesses

Healthcare Facilities

Public⁷⁴ and private hospitals will now be required to report adverse events relating to medical devices directly to the TGA (either on occurrence, or via batch reporting). This will impose additional pressure on existing resources in the form of:

- increased reporting data fields
- increased frequency of submission to the TGA⁷⁵
- upskilling via guidance material on the TGA's reporting requirements.

The current reporting practices among healthcare facilities vary widely, depending on their size, resources and existing systems for incident management and data collection. Larger facilities often

⁷³ Developing, triaging, assessing, escalating and responding to adverse event reports within local incident management systems is already part of BAU for the prescribed populations. Noting this, the implementation of mandatory reporting will need to consider what resources are required, in and above current BAU processes, to adhere to the mandated reporting requirements.

⁷⁴ While the costs and benefits for businesses (i.e., healthcare facilities) have been described for both public and private hospitals, they will be excluded for the purposes of the regulatory burden estimate as it falls under government-to-government regulation.

⁷⁵ The TGA expects implementation of mandatory reporting to correspond with an increase in frequency of reporting to the TGA by medical facilities. However, this is not estimated to be a significant increase as many entities will already be reporting to their respective jurisdictional health department, thereby exempting themselves from reporting to the TGA.

have more sophisticated systems in place that can be adapted to meet new requirements with relative ease. In contrast, smaller facilities may rely on manual or less integrated systems, which could require significant upgrades or additional resources to comply. While this does impose additional strain on existing resources, the population (i.e., public and private hospitals) were chosen initially as they were deemed to have the requisite resources, systems and processes in place to support mandatory reporting most easily. During stakeholder consultation, it was recognised that a one-size-fits-all approach to reporting could disproportionately impact smaller facilities. To address this, multiple reporting channels including online forms, email or portal will be offered initially to accommodate facilities with varying levels of digital maturity. Additionally, the TGA intends to adopt a staged approach to implementation and this approach is designed to leverage existing systems and processes wherever possible, thereby reducing the burden on healthcare facilities. It also provides leeway for facilities to transition into the scheme in a manner that aligns with their operational capabilities, ensuring the scheme's implementation is efficient and equitable.

Medical Device Sponsors and Manufacturers

While the proposed regulatory options do not alter sponsors' / manufacturers' mandatory reporting requirements for medical device adverse events, any regulatory changes that impact the volume of medical device adverse event reporting will likely have downstream impacts. For example, the increased requirement to aid compliance/regulatory activities (i.e., participation in external investigations and/or running of internal investigations), and possibly an increased volume of:

- product recalls
- product defect corrections
- product hazard alerts
- product defect alerts
- product suspensions
- product cancellations
- manufacturing process improvements
- quality system process improvements

However, while these changes will have a significant impact on medical device sponsors and manufacturers, it is important to note that OIA guidance (the Regulatory Burden Measurement Framework) excludes non-compliance and enforcement costs imposed on the regulated community. In the context of this impact analysis, the regulated community refers to healthcare facilities rather than industry entities such as sponsors and manufacturers. As a result, the costs associated with non-compliance and enforcement actions are not factored into the analysis. Quantifying these costs also presents challenges due to the variability of circumstances under which such actions occur and the lack of consistent and comprehensive data in this area.

Of most relevance to this policy option:

- costs such as fines for failing to comply with a policy and legal fees, including costs incurred in court and tribunal processes
- costs that arise when businesses or individuals fail to comply with government requirements and action is necessary by the business or individual/s to ensure compliance.⁷⁶

Contextualised to the introduction of mandatory medical device adverse event reporting; if reporting and subsequently, an investigation, indicates a potential safety issue with a medical device, this could

⁷⁶ In line with the OIA's Regulatory Burden Measurement Framework, accessible at: <https://oia.pmc.gov.au/sites/default/files/2024-02/regulatory-burden-measurement-framework.pdf>

indicate non-compliance with a range of medical device sponsor and manufacturer legal obligations (described in the *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990*, and *Therapeutic Goods (Medical Devices) Regulations 2002*). For example, non-compliance with:

- Essential Principles
- conditions of inclusion (COI)
- conformity assessment procedures (CAP).

This cost, while noted as significant, will therefore be excluded from the regulatory burden estimates.

General Public

In considering the costs borne by these businesses, the potential for these costs to be passed on to consumers must be noted. These flow-on costs are relevant to each policy option and could include:

- **Higher Healthcare Fees:** Healthcare facilities might increase their service fees to cover the additional administrative and operational expenses.
- **Increased Insurance Premiums:** If mandatory reporting reveals a higher number of incidents than previously recognised, insurers might adjust premium upwards to account for these elevated risks. Medical indemnity insurers facing higher costs due to more claims and increased reporting might pass these costs onto healthcare facilities, which in turn might lead to higher health insurance premiums for consumers.
- **Higher Out-of-Pocket Expenses:** Patients might face increased out-of-pocket expenses for medical procedures and treatments as healthcare providers adjust their pricing to cover the new reporting requirements.
- **Indirect Costs:** There might be indirect costs such as longer wait times for medical procedures as facilities manage the increased administrative workload, which could affect the overall quality of patient care.

Government

Therapeutic Goods Administration

Whilst no funding has been allocated to support the rollout of the scheme at this stage, it is expected that the new regulations will impose significant resourcing costs on the TGA. Namely, in the volume of monitoring, compliance and response activities needing to be undertaken. It is assumed that should the volume of reporting increase (estimated to be 10x current reporting⁷⁷), ostensibly, the volume of the following activities would also increase:

- reporting triage and assessment
- regulatory actions e.g., notices for:
 - product recalls
 - product defect corrections
 - product hazard alerts
 - product defect alerts
 - product suspensions
 - product cancellations

⁷⁷ Evidence and logic for estimation is outlined at Appendix B.

-
- manufacturing process improvements
 - quality system process improvements.

The predicted costs to the TGA remain the same across Options 2 – 4, noting they will increase proportionate to the volume of reports being submitted (i.e., as the scope, and estimated reporting volume increases across options, so will the costs to the TGA).

In addition to the IT enhancements and associated costs, there will be operational expenses related to recruitment and training of staff members to manage the expected influx of new incident reports and investigations.

If no upgrades or enhancements to the TGA's IT systems are implemented, and staffing is increased to manage the additional influx of reports, the estimated staffing cost will range from \$1.5m to \$4.4m (under a 3 factor increase in reporting) per annum to \$15.8m (under a 10 factor increase in reporting) per annum.

OPTION 2A

5) reporting in batch

In addition to the benefits and costs outlined in the Option 2 summary section above, Option 2A, utilising batch reporting, has the following additional benefits and costs (in contrast to 2B):

- **Benefits**
 - lower resource impost on healthcare facilities due to the likely lower reporting frequency in comparison to on occurrence reporting. This is of particular benefit to larger public and private hospitals who are likely to experience a higher volume of reports, and thus benefit more from the introduction of batch reporting
 - potential utility of an API as a future option in transferring reporting data from health facilities to the TGA could be a further benefit in the form of increased efficiencies.
- **Costs**
 - potential for a larger time delay in identifying weak signals for medical devices that may pose a potential health risk to health practitioners or patients (noting that the imposition of a monthly cadence to batch reporting, in combination with the ability to directly report to the TGA through other avenues if deemed necessary, largely mitigates this risk).

OPTION 2B

6) reporting on occurrence

In addition to the benefits and costs outlined in the Option 2 summary above, Option 2B, utilising on occurrence reporting, has the following additional benefits and costs (in contrast to 2A):

- **Benefits**
 - more timely reporting of serious medical device adverse events to the TGA, which in turn leads to increased capability for the TGA to identify, in a timelier manner, signals relating to medical devices with potential health risks.
- **Costs**

-
- increased impost on the regulated community, which will disproportionately affect those healthcare facilities that have either, relative high volumes of patients/procedures, or relative low staffing resources to support mandatory reporting.

Regulatory burden measurement framework

Total annualised over a 10-year period, it is estimated that:

OPTION 2A

Average cost per year for all private healthcare facilities (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$1.19 million.

OPTION 2B

Average cost per year for all private healthcare facilities (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$1.20 million.

Regulatory burdens for both Option 2A and 2B, although likely to have flow on impacts to medical device manufacturers and sponsors, primarily effects healthcare facilities. Although impacting both public and private hospitals, for the purposes of the regulatory burden estimate, the figure above represents the average annual cost to private healthcare facilities.⁷⁸ It is expected that the first-year costs will be higher, the main drivers for this being the likely system improvements required to facilitate the expedient transfer of medical device adverse event reports from local incident management systems to the TGA.

Further detail on the costs and benefits, the likely regulatory burden, and the key assumptions and inputs can be found at Appendix A and Appendix B respectively.

⁷⁸ Public healthcare facility costs are excluded as they fall under government-to-government regulation. Which includes all regulation imposed by the Commonwealth on Australian Government, state and territory government, local government and foreign government departments or agencies, and all of their employees where regulation is imposed on them as part of their employment.

3

Option 3 – Public and Private hospitals report adverse events relating to medium and high risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign
- 7) expand scope of 'reportable medical devices' to include Class IIa and IIb medical devices and Class 3 IVDs

OPTION 3A

- 5) reporting in batch

OPTION 3B

- 6) reporting on occurrence

Option 3 seeks to mandate medical device adverse event reporting for healthcare facilities, inclusive of public and private hospitals. However, mandatory reporting would be expanded to include devices deemed to be of medium risk of potential harm to public safety (i.e., those classified as Class IIa, Class IIb, Class III, AIMDs, Class 3 and Class 4 IVD medical devices).

Additionally, Option 3 presents two sub-options:

- Option 3A – reporting medical device adverse events in batch
- Option 3B – reporting medical device adverse events on occurrence.

Benefits

The key differentiator for Option 3 (both 3A and 3B), is the expansion in scope of reportable medical devices prescribed by the regulations. Namely, the addition of Class IIa, Class IIb and Class 3 IVDs. In addition to the benefits described in Option 2, the key benefit of this option is improved coverage of medical devices deemed to be of medium to high potential risk to safety.

By increasing the scope of medical devices to be reported against, it is appropriate to assume this will result in increased volumes of medical device adverse event reporting (in and above the volumes expected of Options 1, 2A and 2B). This, in turn, will improve the TGA's capability to detect and respond to weak signals that may indicate a medical device that poses a safety risk.

This therefore would have some tangential flow on effects on the medical device manufacturers and sponsors. Namely, the reduced likelihood of serious adverse public health events that could result in legal action or significant costs for the medical device manufacturers and sponsors (e.g., surgical mesh case).

Costs

The costs outlined in Option 2 also apply to Option 3, however, the broadening of classes prescribed as reportable medical devices under the regulations, as noted, will further increase the volume of mandatory reports. This has a range of flow on impacts on both healthcare facilities and medical device sponsors and manufacturers.

Businesses

Healthcare Facilities

- increased resources required by healthcare facilities to support the reporting of medical device adverse events, such as:
 - training of staff
 - changes to internal systems of work

-
- increased full-time equivalent (FTE) required to undertake completion, review, compilation and submission of reports
 - changes to information technology systems.

Medical Device Sponsors and Manufacturers

- increased resources expended by medical device sponsors and/or manufacturers in investigating, responding to and addressing any outcomes of adverse event reporting (noting that the monetary cost of this is to be excluded for the purposes of this regulatory burden estimate).

Regulatory burden measurement framework

Total annualised over a 10-year period, it is estimated that:

OPTION 3A

Average cost per year for all private healthcare facilities (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$1.62 million.

OPTION 3B

Average cost per year for all private healthcare facilities (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$1.67 million.

Regulatory burdens for both Option 3A and 3B, although likely to have flow on impacts to medical device manufacturers and sponsors, primarily affects healthcare facilities. Although impacting both public and private hospitals, for the purposes of the regulatory burden estimate, the figure above represents the average annual cost to private healthcare facilities. It is expected that the first-year costs will be higher, the main drivers for this being the likely system improvements required to facilitate the expedient transfer of medical device adverse event reports from local incident management systems to the TGA.

Both Option 3A and 3B represent an increase in regulatory burden cost on the reporting population. The cause of this relates to the expanded scope of reportable medical devices to include Classes IIa, IIb and III and Class 3 IVDs.

Further detail on the costs and benefits, the likely regulatory burden, and the key assumptions and inputs can be found at Appendix A and Appendix B respectively.

4

Option 4 – Public and Private hospitals and approved Residential Aged Care facilities (excluding MPS facilities) are to report adverse events relating to medium and high risk medical devices

Measures:

- 1) impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)
- 2) prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'
- 3) introduction of additional reporting fields relating to medical devices
- 4) awareness / communication campaign
- 5) reporting in batch
- 7) expand scope of 'reportable medical devices' to include Class IIa and IIb medical devices and Class 3 IVDs
- 8) expand mandatory reporting of medical device adverse events to include approved Residential Aged Care Facilities (excluding MPS facilities)

Option 4 will see further expansion to the scope of regulation imposed on healthcare facilities through a broadening of the population mandated to report on medical device adverse events. This is proposed to be achieved through the addition of approved residential aged care facilities (excluding MPS facilities).

Additionally, Option 4 presents two sub-options:

- Option 4A – reporting medical device adverse events in batch
- Option 4B – reporting medical device adverse events on occurrence.

Benefits

The key benefit associated with this addition, is:

- increased access to reporting data related to medical device adverse events.

This option would see the number of healthcare facilities mandated to report medical device adverse events increase from 1,324 to 3,964 (representing an increase of 2,640 healthcare facilities or approximately ~200%). Similar to the expansion in scope to what is deemed an 'approved medical device', the extension of mandatory reporting to approved residential aged care facilities will likely facilitate an increase in volume of reporting to the TGA. It is likely that increased access to relevant data will support, in and above all other options, the timely identification of medical devices with potential safety issues.

Costs

In addition to the costs described in the preceding policy options, Option 4 further increases the regulatory burden on both healthcare facilities and medical device sponsors and manufacturers.

Businesses

Healthcare Facilities

- highest level of resources expended completing, compiling, reviewing and submitting adverse event reports
- disproportionate impact on aged care facilities that do not have the requisite local incident management systems capability to facilitate efficient transfer/submission of medical device adverse event reports.

Medical Device Sponsors and Manufacturers

- highest expenditure of resources (of the options presented) by medical device sponsors and/or manufacturers in investigating, responding to and addressing any outcomes of adverse event reporting (noting that the monetary cost of this is to be excluded for the purposes of this regulatory burden estimate).

While previous options have seen marginal increases in the resources expended to adhere to the proposed regulations, Option 4 would see a more significant increase.

Regulatory burden measurement framework

Total annualised over a 10-year period:

OPTION 4A

Average cost per year for all private healthcare facilities and residential aged care facilities (excluding MPS facilities) (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$5.56 million.

OPTION 4B

Average cost per year for all private healthcare facilities and residential aged care facilities (excluding MPS facilities) (businesses) combined over the default ten-year period under regulatory burden framework measurement is \$5.61 million.

Regulatory burdens for both Options 4A and 4B, although likely to have flow on impacts to medical device manufacturers and sponsors, primarily affects healthcare facilities and residential aged care facilities. Although impacting both public and private hospitals, for the purposes of the regulatory burden estimate, the figure above represents the average annual cost to private healthcare facilities and residential aged care facilities (excluding MPS facilities). It is expected that the first-year costs will be significantly higher, the main drivers for this being the likely system improvements required to facilitate the expedient transfer of medical device adverse event reports from local incident management systems to the TGA.

Beyond the costs and benefits detailed in Options 3A and 3B, the reasoning behind the significant increase in regulatory cost can be attributed to the large increase in reporting population (almost doubling). This results in a significant increase in one-off technological upgrade costs to local incident management systems.

Further detail on the costs and benefits, the likely regulatory burden, and the key assumptions and inputs can be found at Appendix A and Appendix B respectively.

Question Five: Who did you consult with and how was this consultation conducted?

Consultations and Engagement

A wide range of stakeholders have been consulted as part of our engagement process including, jurisdictions, public hospitals, private and day hospitals, the Australian Commission on Safety and Quality in Health Care, Royal Australasian College of Medical Administrators, Australian Medical Association, medical device sponsors and manufacturers

Independent Senate Community Affairs References Committee

On 15 February 2017, an independent Senate Community Affairs References Committee conducted an Inquiry into the *Number of women in Australia who have had transvaginal mesh implants and related matters* and the serious and long-standing impacts reported by women following mesh related procedures. A total of 555 submissions were received which resulted in five public hearings taking place between August 2017 to February 2018 and evidence provided by 184 witnesses. The Inquiry highlighted limited awareness amongst consumers and healthcare practitioners about adverse event reporting to the TGA and debilitating effects on patient safety when a medical device adverse event is not detected in a timely manner.⁷⁹

Preliminary Public Consultations

The Review of Medicines and Medical Devices Regulation (MMDR) that was undertaken in 2014-15, included several recommendations to enhance the post-market surveillance and regulation of medical devices. The review recommended improving post market monitoring of medical devices by implementing more robust data collection and analysis systems and improving the integration of the data sets to enhance monitoring. The review also proposed improvements to the adverse event reporting system for medical devices to make it more user friendly, and to assist healthcare professionals, patients, sponsors and manufacturers to report issues consistently and accurately. The TGA introduced a range of medical device reforms to implement the recommendations of the MMDR review. These included reforms to enhance post market surveillance with better integration and analysis of available datasets for adverse events and device performance.

Amongst the measures to support this were updates to its online medical device adverse event reporting forms for consumers, health professionals and sponsors in 2019, to streamline the process and facilitate reporting.⁸⁰ The TGA conducted a preliminary consultation process in 2020 which sought public feedback on a number of proposed enhancements to medical device adverse event reporting. The options provided on regulatory amendments were intended to improve the reporting, analysis, and communication of medical device adverse events and near adverse events. The proposed enhancements to adverse event reporting and related activities included:

⁷⁹ https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Public_Hearings

⁸⁰ <https://www.tga.gov.au/medical-devices-reforms-enhancements-post-market-monitoring>

- Proposal 1 — make changes to the current adverse event reporting exemptions
- Proposal 2 — strengthen reporting requirements for medical device adverse events
- Proposal 3 — implement a program of TGA inspections and audits of sponsor activities and premises to validate how they conduct their post market surveillance obligations
- Proposal 4 — review post-market definitions in the Medical Device Regulations
- Proposal 5 — find ways to enhance communication between the TGA and the consumers of medical devices

On 18 October 2021, the TGA released a public consultation paper titled *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia*.⁸¹ In addition, targeted consultations with Australian stakeholders, including representatives from each state and territory departments of health, the Commission, and a range of private healthcare organisations and peak bodies, and some OECD countries, were held to explore the potential benefits and limitations of mandatory reporting for adverse events related to medical devices.

Countries such as the USA, and more recently Canada, have made it mandatory for healthcare facilities to report suspicious events that may be caused by a medical device. These mandates are considered to:

- increase the potential quality of reporting to the regulator, particularly information relating to specific medical devices that may otherwise be unavailable to individual health care professionals at the time of incident notification
- provide greater flexibility for the healthcare facilities to adequately assign resources to report against adverse medical devices
- be less burdensome than requiring individual health practitioners to report against adverse medical devices.

Consultation

With the aim to improve the quality and timeliness of monitoring the safety and performance of medical devices, issues and approaches to mandatory reporting were explored by key state and territory representatives, industry, consumers and health care (including healthcare organisations, CRAFT groups, healthcare practitioners and health funds) in *Potential for Mandatory Reporting of Medical Devices Adverse Events by Healthcare Facilities in Australia*. The consultation paper presented the broad level of support for expanding the list of entities required to report adverse events of medical devices and acknowledged existing jurisdictional data collection and reporting systems need to be developed to make better use of the data and minimise unnecessary regulatory cost.

The consultation paper sought broader feedback on the potential benefits and challenges of implementing mandatory reporting of medical device related adverse events by healthcare facilities in Australia. The consultation paper was published on the TGA website and the TGA Consultation Hub, on 18 October 2021, closing on 13 December 2021; with a number of late email submissions after this date.

There were 56 submissions to the consultation paper:

- 39 via the TGA's Consultation Hub; and

⁸¹ TGA, Potential for mandatory reporting of medical device adverse events by healthcare facilities: discussion paper, available at: https://consultations.tga.gov.au/tga/potential-for-mandatory-reporting-of-medical-device/supporting_documents/Discussion%20paper%20Potential%20for%20Mandatory%20Reporting%20of%20Medical%20Device%20Adverse%20Events%20by%20Healthcare%20Facilities%20in%20Australia.pdf

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- 17 via direct email to the TGA.

For the purpose of this analysis, respondents were divided into four main categories:

1. Consumers (including consumer groups and individual consumers)
2. Industry (including peak industry bodies and individual sponsors)
3. Healthcare (including healthcare organisations, CRAFT groups (a group of specialty medical accredited practitioners who provide oversight of clinical governance), state and territory governments, healthcare practitioners and health funds) and the Therapeutic Goods Administration
4. Unknown (two respondents provided insufficient information to allow us to determine whether the respondent was an individual or other entity, and which sector, if any, they belonged to).

Responses were received as follows:

- Healthcare (25 respondents, 44%)
- Industry (16 respondents, 29%)
- Consumers (13 respondents, 23%)
- Unknown (2 respondents, 4%)

Almost three quarters of respondents to the consultation paper (n=56) expressed broad support for the introduction of mandatory reporting for *all* healthcare facilities in Australia. Some stakeholders also expressed an opinion that the mandatory reporting for healthcare facilities was long overdue and does not currently support the early identification of emerging safety and performance issues.⁸² While the majority (73%) of respondents were in favour of the inclusion of all healthcare facilities, some (9%) raised concerns about smaller facilities, such as general practices and residential aged care facilities, due to them potentially lacking the capacity to undertake mandatory reporting.

The consultation revealed strong consumer support for mandatory reporting in healthcare facilities, who emphasised the need for a comprehensive approach to patient safety, including improved data collection through enhanced adverse event reporting. Among the respondents opposed to mandatory reporting, the majority were from industry who expressed concerns around the potential burden and cost on staff, data duplication and quality issues, and the lack of existing feedback systems and additional efforts needed on education and awareness. Support for mandatory reporting was indicated by the Commission, Australian Medical Association and the Australian Private Hospitals Association, while state and territory health departments had mixed views, with three out of the five who responded were in favour. Some other concerns were also raised in relation to submission of duplicate reports by both the healthcare facility and the sponsor. However, the TGA already has processes and controls in place to identify duplicate reports and reconcile the overall reporting data so that the number of adverse events associated with a device are not artificially inflated.

Feedback from stakeholders highlighted concerns about the potential burden and administrative costs associated with requiring individual practitioners to report adverse events. The Government noted the reporting systems were already in place at healthcare facilities and considered that it was more appropriate for these facilities to report adverse events to the TGA, especially since patients are more likely to present at hospitals in the event of serious adverse events. The reporting burden and financial costs including training, systems development and ongoing monitoring by individual practitioners is reduced by centralising reporting at the facility level. Healthcare facilities typically have centralised systems and more streamlined processes for data collection and management, enabling adverse event data to be consolidated and managed more efficiently.

⁸² Therapeutic Goods Administration, *Discussion paper feedback – Analysis Report – Potential for Mandatory Reporting by Medical Device Adverse Events by Healthcare Facilities in Australia*, February 2022, p.5 (not publicly released).

The Commission supported mandatory reporting, indicating their willingness to take a leadership role in working with the TGA and other stakeholders to incorporate mandatory reporting within the existing frameworks for hospital quality assurance and accreditation processes thus minimising any additional regulatory burden. During roundtable discussions, healthcare facilities expressed their support to the suggestion to incorporate the reporting of adverse events to NSQHS Standards. The suggestion to use NSQHS Standards as a compliance mechanism, proposed by the Commission, aligns with industry best practices and regulatory frameworks in other jurisdictions. The NSQHS Standards provide clear guidelines and benchmarks for healthcare facilities to follow, ensuring consistency and quality in adverse event reporting practices. By incorporating mandatory reporting requirements into existing standards and providing guidance on the Commission's website, healthcare facilities can integrate reporting seamlessly into their quality assurance processes.

During consultations stakeholders emphasised the importance of ensuring data integrity and integration into existing systems. Effective integration of adverse event reporting mechanisms with healthcare facilities' existing processes and information systems is crucial for accurate and timely reporting. Health care facilities might also be able to leverage existing sentinel event reporting systems with the goal of minimising administrative burden and leveraging existing infrastructure.

Focusing on high and medium-risk devices allows for a targeted approach to mandatory reporting, prioritising resources and efforts where they are most needed. These devices often pose greater potential for adverse events, making them a priority for enhanced monitoring and reporting. Stakeholders expressed concerns that the current under reporting of adverse events hampers the early identification of medical device safety and performance issues. By prioritising medium and high-risk devices, mandatory reporting could focus resources on adverse events that are most likely to have significant clinical and regulatory implications. While most stakeholders supported mandatory reporting, their concerns about implementation and resource allocation highlight the importance of a phased and targeted approach. Starting with medium and high-risk devices provides a manageable pathway for facilities to adapt, creating a foundation for broader implementation in future, if necessary.

Regulations Development and Implementation

Round Tables

To support the development of fit-for-purpose, implementable regulations, the TGA have held a number of Round Tables with key stakeholders from across the country (e.g., jurisdictional health departments, the Commission and private and day hospital representatives). The roundtables sought to stimulate discussion and elicit issues and concerns that may not have been anticipated across the breadth of representative stakeholders and to identify gaps in information and where further work needs to be undertaken. The intent was to identify next steps and "road test" for relevance, practicality, acceptability, feasibility for implementation and assess the level of support from stakeholders. The themes of these round tables have included:

- Round table 1: Introduction to Mandatory Reporting
- Round table 2: National Standards to Support Mandatory Reporting of Medical Device Adverse Events
- Round table 3: Data Fields for Mandatory Reporting
- Round table 4: Instruments to Support Mandatory Reporting
- Round table 5: Analysis and Feedback from Mandatory Reporting
- Round table 6: Data Transfer Requirements

These roundtables are further supported by an interjurisdictional steering committee, established by the TGA to continue the engagement and consultation. The interjurisdictional steering committee has representation from all states and territory health departments, private and day hospitals and hospital peak bodies and specialist organisations such as the Royal Australasian College of Medical

Administrators and Australian Medical Association. The interjurisdictional steering committee's main objective is to formulate effective implementation strategies for the mandatory reporting framework.

Development of the options outlined in the IA was deeply informed by stakeholder engagement through roundtables in 2023 and jurisdictional steering committee meetings in 2024. The roundtables were attended by representatives from all states and territories, private hospitals, day hospitals, peak body organisations such as the Australian Private Hospitals Association, Day Hospitals Australia, and the Commission. To maintain ongoing engagement and consultation, an interjurisdictional steering committee was established comprising of the roundtable representatives along with additional members from the Australian Medical Association, and the Royal Australasian College of Medical Administrators. An additional technical working group was also formed comprising of data and security representatives from the same organisations involved in the steering committee to specifically consult on the technology landscape and to assess system readiness to identify and develop workable solutions. These discussions were instrumental in refining a framework that balances patient safety with practical implementation considerations for healthcare facilities and jurisdictions.

Focus on Medium- and High-Risk Devices: Stakeholders have consistently emphasised the importance of leveraging existing reporting systems and procedures. During consultations they also stressed the importance of maintaining a risk-based focus for the scheme. Medium to high-risk devices are associated with the greatest potential for serious adverse events, making them a logical starting point to maximise safety outcomes while managing implementation complexity.

Staged Implementation: During consultations and based on the TGA's analysis of data from jurisdictions, it became evident that healthcare facilities generally record incidents involving deaths and serious injuries consistently. However, capturing near misses and treatment related issues presents challenges due to variability across jurisdictions in how these incidents are rated and categorised. To address this, a phased approach has been designed, with reporting requirements for near misses and treatment-related incidents scheduled for introduction in the later stages of the reporting timeline. Additionally, a 12 month transition phase will allow time to build awareness, improve education, and allow for necessary upgrades in processes and systems.

Data Fields, Format, and Intervals: Extensive discussions during the roundtables and steering committee meetings focused on the specific data fields required for reporting, the format of submissions, and appropriate time intervals. This was vital to ensuring the framework aligns with existing workflows and minimises duplication while maintaining data integrity.

IT Landscape and System Readiness: A significant focus of stakeholder discussions was understanding the IT systems currently used by jurisdictions, private hospitals, and day hospitals for incident management. Stakeholders provided critical insights into the capabilities and limitations of their existing systems, any planned upgrades, and their readiness to transition to mandatory reporting. To accommodate varying levels of technical preparedness, a level of flexibility has been incorporated within the implementation stages. During the initial phases, multiple channels for reporting will be maintained, including email, online portal. This multi-channel approach ensures that all stakeholders, regardless of their IT infrastructure maturity, can participate in the reporting process. It will also provide time for facilities to upgrade their systems while ensuring continuity in reporting critical incidents. This phased and inclusive approach reflects stakeholder feedback, emphasising the need for adaptability while progressing toward a unified and efficient reporting framework.

Time and Resources for Reporting: Stakeholders consistently emphasised the significant time and resources required to capture the additional data needed for mandatory reporting. During consultations, participants detailed the effort hours involved in reporting, the internal review processes necessary to ensure accuracy, and the alignment required with existing regulatory frameworks. The assumptions for effort hours in the costings were directly informed by these stakeholder discussions.

Data Privacy and Legislative Compliance: A key focus was integrating data privacy and data-sharing obligations under state, territory, and Commonwealth legislation into the design of the mandatory reporting scheme. Patient consent was also a key consideration in discussions with healthcare facilities. Feedback indicates that healthcare facilities already have established arrangements for

sharing de-identified patient data under circumstances that require it, such as reporting adverse events. These practices help address privacy concerns while ensuring that essential safety data can be collected and analysed without compromising patient confidentiality. Stakeholders also stressed the need for stringent compliance with privacy laws while facilitating efficient data reporting. To address these concerns, the proposed data fields are designed to minimise the use of free-text responses, relying instead on structured, predefined fields. This reduces variability and ensures consistency while maintaining compliance with privacy laws. Furthermore, the reporting scheme only requires deidentified data; no patient details are requested. This approach aligns with jurisdictional privacy laws, safeguarding sensitive information while enabling effective regulatory oversight.

In addition, the TGA has also engaged with industry stakeholders through the Regulatory and Technical Consultative Forum for medical devices⁸³ to provide updates and raise awareness about the new reporting requirements. This collaboration is essential to enable coordination between hospitals and sponsors to conduct investigations and implement corrective actions,

A Government response was drafted after discussions with state and territory health departments, private and day hospitals, the Commission, hospital peak bodies, and professional groups such as the Royal Australasian College of Medical Administrators and the Australian Medical Association on the preferred option (Option 3A) to introduce mandatory reporting in healthcare facilities.

Despite the overall support for mandatory reporting, some limitations and barriers were identified during consultations. These included concerns about the capacity of smaller healthcare facilities to manage additional administrative requirements, potential duplication of reporting efforts, and the need for additional resources and training to support compliance with reporting standards. Striking a balance between regulatory compliance and operational priorities at the hospitals is a key challenge for healthcare facilities. Private healthcare facilities operating across different jurisdictions raised concerns about the inconsistencies across different jurisdictions. Divergent regulatory standards and reporting processes can create challenges leading to operational inefficiencies.

Stakeholders have raised that adverse events reported directly to health professionals or doctors often remain siloed, with limited mechanisms for ensuring that such reports are communicated to healthcare facilities or centralized reporting systems. The lack of an integrated reporting framework limits the ability to share essential safety data among stakeholders, including health professionals, health care facilities, sponsors and regulatory bodies. By integrating complementary initiatives, such as Unique Device Identification (UDI) and leveraging the Australian Digital Health Agency's infrastructure to store and share adverse event information in My Health Records, the proposed mandatory reporting framework could bridge the gaps in data interoperability and create a more robust and effective mechanism for monitoring medical device safety.

A limitation of the consultation process is that not all private and day hospitals were directly engaged. This also meant that a comprehensive review of all hospital incident reporting systems could not be conducted to fully understand their capabilities in terms of data transfer, quality control, and interoperability. Our outreach efforts included consultations with the relevant hospital peak bodies, publishing information on our website, and engaging extensively with those involved in the steering committee and sending consultation updates to private hospital networks who chose not to participate in the steering committee. Moving forward, it will be important for healthcare facilities to assess and ensure their systems are equipped to support data transfer requirements when the scheme is implemented, with the TGA providing guidance and support where needed.

Extensive consultation and strong ongoing collaboration will assist in identifying ways for the practical implementation of the reporting scheme.

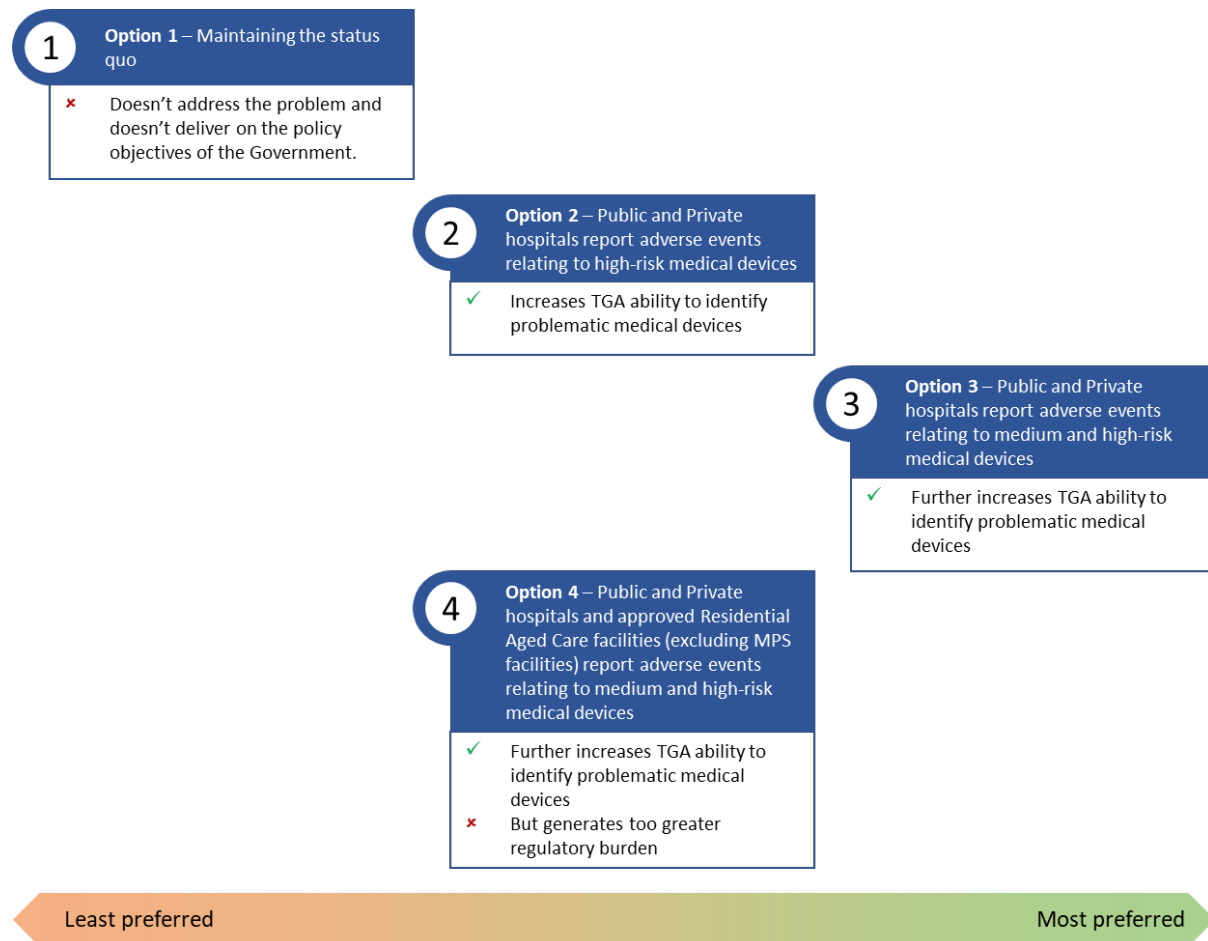
⁸³ <https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/regulatory-and-technical-consultative-forum-medical-devices-regtech-forum>

Question Six: What is the best option from those you have considered and how will it be implemented?

Preferred Option

Option 3A is considered the preferred option, expected to provide the greatest balance between achievement of policy objectives (through data driven signal detection) and regulatory burden on the populations prescribed.

Figure 13 - Summary of options analysis



Option 1, maintaining the status quo doesn't address the public health problem and doesn't meet the policy objectives of the Government. It doesn't address the core objective of strengthening patient safety and post-market monitoring of medical devices. Medical device adverse events would continue to be underreported, thereby not improving the TGA's ability to detect emerging signals relating to medical devices that pose a potential health risk. The absence of an additional regulatory burden is not a reasonable basis for supporting the status quo. Consequently, this option should not be considered any further.

Option 2A, public and private hospitals report adverse events relating to high-risk medical devices (namely Class III medical devices, AIMDs and Class 4 IVDs), **via batch reporting**, would likely improve TGA's current ability to identify weak signals relating to medical devices with potential safety issues/risks. However, it doesn't cover the medium – high risk medical devices (which accounts for a significant proportion of current reporting), and therefore does not adequately meet the government's policy objectives. Therefore, this option should not be considered.

Option 2B, public and private hospitals report adverse events relating to high-risk medical devices (namely, Class III medical devices, AIMDs and Class 4 IVDs), **on occurrence**, will also likely improve TGA's current ability to detect weak signals. However, as described above, this option also does not cover medium – high risk medical devices. In comparison to Option 2A (batch reporting), the on-occurrence reporting frequency proposed by Option 2B will provide timelier access to key information, however it will likely impose a higher regulatory burden on the reporting population. While having some merits, this option should not be considered.

Option 3A, public and private hospitals report adverse events relating to both medium and high-risk medical devices (expanding the scope to include Class IIa, Class IIb and Class III medical devices, AIMDs and Class 3 and 4 IVDs), **via batch reporting** will likely significantly improve the TGA's ability to detect weak signals, resulting in many positive patient and health practitioner health and safety outcomes. In comparison to the prior options (2A and 2B), Option 3B provides much greater coverage of medical devices considered medium – high risk, with the inclusion of Class IIa and IIb. The utilisation of batch reporting will minimise the additional regulatory burden placed on the reporting population. Option 3A provides the best balance between addressal of the policy objectives and regulatory burden placed on the reporting population and is therefore the preferred option.

Option 3B, public and private hospitals report adverse events relating to both medium and high-risk medical devices (expanding the scope to include Class IIa, Class IIb and Class III medical devices, AIMDs and Class 3 and 4 IVDs), **on occurrence**, will also significantly improve the TGA's ability to detect weak signals. The increased coverage of medical devices (i.e., the addition of Classes IIa and IIb and Class 3 IVDs), in combination with on occurrence reporting, will provide the TGA with the timeliest information relating to medical device adverse events of the other options proposed thus far. However, the proposed report submission frequency will impose a more significant regulatory burden on the reporting population, and disproportionately affect medical facilities with either limited resources, or much higher patient demand. While having significant benefits, this option has too great an impact on health facilities that are least able to manage the burden and the option should not be considered.

Option 4A, public and private hospitals and approved residential aged care facilities (excluding MPS facilities) **report adverse events relating to both medium and high-risk medical devices** (inclusive of Class IIa, Class IIb and Class III medical devices, AIMDs and Class 3 and 4 IVDs), **via batch reporting**, involves the significant broadening of the population (roughly 200% increase⁸⁴), namely, the inclusion of approved residential aged care facilities. This option will provide the TGA the greatest opportunity to improve their ability to detect weak signals, which would in turn lead to the best public health outcomes relating to patient and medical practitioner safety. However, this option also imposes the most significant regulatory burden on the reporting population. The existing incident management systems used in residential aged care facilities, current reporting practices and accreditation requirements need to be further explored and consulted to accurately gauge the data

⁸⁴ Eligible public and private hospitals account for 1,329 entities. The addition of residential aged care facilities will increase this number by 2,640 entities, representing roughly a 200% increase.

requirements and costing implications before proceeding with the implementation of this option. Further consultation with stakeholders in the aged care sector is necessary to tailor the reporting framework to the needs of this population. A comprehensive cost benefit analysis may also be required prior to the expansion of mandatory reporting requirements to residential aged care facilities.

Option 4B proposes that public and private hospitals and approved residential aged care facilities (excluding MPS facilities), **report adverse events related to both medium and high-risk medical devices** (including Class IIa, Class IIb, and Class III medical devices, AIMDs, and Class 3 and 4 IVDs), **on occurrence**. This option also significantly broadens the reporting population, approximately doubling its size. In comparison to Option 4A, the ability to report adverse events on occurrence will enable more timely provision of information to the TGA, enhancing their ability to detect weak signals and leading to the best public health outcomes and increased safety for patients and medical practitioners (in comparison to prior options). However, this approach imposes the most substantial regulatory burden on the reporting entities. The existing incident management systems used in residential aged care facilities, current reporting practices, and accreditation requirements need to be fully tested and consulted to understand the data requirements and costing implications before proceeding with implementation of this option. The significant increase in the reporting population would lead to heightened administrative and operational demands, specifically, on aged care facilities. Despite the potential for considerable public health benefits, a comprehensive evaluation of the financial and operational impacts is essential to understand the regulatory burden on these facilities for further consideration in future.

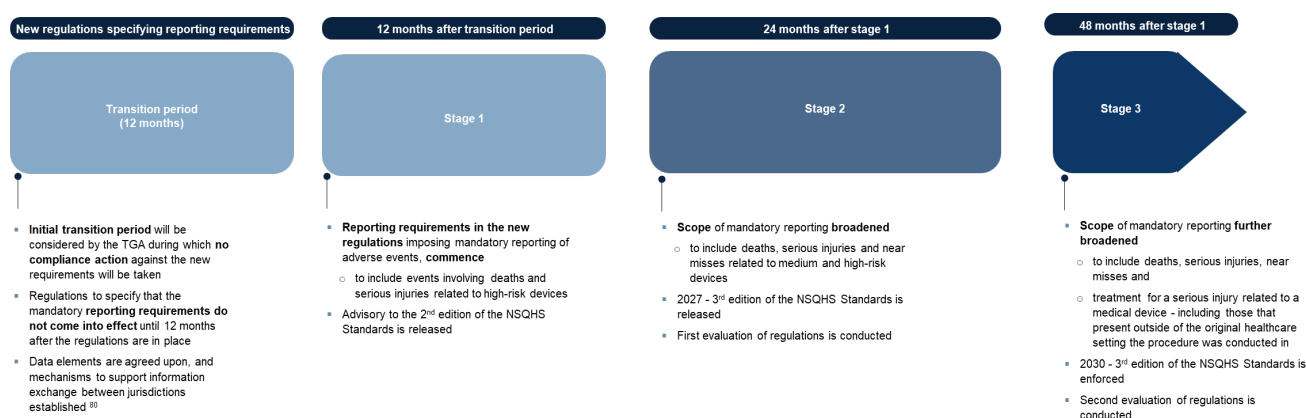
Implementation

Approach

An iterative approach to implementation will ensure that health care facilities will be prepared for mandatory reporting. The approach consists of four stages, progressively broadening the scope of events in which reporting is mandatory, implemented in line with the update and release of the NSQHS Standards.⁸⁵ The TGA will consider an initial 12-month transition period from the date of commencement of the scheme, during which no compliance actions against the new reporting requirements will be taken. This could be achieved by specifying in the regulations that the mandatory reporting requirements do not come into effect until 12 months after the commencement of the regulations. This period will provide an opportunity to identify potential challenges in data transfer, gather feedback, and make necessary adjustments to ensure smoother integration of reporting systems.

Staging

Figure 14 - Staged approach to the implementation of new regulations



Roles and Responsibilities

Introduction of New Regulations

The TGA and the Commission is responsible for the introduction and implementation of the *Therapeutic Goods Amendment (2022 Measures No. 1)* and updating the NSQHS Standards, respectively.

The implementation of the *Therapeutic Goods Amendment (2022 Measures No. 1)* will progress in stages to ensure stakeholder familiarity with reporting requirements, as well as adequate time to embed incident management system/process updates.

The Commission is responsible for the:

- publication of the NSQHS Standards Advisory Notice to give effect to the introduction of mandatory reporting
- development of the third edition of the NSQHS Standards which will incorporate any lessons learnt/issue encountered in complying with the second edition of the NSQHS Standards
- publication of the third edition of the NSQHS Standards which will outline reporting and incident management requirements that must be adhered to for accreditation.

⁸⁵ Data exchange is dependent on the development and implementation of IT upgrades at the TGA, jurisdictions and healthcare facilities.

Implementation of Supporting Systems and Processes

Private and public hospitals would be responsible for complying with the reporting requirements detailed in each stage, and ultimately, as determined in the *Therapeutic Goods Amendment (2022 Measures No. 1)*. These healthcare facilities will also be required to update and implement new reporting / incident management systems and process requirements to remain accredited to the NSQHS Standards.

Implementation of new regulations

As detailed earlier, the regulations imposing mandatory reporting of medical device adverse events by healthcare facilities are expected to be in place by 2025. An iterative/progressive rollout of mandatory reporting regulations will be taken to provide adequate time for:

- healthcare facilities to understand and embed systems and processes to support the new reporting requirements (i.e., develop and implement the required systems and processes to facilitate reporting of medical device adverse events to the TGA)
- medical practitioners and nurses to familiarise themselves with the particular situations within which medical device adverse event reporting is mandatory (i.e., death, serious injury and/or near misses).

It is proposed that implementation of the preferred option (Option 3A) will occur over four stages including an initial transition period.

Transition period – 12 months

The new regulations specifying the mandatory reporting requirements will be in place, but the commencement of the reporting requirements will be deferred for the first 12 months to allow sufficient time for health care facilities to adapt and prepare for full implementation.

Stage 1 – new regulations commence

Stage 1 will involve mandatory reporting of medical device adverse events relating to:

- medical devices rated to be of high risk, inclusive of Class III, AIMDs and Class 4 IVDs
- a reportable medical device is used in the facility; and the use of a device has resulted in the death, or serious deterioration in the health, of a person while the device is used in the facility.

In short, the first stage will only impose mandatory requirements to report on events involving the death or serious injury of a person where the medical device in question is deemed to be of high risk. In line with this stage, the Commission will release an Advisory to the 2nd Edition of NSQHS Standards outlining the various reporting systems and process requirements for healthcare facilities to be accredited under the NSQHS Standards.

Stage 2 – 24 months after stage 1

Stage 2 will involve mandatory reporting of medical device adverse events relating to:

- medical devices rated medium to high risk, inclusive of Class IIa, IIb and III, Class 3 and 4 IVDs, and AIMDs
- a reportable medical device is used in the facility; and the use of a device has resulted in the death, or serious deterioration in the health, of a person while the device is used in the facility.

-
- a reportable medical device is not used in the facility because of the intervention of a person in the facility; and the use of the device, if the device were used, would result in, or would likely to result in, the death, or a serious deterioration in the health, of a person.

Stage 2 will involve expanding the scope of medical devices to be reported on, as well as adding near misses to the types of events to be included in mandatory reporting for medical device adverse events (i.e., it will now cover death, serious injury and near misses). The 3rd edition of the NSQHS Standards, which is currently planned to be released in 2027 will incorporate mandatory reporting requirements into the edition.

Stage 3 – 48 months after stage 1

Stage 3 will involve mandatory reporting of medical device adverse events relating to:

- a reportable medical device is used in the facility; and the use of a device has resulted in the death, or serious deterioration in the health, of a person while the device is used in the facility.
- a reportable medical device is not used in the facility because of the intervention of a person in the facility; and the use of the device, if the device were used, would result in, or would likely to result in, the death, or a serious deterioration in the health, of a person.
- a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person; and the use of a reportable medical device has resulted in the serious deterioration in the health of the person.

Stage 3 will see the rollout of all possible events required for mandatory reporting (i.e., it will now include death, serious injury, near misses, and instances where patients present outside the healthcare setting the original procedure was conducted). The enforcement of the 3rd Edition of NSQHS Standards is currently planned to occur in 2030 (i.e., from 2030 healthcare facilities will be accredited against the 3rd edition of the NSQHS Standards).

Implementation of new standards

The Commission develops the NSQHS Standards in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, patients and carers. The primary aims of the standards are to protect the public from harm and to improve the quality of health service provision. Implementation is mandated in all Australian hospitals, day procedure services and public dental hospitals. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure that the expected standards of safety and quality are met. There are currently eight standards, as detailed in the figure below.

Figure 15. NSQHS Standards⁸⁶



Each standard does not operate in isolation but are applied in conjunction with the other standards. Of the eight listed standards, the 'Clinical Governance Standard' under the 'Patient safety and quality systems' criteria, already includes a requirement for health service organisations to have 'organisation-wide incident management and investigation systems'. The listed elements for incident management systems are detailed in the figure below.

Figure 16. Standards requirements for incident management systems⁸⁷

Item	Action
Incident management systems and open disclosure	<p>1.11 The health service organisation has organisation-wide incident management and investigation systems, and:</p> <ul style="list-style-type: none"> a. Supports the workforce to recognise and report incidents b. Supports patients, carers and families to communicate concerns or incidents c. Involves the workforce and consumers in the review of incidents d. Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers e. Uses the information from the analysis of incidents to improve safety and quality f. Incorporates risks identified in the analysis of incidents into the risk management system g. Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems

The TGA notes that adverse event reporting requirements are already in place for medicines (Medication Safety Standard) (Figure 17) and blood and blood products (Blood Management

⁸⁶ The Commission, 'The NSQHS Standards', available at: <https://www.safetyandquality.gov.au/standards/nsqhs-standards>

⁸⁷ Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2nd edition, 2021, available at:

https://www.safetyandquality.gov.au/sites/default/files/2021-05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf

Standard) (Figure 18). Similar phrasing to Action 4.09 referencing TGA requirements should be sufficient to embed mandatory reporting on medical devices adverse events (utilising the already mandated incident management systems) into the NSQHS Standards while allowing the TGA to provide, and modify, specific requirements via the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Figure 17. Requirement to report adverse drug reactions

Documentation of patient information

A patient's best possible medication history is recorded when commencing an episode of care. The best possible medication history, and information relating to medicine allergies and adverse drug reactions are available to clinicians.

Item	Action
Medication reconciliation	4.05 Clinicians take a best possible medication history, which is documented in the healthcare record on presentation or as early as possible in the episode of care
	4.06 Clinicians review a patient's current medication orders against their best possible medication history and the documented treatment plan, and reconcile any discrepancies on presentation and at transitions of care
Adverse drug reactions	4.07 The health service organisation has processes for documenting a patient's history of medicine allergies and adverse drug reactions in the healthcare record on presentation
	4.08 The health service organisation has processes for documenting adverse drug reactions experienced by patients during an episode of care in the healthcare record and in the organisation-wide incident reporting system
	4.09 The health service organisation has processes for reporting adverse drug reactions experienced by patients to the Therapeutic Goods Administration, in accordance with its requirements

Figure 18. Requirement to report blood and blood product transfusion-related adverse events⁸⁸

Prescribing and clinical use of blood and blood products

The clinical use of blood and blood products is appropriate, and strategies are used to reduce the risks associated with transfusion.

Item	Action
Optimising and conserving patients' own blood	7.04 Clinicians use the blood and blood products processes to manage the need for, and minimise the inappropriate use of, blood and blood products by: <ul style="list-style-type: none"> a. Optimising patients' own red cell mass, haemoglobin and iron stores b. Identifying and managing patients with, or at risk of, bleeding c. Determining the clinical need for blood and blood products, and related risks
Documenting	7.05 Clinicians document decisions relating to blood management, transfusion history and transfusion details in the healthcare record
Prescribing and administering blood and blood products	7.06 The health service organisation supports clinicians to prescribe and administer blood and blood products appropriately, in accordance with national guidelines and national criteria
Reporting adverse events	7.07 The health service organisation uses processes for reporting transfusion-related adverse events, in accordance with national guidelines and criteria
	7.08 The health service organisation participates in haemovigilance activities, in accordance with the national framework

⁸⁸ Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2nd edition, 2021, available at:

https://www.safetyandquality.gov.au/sites/default/files/2021-05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf

Risk Management

The effectiveness of risk management is dependent on the TGA's commitment to effectively communicate reporting requirements throughout implementation of the new regulations. Identified risks must be regularly addressed and resolved to ensure public and private hospitals are well-equipped to report medical device adverse events.

Key risks associated with the implementation of new regulations:

- Stakeholders are resistant to change
- Stakeholders are unaware of the reporting requirements in line with the new regulations
- Incident management processes are not accredited according to the relevant edition of the NSQHS Standards
- Duplicate reporting, flagged as an implementation risk, could also serve as a mechanism for cross-verification to ensure both sponsors/manufacturers and health care facilities are capturing the same types of adverse events effectively.
- The security and integrity of interfaces between incident management systems and other patient records, such as discharge summaries, pose a risk to healthcare facilities. This risk includes the potential for unauthorised access, breaches or mishandling of sensitive private data during the implementation of mandatory reporting requirements.

Mitigation strategies include:

- Implementation of the ADKAR (an acronym for the five outcomes an individual needs to achieve for a change program to be successful - Awareness, Desire, Knowledge, Ability and Reinforcement) approach to change management to prepare stakeholders
 - Conduct information sessions, develop guidance documents and use tailored communication strategies
 - Engage early, showcase the benefits of reporting and continuous communication with stakeholders
 - Provide guidance material, helpdesk or email support
 - 12-month transition period and staged implementation to allow stakeholders adapt to the new requirements and provide 2-way feedback to address gaps in understanding or execution
 - Establish ongoing monitoring and evaluation mechanisms to track progress and compliance
- Early notification of changes to reporting requirements throughout implementation. Establishing precise timeframes for notifications poses challenges due to the iterative nature of the process. To mitigate this risk, detailed communication plan will be developed to provide clear and consistent updates, including specific requirements for each stage. Stakeholders will be also engaged proactively through steering committee and technical working group meetings to address concerns and clarify expectations.
- Early notification of requirements needed to be accredited by the appropriate edition of the NSQHS Standards.
- Implementation of robust data matching and reconciliation tools to identify and manage duplicate reports across different sources.
- Ensure that de-identified data is collected by the TGA for reporting purposes, minimising the exposure of sensitive private data and healthcare facilities implement robust deidentification processes and maintain compliance with relevant privacy legislation in the respective jurisdictions.

Question Seven: How will you evaluate your chosen option against the success metrics?

Evaluation

Should Option 3A be chosen, a monitoring and evaluation program will be established in line with the *Commonwealth Evaluation Policy*.

Evaluation

To ensure the chosen option is effectively meeting the success metrics identified in Question 2, ongoing evaluation of the implemented regulations should be undertaken. The following section outlines the proposed timeframes, roles and approach taken to carry out an effective evaluation of the chosen policy option (Option 3A).

Timeline

The proposed timeframes for undertaking the evaluation are in line with key milestones for implementation:

- Stage 1
 - Introduction of the new regulations and implementation
- Stage 2 (evaluation 1)
 - 2 years post-implementation of the regulations
 - 2027 - release of the 3rd edition of the NSQHS Standards
- Stage 3 (evaluation 2)
 - 5 years post-implementation of the regulations
 - 2030 - enforcement/accreditation against the 3rd edition of the NSQHS Standards.

This approach has been taken to ensure the lessons learnt throughout each stage of the implementation process are identified, communicated and addressed. Each evaluation is estimated to take up to six-months to complete.

Roles and Responsibilities

Evaluation Lead

- Service Provider - Independent third-party policy evaluation specialist (pending availability of funding as no funding has been allocated to support the roll out of the scheme at this stage).
 - Funding will be sought at the time to engage with the service provider to collect, analyse and interpret data and complete either (or both) the 2-, or 5-year evaluation. If an independent third-party policy evaluation specialist cannot be engaged, funding may also be sought through the Government's Health Economics and Research Division (HERD). If no funding is secured, the TGA will conduct in-house evaluation in consultation with the Evaluation Centre in HERD.

Evaluation Support

- TGA
 - Personnel from the relevant teams will provide ongoing support to the Evaluation Lead in the form of information exchange and coordination of engagement with key stakeholders.

Subject Matter Experts

Identified throughout the evaluation process, Subject Matter Experts (SMEs) should be engaged to provide specialist insights into the operation of the regulation in context (i.e., how is the regulation operating within the regulated community, and what outcomes is it achieving). SMEs could include, but is not limited to:

- medical practitioners and surgeons
- private and day hospital representatives
- industry representatives
- jurisdictional department representatives
- medical device sponsors and manufacturers.

Approach

Option 3A will be evaluated in line with the *Commonwealth Evaluation Policy*⁸⁹, which outlines a principles-based approach for conducting evaluations. These principles, when applied effectively, improve the way entities assess both implementation and the achievement of outcomes (i.e., it will enable a comprehensive evaluation of both the implementation of the new regulations, as well as whether or not the regulations have/is achieving the broader policy objectives it was designed to deliver). These assessments become a critical input into the design of new programs or policy decisions. The key principles are listed below:

- fit-for-purpose
- useful
- robust, ethical and culturally appropriate
- credible
- transparent where appropriate.

Department of Finance – Evaluation in the Commonwealth (Resource Management Guide (RMG) 130)

The guidance (RMG 130)⁹⁰ was developed to assist Commonwealth entities meet the requirements and policy intent of the *Commonwealth Evaluation Policy* and the evaluation requirements in related legislative and policy frameworks.

RMG 130 will be used as a guiding tool in the development of an Evaluation Plan and will be key in:

- understanding the importance of planning how to evaluate early
- understanding the role of monitoring, evaluation and learning across the policy lifecycles

⁸⁹ Australian Government Treasury, *Commonwealth Evaluation Policy*, accessible at: <https://evaluation.treasury.gov.au/about/commonwealth-evaluation-policy>

⁹⁰ Australian Government Treasury, *Evaluation in the Commonwealth RMG 130*, accessible at: <https://www.finance.gov.au/government/managing-commonwealth-resources/planning-and-reporting/commonwealth-performance-framework/evaluation-commonwealth-rmg-130>

- choosing fit-for-purpose evaluative approaches
- planning and undertaking high-quality evaluations.

RMG 130 describes eight key evaluative steps in planning, undertaking and reporting against an evaluation. Figure 17 displays how and where this Evaluation Plan interacts with this sequence and will be used as a guide to develop the Evaluation Plan.

Figure 19 - Key elements for the conduct of an evaluation



In developing the Evaluation Plan, TGA will seek to assess the achievement of the following success criteria:

1. increased volume of reported medical device adverse events by healthcare facilities
2. timelier signal detection of medical device adverse events as they occur
3. improved identification of rarer events and potential emerging issues across the country
4. earlier regulatory responses to address safety concerns
5. more frequent provision of information to healthcare facilities regarding alerts to patient and professional safety
6. proactively identify and mitigate risks associated with medical devices
7. improved data quality enabling meaningful trend identification and analysis.

To interrogate the achievement of said criteria, the evaluation will explore two key elements:

- efficacy, efficiency and compliance against the mandated reporting **process** - i.e.,
 - efficacy and efficiency of the reporting process
 - extent to which regulated entities comply with the requirements outlined in the legislation
- **outcomes** achieved as a result of the new regulations - i.e., have the new regulations enabled TGA to:

-
- effectively monitor the safety and performance of medical devices
 - identify and address emerging issues with the safety and performances of medical devices in a timely fashion
 - enact necessary regulatory action and notification of issues to manufacturers, suppliers and users of the impacted devices.

Process Evaluation

Process evaluation will be valuable to monitor the extent to which requirements in the legislation (and supporting regulations) are being met by healthcare facilities (i.e. public and private hospitals). This component of the evaluation will seek to identify and assess whether there are any risks/factors that may impact on the Government's ability to achieve its policy objectives. This includes identification of areas for improvement to enable the achievement of objectives. Some suggested key evaluation questions are listed below:

- Effectiveness
 - Increase in volume of medical device incident reports?
 - Increased proportion of medical device incident reports from healthcare facilities (vs. manufacturers and sponsors and others)?
 - Increase in identification of trends and emerging risks of medical devices?
 - Proportion of medical device incident reports submitted in batch vs on occurrence (indicates stakeholder compliance with reporting timeframes and protocols). The proportion of batch versus on-occurrence reporting can indicate healthcare facilities' responsiveness to incident severity. A balanced proportion, where less severe incidents such as near misses are reported in batches and serious adverse events such as deaths are reported on occurrence, would reflect higher compliance with reporting timeliness requirements. Variations in these proportions can identify areas where additional guidance and support may be required to ensure alignment with reporting expectations.
- Efficiency
 - Relative increase in resources expended in complying with the legislation (and supporting regulations)?
 - Timeliness of medical device adverse event reporting (i.e., average time from event occurrence to date of submission. Should also consider severity of event)? (While batch reporting is the preferred approach, it does not eliminate the requirement to report more severe adverse events, such as deaths and cases of serious harm, on occurrence to ensure timely response and appropriate action. For more serious adverse events, timeliness can be measured by the promptness of reports submitted after the event and for less severe adverse events, timeliness can be evaluated based on the frequency and regularity of batch submissions).
- Compliance
 - Number of instances of non-compliance against the legislation (and supporting regulations) across public and private hospitals?
- Continuous Improvement
 - What lessons (best practices) have been identified?
 - How could the process be improved (i.e., the regulations) to best meet Government's objectives?

Outcome Evaluation

In contrast to the process evaluation component which is largely volume/quantitative focussed, the outcome evaluation element seeks to understand the extent to which the new legislation and support regulations have achieved government objectives. Some suggested key evaluation questions, linked to the success criteria, are listed below:

- Has there been more rapid identification and response to significant issues associated with medical devices?
 - Number of significant adverse events identified and resolved within a reporting period
 - Monitoring outcomes such as reduction in related adverse events
 - Stakeholder feedback
- Have the TGA more systematically identified emerging signals that could indicate potential threats to the quality of care or quality of life experienced by Australians?
 - Number of emerging signals detected and validated over time
 - Time taken for signal validation from initial detection
- Has there been more timely and comprehensive information-sharing and analysis between governments and healthcare organisations?
 - Frequency and timeliness of data sharing between jurisdictions and health care facilities
 - Quality and comprehensiveness of shared data
 - Stakeholder feedback
- Have the regulations facilitated more timely signal detection of medical device adverse events?
 - Reduction in time to detect signals
 - Increase in the number of signals detected and acted upon
 - Proportion of adverse events identified as signals
- Has there been better identification of rarer events and potential emerging issues across the country?
 - Comparative analysis of data from diverse sources – contributing to identification of rarer events, ensuring that data from various health care facilities, manufacturers/sponsors and jurisdictions is integrated and utilised.
- Have there been earlier investigations and/or actions to address safety concerns by national regulators?
 - Reduction in time for reporting
 - Number of regulatory actions implemented early due to prompt reporting and analysis
- Has there been the provision of more frequent information to health care providers about possible threats to patient and professional safety?
 - Earlier issuance of safety bulletins or advisories
 - Stakeholder feedback

Data Collection Methods

The evaluation would utilise mixed methods to collect the data (i.e., quantitative and qualitative) and thus requires a range of data collection methods. The methods outlined below would be considered for use.

Data Collection Method	How to derive qualitative/quantitative data
Administrative data, statistics, linked datasets	An aggregated selection of quantitative data will assist in measuring activity-based metrics
Focus group discussions/monitoring groups meetings	Forum-like discussions with affected stakeholders will assist in collating qualitative data.
Literature review	A systematic review of similar regulations introduced in international jurisdictions. Understanding best practice and findings in other jurisdictions will enhance the understanding of the efficacy of the new regulations
Stakeholder interviews	Interviewing stakeholders will provide a more subjective insight to the efficacy of the new regulations
Survey	Surveys could be structured to query and answer key aspects of the evaluation of the new regulations
Compliance monitoring	Conduct random sampling of reports for completeness and accuracy and perform regular audits to ensure ongoing compliance with reporting requirements.

Future consultation and reporting

The following consultation and reporting strategies are proposed:

- Maintain regular communication with stakeholders, including the Commission, public and private hospitals, industry representatives and patient advocacy groups to gather feedback and address emerging issues.
- Provide guidance and training materials on the reporting requirements and procedures.
- The TGA will continue engagement with jurisdictions, private and day hospitals to provide periodic updates on the progress of implementation and any modifications to the IT systems or processes based on organisational requirements.
- Regular updates on the TGA website on the progress of the mandatory reporting scheme including key metrics, milestones achieved and any changes to the implementation plan.

Appendix A: Cost Benefits Summary and Multi-Criteria Analysis

The following table provides a summary of the benefits and costs of each measure, relative to each of the key stakeholder groups (i.e., government, manufacturers and sponsors, healthcare facilities, and the general public).

Table 10. Cost Benefits Summary

IMPACT				
Measure	Government	Manufacturers & Sponsors	Healthcare Facilities	General Public
Measure 1 Impose mandatory reporting of medical device adverse events for public and private hospitals (including day hospitals)	✓ Increased volume of medical device adverse event data ✓ Improved ability to detect rarer events / weaker signals ✓ Increased assurance relating to medical device adverse events reported by medical device sponsors and manufacturers	✓ Increased quality of medical device reporting from healthcare facilities ✓ Improved ability to prevent serious public health events (e.g., Urogynaecological Mesh case)	✓ More informed clinical decision making in relation to the procurement and use of medical devices	✓ More timely notification of potential health risks relating to medical devices
	✗ Cost of resources required to review, assess and respond to incoming medical device adverse event reports (e.g., investigations)	✗ Increased volume and therefore cost of compliance and response activities related to medical device adverse events (e.g., fines, recalls, defect corrections, hazard alerts etc.)	✗ Cost of resources required to complete, review, compile and submit medical device adverse event reports ✗ Cost of resources required to review guidance material relating to reporting of medical device adverse events	✗ Potential to reduce consumer choice through a reduction in the number of medical device options available

IMPACT				
Measure 2 Prescribe Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices'	✓ More rapid estimation of the frequency and severity of safety problems associated with high-risk medical devices		✓ Lowest resource impost on the regulated community (i.e., the smallest scope of reporting)	
	✗ Smallest scope of reporting of the policy options presented		✗ Resources required to upskill staff on how to identify and verify the class of medical device involved in the adverse event	
Measure 3 Introduction of additional reporting fields relating to medical devices	✓ Improved ability to detect rarer events / weaker signals ✓ Increased consistency in the quality and content of medical devices adverse event reports	✓ Increased consistency in the quality and content of medical devices adverse event reports	✓ Improved guidance on the minimum data requirements for medical device adverse event reporting	
	✗ Significant system development is required to facilitate the expedient transfer of medical device adverse event reporting data		✗ Cost of resources required to complete, review, compile and submit medical device adverse event reports ✗ Cost of local incident management system improvements necessary to facilitate additional reporting fields	

IMPACT				
Measure 4 Awareness / communication campaign	✓ Support an increase in quantity and quality of medical device adverse event reporting		✓ Improved understanding of the benefits of reporting medical device adverse events ✓ Improved understanding of when and when not to report a medical device adverse event	
	✗ Cost of campaign		✗ Communication campaign may not be relevant for all healthcare facilities (e.g., smaller hospitals without the requisite reporting systems)	
Measure 5 Reporting in batch	✓ Potential use of an API could result in significant efficiencies gained in terms of resources expended on reporting		✓ Lower resource impost on the reporting population ✓ Potential for increased quality of reporting due to the time delay (i.e., if the healthcare facility has additional time to investigate the incident, it will enable more accurate / informed reporting information) ✓ Use of an API in future could result in significant efficiencies gained in terms of resources expended on reporting	

IMPACT				
	✗ Potential time delay in receiving adverse event reports	✗ Potential time delay in notification of a medical device with a potential safety issue	✗ Potential time delay in notification of a medical device with a potential safety issue	✗ Potential time delay in notification of a medical device with a potential safety issue
Measure 6 Reporting on occurrence	✓ Improved timeliness of medical device adverse event reporting ✓ Improved response time to serious medical device safety issues / risks			✓ Improved timeliness of notification of a medical device with a potential safety issue
	✗ Potential for lower quality / fidelity of reporting information submitted by healthcare facilities (i.e., less time for internal review/investigation of the incident)		✗ Likely increased time/resource impost on the reporting population, disproportionately impacting on facilities with limited disposable resources (e.g., smaller facilities)	
Measure 7 Expand scope of 'reportable medical devices' to include Classes IIa and IIb and Class 3 IVDs	✓ Improved coverage of medical devices deemed to be medium – high potential risk to safety ✓ Increased volume of medical device adverse event reporting ✓ Improved ability to detect weak signals / rare events	✓ Increased quality of medical device reporting from healthcare facilities ✓ Improved ability to prevent serious public health events (e.g., Urogynaecological Mesh case)	✓ More informed clinical decision making in relation to the procurement and use of medical devices	✓ More timely notification of potential health risks relating to medical devices

IMPACT				
	<ul style="list-style-type: none"> ✗ Increased resources required to review, assess and respond to submitted medical device adverse event reports 	<ul style="list-style-type: none"> ✗ Increased volume and therefore cost of compliance and response activities related to medical device adverse events (e.g., fines, recalls, defect corrections, hazard alerts etc.) 	<ul style="list-style-type: none"> ✗ Higher cost of resources required to complete, review, compile and submit medical device adverse event reports (due to increased volumes of reporting) ✗ Higher cost of resources required to review guidance material relating to reporting of medical device adverse events (due to increased guidance material re medical device classes) 	
Measure 8 Expand mandatory reporting of medical device adverse events to include approved Residential Aged Care Facilities (excluding MPS facilities)	<ul style="list-style-type: none"> ✓ Improved coverage of healthcare facilities likely to experience medical device adverse events ✓ Increased volume of medical device adverse event reporting ✓ Improved ability to detect weak signals / rare events 	<ul style="list-style-type: none"> ✓ Increased quantity of medical device reporting from healthcare facilities ✓ Improved ability to prevent serious public health events (e.g., Urogynaecological Mesh case) 	<ul style="list-style-type: none"> ✓ More informed clinical decision making in relation to the procurement and use of medical devices 	<ul style="list-style-type: none"> ✓ More informed decision making in relation to the procurement and use of medical devices

IMPACT				
	<ul style="list-style-type: none"> ✖ Highest cost of resources required to review, assess and respond to submitted medical device adverse event reports 	<ul style="list-style-type: none"> ✖ Largest cost impact relating to compliance and response activities related to medical device adverse events (e.g., fines, recalls, defect corrections, hazard alerts etc.) 	<ul style="list-style-type: none"> ✖ Highest cost of resources required to complete, review, compile and submit medical device adverse event reports (due to increased volumes of reporting) ✖ Disproportionate impact on facilities that do not have the systems capability to facilitate efficient adverse event reporting (in particular, aged care facilities and small hospitals) 	

The table below provides a summary of the achievement of success criteria for each policy option, whether it has met the government objective and its ranking. *Table 11. Multi-Criteria Analysis – Summary of Achievement of Success*

MCA Criteria	Achievement of Success Criteria		
Options	Government Objective met	Ranking Weighting (40%)	Explanation
Option 1	×	7	Option 1 will not meet the described success criteria. The status quo approach will have no impact on improving signal detection on medical device adverse events and will not meet the government objective for the mandatory reporting scheme.
Option 2A	×	6	Option 2A will meet the success criteria of the government objectives to a moderate level however is limited to high-risk medical devices reported in batch. Coverage is limited to only 9.8% of registered medical devices which may result in underreporting to continue.
Option 2B	×	5	Option 2B will meet the success criteria of the government objectives to a moderate level and will include high-risk medical devices reported on occurrence. Coverage is limited to only 9.8% of registered medical devices which may result in underreporting to continue.
Option 3A	✓	4	Option 3A is estimated to meet the success criteria to a moderate to high level. The scope for medical devices mandated to be reported on is expanded to include medium-high risk medical devices including Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs and will be reported in batch. This option will enable timelier signal detection and respond to possible threats to patient and professional safety whilst mitigating risks associated with medical devices. This option meets the government objective.
Option 3B	✓	3	Option 3B is estimated to meet the success criteria to a moderate to high level. The scope for medical devices mandated to be reported on will include medium-high risk medical devices including Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs) to be reported on occurrence. Option 3B will enable timelier signal detection and respond to possible threats to patient and professional safety whilst mitigating risks associated with medical devices. This option meets the government objective.
Option 4A	✓	2	Option 4A comprehensively addresses the success criteria to include approved Residential Aged Care facilities in addition to medium to high-risk medical devices (i.e. Class IIa, IIb and III medical devices, AIMDs and Class 3 and 4 IVDs). increasing the volume of adverse event reporting and thus the TGA's ability to identify, assess and respond to emerging safety issues relating to medical devices. This option meets the government objective.
Option 4B	✓	1	Option 4B most comprehensively addresses the success criteria, in addition to achieving the Government's objectives from the introduction of new regulations. The reporting population to include approved Residential Aged Care facilities would further increase the volume of adverse event reporting and thus the TGA's ability to identify, assess and respond to emerging safety issues relating to medical devices. This option meets the government objective.

The table below provides a summary of the benefits and costs criteria for each policy option, whether it has met the government objective and its ranking.
Table 12. Multi-Criteria Analysis – Summary of Benefits and Costs

MCA Criteria	Benefits and Costs		
Options	Government Objective met	Ranking Weighting (20%)	Explanation
Option 1	x	7	Under Option 1, mandatory reporting of medical device adverse events will not be imposed on public and private hospitals (including day hospitals). The benefit to patients will remain unchanged. It is likely that underreporting will continue and notification of potential health risks related to medical devices will remain unchanged. No additional cost to resources will be required to complete, review and compile and submit medical device adverse event reports.
Option 2A	x	6	Option 2A will introduce mandatory reporting to cover Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices' reported in batch. This option benefits the larger and private hospitals likely to experience a higher volume of reports and safety problems associated with high-risk medical devices will be identified earlier. The potential use of an API could result in significant efficiencies gained in terms of resources expended on reporting as well as lowering the resource impost on the reporting population. Costs to complete, review and submit medical device adverse event reports and identify weak signals may pose health risks to health practitioners or patients. Due to the limited scope of medical devices covered, Option 2A will not meet the overall government objective in terms of benefit and cost.
Option 2B	x	5	Option 2B will introduce mandatory reporting to cover Class III medical devices, AIMDs and Class 4 IVDs as 'reportable medical devices' reported on occurrence. This option will enable timelier reporting of medical device adverse events and earlier identification and response to potential medical device safety issues should a public health issue arise. Reporting on occurrence has the potential to produce lower quality reporting information submitted by healthcare facilities due to the reduced amount of time to review and investigate incidences. Costs may cause increased impost on the regulated community, especially healthcare facilities with disproportionate high volumes of patients/procedures, or relative low staffing resources to support mandatory reporting. Due to the limited scope of medical devices covered, Option 2B will not meet the overall government objective in terms of benefit and cost.
Option 3A	✓	4	Option 3A will expand the scope of 'reportable medical devices' to include Classes IIa and IIb and Class 3 IVDs deemed to be medium - high risk with reporting to be in batch. This option has the potential to detect weak signals and rare events and allow for timely notification of potential health risk relating to medical devices, benefiting the general public and some flow on effects on medical device manufacturers and sponsors. The potential use of API for data transmission in batch reporting will reduce the resource burden on the reporting population, enhance reporting quality, and improve efficiency in resource usage. Option 3A meets the government objective in terms of benefit and cost.
Option 3B	✓	3	Option 3B will expand the scope of 'reportable medical devices' to include Classes IIa and IIb and Class 3 IVDs with reporting to be on occurrence. Option 3B will enable detection of weak signals/ rare events related to a medical device adverse event. On occurrence reporting has the potential to produce lower quality reporting information submitted by healthcare facilities due to the reduced amount of time to review and investigate incidences. Similar to Option 3A, the volume of mandatory reports will likely increase and have flow on impacts on both healthcare facilities and medical

			device sponsors and manufacturers. There will be increased resources by healthcare facilities to support training of staff and changes to internal procedures. Medical device manufacturers and sponsors will likely increase resources in investigating, responding to and addressing any outcomes of adverse event reporting. Option 3B meets the government objective in terms of benefit and cost.
Option 4A	✓	2	Option 4A will improve coverage of healthcare facilities to include approved Residential Aged Care Facilities (excluding MPS facilities) as well as Classes IIa and IIb and Class 3 IVDs with reporting to occur in batch. There will be improved ability to detect and prevent serious public health events and allow for timelier detection of weak signals/ rare events related to a medical device adverse event, improved clinical decision making in relation to the procurement and use of medical devices. Option 4A will enable increased access to relevant data to support the timely identification of medical devices with potential safety issues. In addition to costs described in preceding policy options, there is a significant increase in regulatory burden on healthcare facilities, manufacturers and sponsors. Option 4A meets the government objective in terms of benefit and cost.
Option 4B	✓	1	Option 4B will expand coverage of healthcare to include Classes IIa and IIb and Class 3 IVDs and approved Residential Aged Care Facilities (excluding MPS facilities) with reporting to occur on occurrence. There will be improved ability to detect and prevent serious public health events and allow for timelier detection of weak signals/ rare events related to medical device adverse events, improved clinical decision making in relation to the procurement and use of medical devices. In addition to costs described in preceding policy options, there is a significant increase in regulatory burden on healthcare facilities, manufacturers and sponsors. Option 4B best meets the government objective in terms of benefit and cost.

The table below provides a summary of the regulatory burden criteria for each policy option, whether it has met the government objective and its ranking
Table 13. Multi-Criteria Analysis – Summary of Regulatory Burden

MCA Criteria	Regulatory Burden		
	Objective met	Ranking Weighting (40%)	Explanation
Option 1	x	1	Option 1 has the least regulatory burden on public and private hospitals (including day hospitals), however, it does not meet the government's policy objective for the mandatory scheme and the public health problem. Medical device adverse events would continue to be underreported, thereby not improving the TGA's ability to detect emerging signals relating to medical devices that pose a potential health risk.
Option 2A	x	2	Option 2A will cost private healthcare facilities \$1.19 million annualised over a ten- year period. There is some regulatory burden imposed on private healthcare facilities, however the scope of medical device reporting is limited and does not cover medium-high risk devices (i.e. Class III medical devices, AIMDs and Class 4 IVDs) which makes up a significant proportion of registered medical devices. Option 2A will be limited in its ability to detect weak signals relating to medical devices with potential safety issues/risks.
Option 2B	x	3	Option 2B will cost private healthcare facilities \$1.20 million annualised over a ten-year period. There will be some regulatory burden imposed on private healthcare facilities, however the scope of medical device reporting is limited and does not cover medium-high risk devices (i.e. Class III medical devices, AIMDs and Class 4 IVDs) which makes up a significant proportion of registered medical devices.
Option 3A	✓	4	Option 3A will cost private healthcare facilities \$1.61 million annualised over a ten-year period. Option 3A via batch reporting will minimise the additional regulatory burden placed on the reporting population, improve the TGA's ability to detect weak signals, resulting in many positive patient and health practitioner health and safety outcomes. Option 3A provides greater coverage of medium – high risk medical devices and provides the best balance between addressal of the policy objectives and regulatory burden placed on the reporting population and is therefore the preferred option.
Option 3B	✓	5	Option 3B will cost private healthcare facilities \$1.67 million annualised over a ten-year period. Option 3B expanding the scope to include medium – high risk medical devices however, the proposed on occurrence report submission frequency will impose a more significant regulatory burden on the reporting population, and disproportionately affect medical facilities with either limited resources, or much higher patient demand.
Option 4A	✓	6	Option 4A will incur a cost of \$5.56 million annualised over a ten-year period on private healthcare facilities and would impose a significant regulatory burden estimated to increase the reporting population by 200%. This option would see the

			number of healthcare facilities mandated to report medical device adverse events increase from 1,324 to 3,964 (representing an increase of 2,640 healthcare facilities or approximately ~200%).
Option 4B	✓	7	Option 4B will incur the highest cost estimated at \$5.61million annualised over a ten-year period. This option will have the most regulatory burden to private healthcare facilities. Similar to Option 4A, this option would see the number of healthcare facilities mandated to report medical device adverse events representing an increase of 2,640 healthcare facilities or approximately ~200%. Option 4B would have the most regulatory burden in relation to staff training, IT upgrades, administrative costs.

Appendix B: Regulatory Burden Estimate

Overview

This appendix provides further detail on the approach taken to determine the Regulatory Burden Estimate (RBE) for each option, with the approach taken being in line with the OIA's Regulatory Burden Measurement Framework. The estimates are largely based on publicly available data and a number of explicit assumptions (detailed below). Consultation with government, industry and consumer groups assisted in developing / identifying a number of the assumptions and inputs.

Stakeholder types

The standard RBE estimates the incremental cost imposed on **Business, Community Organisations** and **Individuals** by each of the proposed options.

We have also included key impacts on the **Public Sector** (specifically Public Hospitals) for information purposes given materiality.

The key stakeholders assessed in RBE are tabled below:

Table 14 - Stakeholders considered in the Regulatory Burden Estimate

Category	Stakeholders
Business	<ul style="list-style-type: none">Sponsors / ManufacturersPrivate HospitalsResidential Aged Care Facilities
Community Organisations	-
Individuals	-
Public Sector	<ul style="list-style-type: none">Public Hospitals

It has been assumed that no material regulatory burden is placed on either Community Organisations or Individuals by the proposed options.

Cost types

Included costs

Per the OIA's Regulatory Burden Measurement Framework, the categories of costs to consider in the RBE are **Administrative Costs**, **Substantive Compliance Costs** and **Delay Costs**.

Table 15 - OIA guidance on costs to include in the RBE

Included Cost Types	Definition
Administrative Costs	Costs incurred by regulated entities primarily to demonstrate compliance with the policy (usually record keeping and reporting costs)
Substantive Compliance Costs	Costs incurred to deliver the outcomes being sought (usually purchase and maintenance costs).
Delay Costs	Expenses and loss of income incurred by an entity through an application or approval delay

Within these categories, the key costs quantified in this impact assessment are as tabled below.

Table 16 - Costs included in the RBE for this Impact Assessment

Cost Type	Cost	Description
Administrative Costs	Reporting	Cost of administrative effort to each facility of the review and submission of additional reporting relating to medical device adverse events
Substantive Compliance Costs	Staff Training	Cost of initial training of facility staff to get them ready to comply with new reporting requirements
Substantive Compliance Costs	IT system upgrades	Cost of upgrades/expansion/improvements to IT systems to both capture additional reporting fields and to facilitate timely reporting of new requirements

It has been assumed that the proposed policy options will impose no Delay Costs on reporting populations.

Excluded costs

The following costs are excluded from the Regulatory Burden Measurement Framework and are not required to be considered when quantifying an estimate of burden. However, depending on the significance of the following impacts, they should be analysed in the Impact Analysis so the decision maker can understand the importance of the impacts.

Table 17 - OIA guidance on costs to exclude from the RBE

Excluded Costs	Consideration in this Impact Assessment
Opportunity costs (unless they relate to a delay)	N/A
Business-as-usual costs	While we include the initial cost of facilities transitioning to the additional regulation; such costs are deemed to be BAU for any new facilities or for any additional people needing to be trained in the future, and hence those future costs are left out of the estimate.
Non-compliance and enforcement costs	Non-compliance and enforcement costs imposed on the medical device sponsors and manufacturers, or health care facilities are excluded from the regulatory burden estimate
Regulatory impacts related to the administration of courts and tribunals	N/A
Indirect costs	Indirect costs such as greater report volumes leading to a potential increase in medical device recalls by sponsors/manufacturers have not been included in the RBE. (An increase in the timely recall of problematic medical devices would be a net win, irrespective of the dollar cost to sponsors/manufacturers).
Direct financial costs	N/A beyond the Administrative and Substantive Compliance costs
Costs of international obligations imposed as a prerequisite for participation in international markets	N/A
Government-to-government policy	Any costs of changes to interactions between TGA and other government healthcare facility oversight bodies has not been included in the RBE.

Assumptions

Populations

Key inputs

For the purposes of the RBE, population refers to the number of facilities impacted.

Table 18 - Population of Health Facilities covered in the RBE

Facility type	Count	Basis
Private Hospitals		
...with High exposure to incidents	101	As per the list of Commonwealth Declared Hospitals at 22 February 2024, with breakdown into High / Medium / Low based upon the “Second-tier category” therein. Further detail provided in the section directly below.
...with Medium exposure to incidents	110	
...with Low exposure to incidents	432	
Residential Aged Care	2,640	As per the GEN Aged Care data at 30 June 2023. Further detail provided in Annex B.
Public Hospitals	686	As per the list of Commonwealth Declared Hospitals at 22 February 2024. Further detail provided in Annex B.

Private hospital categories

The Private Hospitals within the Public and Private Hospitals listed in the “Commonwealth Declared Hospitals” are further divided into categories A-G based on their size and role.

For the purposes of the Impact Analysis, we have grouped these into subsets which can be assumed to align to High, Medium and Low levels of exposure to potential incidents. These groupings can also be assumed to broadly align to average technological capabilities with the larger hospitals with higher exposure to potential incidents also more likely to have technology infrastructure which is more ready to handle an additional reporting load.

Figure 20 - Private Hospitals classified by assumed exposure to medical device incidents

Private Hospital Categories		
Description	Category	Count
High exposure to incidents		
Over 100 beds - with A&E or SCCU or ICU	F	82
Over 100 beds - no A&E or SCCU or ICU	E	19
Subtotal		101
Medium exposure to incidents		
51-100 beds	D	49
Up to 50 beds	C	61
Subtotal		110
Low exposure to incidents		
Psychiatric Care	A	48
Rehabilitation Care	B	35
Day Surgeries	G	349
Subtotal		432
Total		643

*A&E = Accident & Emergency Unit,
 SCCU = Specialised Care Cardiac Unit,
 ICU = Intensive Care Unit

Labour costs

Key inputs

The value of the time used by staff in adhering to the new requirements is measured in their hourly pay rates **inclusive of on costs**, with assumed rates tabled below.

Table 19 - Assume hourly labour costs of Health Facility staff (including on costs)

Role	Hourly rate	Basis
Administrative staff⁹¹	\$83.48	As per ABS data, with further details provided in the section below.
Management staff⁹²	\$182.76	Scaled up from Administrative staff rate based on average weekly cash earnings for Managers vs Clerical and Administrative workers. Further details below.

Administrative Staff

The Australian Bureau of Statistics (ABS) published 'Employee Earnings and Hours' on 24 Jan 2024 for the period of May 2023. <https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/employee-earnings-and-hours-australia>

⁹¹ The term 'administrative staff' is being used to describe non-managerial staff that may be involved in the report creation, review and submission process. This category covers health care and social assistance staff (e.g., nurses, hospital clerks and general hospital administration staff).

⁹² The term 'management staff' has been used to describe medical professionals that may be involved in the report creation, review and submission process (e.g., doctors, hospital expert panels, clinical management and IMS staff etc.).

Given that private healthcare facilities could be based in any state/territory, the national dataset was used. The relevant table is Table 7 of DataCube 4 i.e. "NON-MANAGERIAL EMPLOYEES, Number of employees, Average weekly total cash earnings, Average weekly total hours paid for, Average hourly total cash earnings-Rate of pay, industry". Two Australian and New Zealand Standard Industrial Classification (ANZSIC) divisions were considered as being relevant to the particular activities being costed:

- 1.) **Professional, Scientific and Technical Services** (ANZSIC Division M). Industry subdivisions are: Professional, Scientific and Technical Services (Except Computer System Design and Related Services), and Computer System Design and Related Services. For May 2023, the average hourly total cash earnings for this industry was **\$53.70**
- 2.) **Health Care and Social Assistance** (ANZSIC Division Q). Industry subdivisions are: Hospitals, Medical and Other Health Care Services, Residential Care Services, and Social Assistance Services. For May 2023, the average hourly total cash earnings for this industry was **\$47.70**

It was assessed that the **Health Care and Social Assistance** was the more appropriate industry division because it is the division most likely to include the hospital staff who would undertake the reporting activities within the healthcare setting.

Assuming a **1.75 multiplier for on-costs** (as directed in Appendix 2 of the Regulatory Burden Measurement Framework) this translates to an hourly rate of:

$$1.75 \times 47.70 = 83.48$$

For the purpose of the regulatory costing this rate has been **assumed for all healthcare facility populations**.

Management staff

The above ABS data does not include a breakdown of hourly rates for management employees but does include a table of average weekly total cash earnings split by occupation (shown below). This allows us to see that the ratio of average Manager earnings to average Administrative worker earnings is 2,712.4 to 1,238.9 i.e. 219%. Hence have assumed the hourly rate for Management staff (inclusive of on costs) to be

$$\left(\frac{2712.40}{1238.90}\right) \times 83.48 = 182.76$$

Table 20 - Comparison of average weekly earnings across occupation types

All employees, number of employees, average weekly total cash earnings - occupation

	Number of employees ('000)	Average weekly total cash earnings (\$)
Managers	1,068.00	2,712.40
Professionals	3,030.00	1,954.00
Technicians and trades workers	1,451.10	1,614.20
Community and personal service workers	1,763.60	953.1
Clerical and administrative workers	1,900.90	1,238.90
Sales workers	1,390.30	785.4
Machinery operators and drivers	724.1	1,631.00
Labourers	1,265.00	1,022.00
All occupations	12,593.10	1,489.80

Administrative Cost: Reporting

Calculation and key inputs

The effort required to report incidents has been modelled as two components:

1. The **review** of each reported incident by **Management staff**
2. The **submission** of the report by **Administrative staff**.

In both cases the standard way to calculate administrative costs is as $Price \times Cost$ where

- $Price = Time\ required \times Labour\ Cost$
- $Cost = Times\ performed \times Number\ of\ facilities \times Number\ of\ staff$

The effort of reviewing each reported incident is the same in either the batch or on-occurrence approach as it needs to be done for every incident individually.

The submission of reports though differs based on whether there's any saving when reporting incidents in bulk.

We have assumed in the RBE that no further effort is required by the reporting facility after their report submission i.e., any costs related to follow up discussions with the TGA have been excluded from the estimate on the basis that only a very small proportion of reported incidents result in further action being required.

Table 21 - Inputs into labour cost for incident reporting

Item	Component	Value	Basis
Report review	Minutes	50	Based on initial input from Australian Private Hospitals Association (APHA) members and further information from the interjurisdictional steering committee representatives
	Hourly rate	\$182.77	Management staff rate (per Labour Costs sections)
	Frequency	Expected # of incidents	Needs to be done for each incident. Details in the next table
Report submission on occurrence	Minutes	22.5	Based on input from APHA, interjurisdictional steering committee representatives and Medical Software Industry Association Ltd (MSIA) members
	Hourly rate	\$83.48	Administrative staff rate (per Labour Costs section)
	Frequency	Expected # of incidents	Needs to be done for each incident. Details in the next table
Report submission in batch	Minutes	22.5	Based on input from APHA, interjurisdictional steering committee representatives and MSIA members
	Hourly rate	\$83.48	Administrative staff rate (per Labour Costs section)
	Frequency	12 times a year	Assuming this will be done monthly. (We assume incidents are evenly spread through year to be conservative). Details in the next table.

Table 22 - Assumed incident frequency by facility and medical device type

Facility	Device Type	Expected Incidents per year	Basis
Private Hospital – High Exposure to incidents	High Risk	14	See section below on "Reportable volumes"
	Medium Risk	14	
Private Hospital – Medium Exposure to incidents	High Risk	6-7	
	Medium Risk	6-7	

Private Hospital – Low Exposure to incidents	High Risk	1	
	Medium Risk	1	
Residential Aged Care	High Risk	1	
	Medium Risk	1	
Public Hospital	High Risk	3-4	
	Medium Risk	3-4	

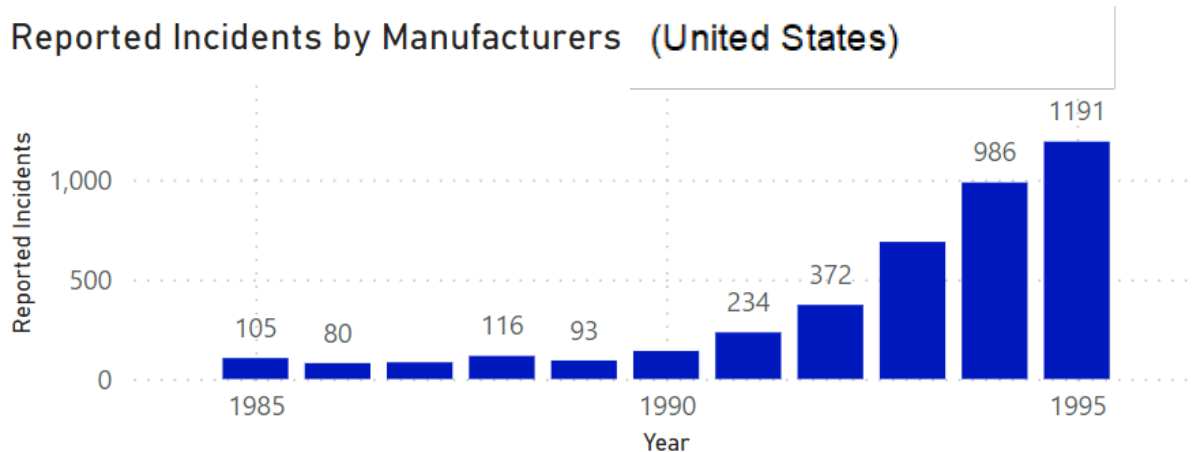
Reportable volumes

Increase in total incidents reported

The TGA currently experiences around 10,000 medical device incident reports per year⁹³, with around 90% coming from sponsors. When Canada and the US introduced their regulations around mandatory reporting by hospitals, they not only saw an increase in reporting by hospitals, but **also a material increase in reports by manufacturers who were already subject to existing mandatory reporting requirements**. Specifically

1. There was an ~6x increase in reports by US manufacturers before and after 1991:

Figure 21 - US reported incidents

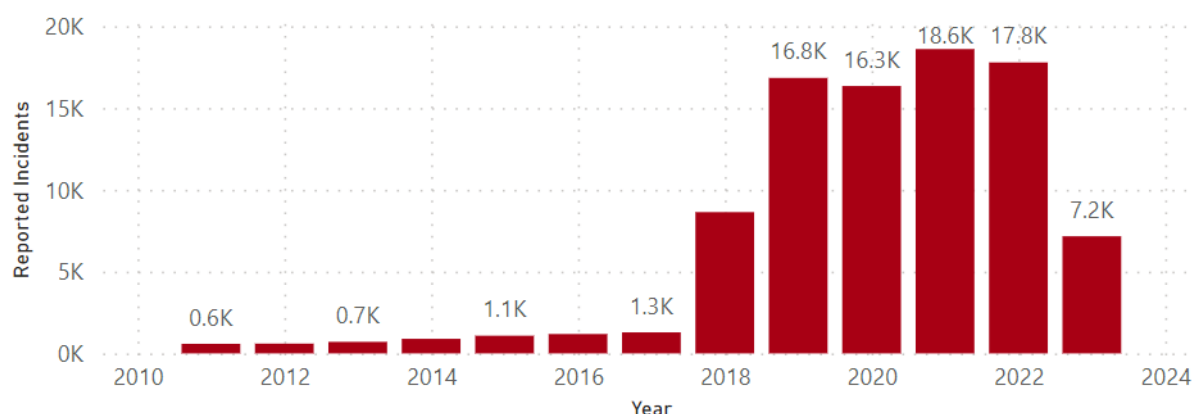


2. There was a ~14x corresponding increase for manufacturers in Canada around 2018:

⁹³ 10,000 medical device incident reports were reported to the TGA in 2023-2024 FY

Figure 22 - Canada reported incidents

Reported Incidents by Manufacturers (Canada)



Based on the above we've assumed a one-off and immediate 10x increase in the total number reported incidents of adverse effects relating to medical devices for the Australian scenario at the time mandatory regulation commences. This assumption implies:

- **100,000 reports annually** (in total from across all report sources) going forward rather than the current 10,000 per year; and
- is akin to assuming that **only 10% of incidents are being currently reported**.

While these numbers appear extreme, they are relatively conservative in comparison to the 5% or 0.5% figures suggested by some of the literature (which would imply a 20x and 200x increase respectively in reporting volumes).

Increase in incidents reported by hospitals

Focusing just on hospitals, in the US and Canadian data there is large variation in the impact of regulation on the number of incidents reported by hospitals specifically, and in the US the hospitals can just report directly to manufacturers to satisfy their regulatory requirement, which also muddies the waters.

Hence, it has been assumed that **10% of the new total incidents reported are at least reported by hospitals, i.e., 10,000 reports across public and private** (noting there can be double counting across reporting by hospitals and manufacturers). This implies approximately **5,000 new reports being submitted by private hospitals** given the relative counts of public and private hospitals. This assumption is based on the most comparable overseas data in Canada. In 2019, mandatory reporting was introduced for manufacturers with reports surging from 1,185 per year (2015-2017) to 16,834 (2019-2021), with hospitals contributing only 1,844 of these. Hospital reporting prompted manufacturers to be more thorough, but less than 10% of the increase was due to hospitals. This supports our assumption that only 10% of the reporting increase in Australia will come from new hospital reporting, with the rest from more thorough manufacturer reporting, similar to Canada.

Further **the total of these reports have been assumed to split 4:2:1 across private hospitals with High:Medium:Low exposure to incidents**, i.e. incidents are twice as likely in High exposure facilities than Medium, which are in turn twice as likely to be exposed to incidents as Low exposure facilities.

Residential Aged Care facilities have been assumed to have similar incident exposure to Low exposure hospitals i.e. around two per year.

For **Public Hospitals** the assumed rate is akin to a blended rate for the private hospitals and is ~6 to 7 per year.

The frequency of reports for each facility is summarised in the table below.

Table 23 - Estimated reports per hospital (private and public)

Type of facility	Reports	Number of hospitals	Reports per hospital per year
Private Hospitals – High exposure	2858	101	28
Private Hospitals – Medium exposure	1429	110	13
Private Hospitals – Low exposure	713	432	2
Public Hospitals	5000	686	7

In all cases these amounts have further been **assumed to split 50:50 across High and Medium risk medical devices**. This assumption is based on a high-level comparison of the nature of the residents in each facility, with the overall risk of exposure to problematic medical devices for residents in aged care facilities deemed to be comparable to the level of potential exposure of people in low-exposure hospitals. Although this comparison is somewhat subjective, it seeks to focus on the key relative facets of the facilities being compared.

Hence, for example, for High exposure private hospitals we expect 14 reports per annum for high-risk devices and 14 per annum for medium risk devices – as shown in the earlier key inputs table.

Additional notes on this cost

- Under batch reporting it would still be expected that incidents which pose a significant public health threat would be reported on occurrence. Such instances are assumed to be rare, and likely at least partly already included in the existing voluntary reporting done by health facilities. Hence no adjustment has been made to the modelling of the batch reported numbers to reflect this difference.
- Given the difficulty in estimating the volume of additional reported incidents, no additional growth in reported numbers has been included. The increase in volume of reports by a factor of 10 occurring immediately at the onset of the new mandatory reporting requirements has been deemed appropriately conservative given there may actually be a delay in the increase of reports if new requirements are phased in.

Substantive Compliance Cost: Staff training

Calculation and key inputs

All individuals responsible for reporting requirements in a healthcare facility will be required to read the guidance material, with the cost of this effort calculated as the labour cost along similar lines to what was done for the administrative costs above.

The estimated time taken to read through the incremental regulatory changes is an additional regulatory burden for existing healthcare facilities. For any new healthcare facilities that come online after the initial rollout it will just be seen as part of their expected regulatory burden, and so no additional awareness burden is needed beyond the current population.

Table 24 - Labour costs relating to staff training on the new reporting requirements

Item	Value	Basis
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Number of staff to train per facility	2	Indicative times and resources came from TGA discussions with members from the APHA and representatives of the interjurisdictional steering committee.
Minutes needed by each person for training	30	Indicative times and resources came from TGA discussions with members from the APHA and representatives of the interjurisdictional steering committee.
Hourly rate of staff being trained	\$83.48	Administrative staff rate (per Labour Costs section)
Frequency	1	As per comments above

Substantive Compliance Cost: IT system upgrades

Calculation and key inputs

The cost of upgrades/expansion/improvements to IT systems required to add additional reporting fields and prepare each facility for the additional reporting burden has been universally estimated as below. It should be noted that the TGA will examine the feasibility of developing and implementing an Application Programming Interface (API) or other data exchange software, and systems as a future option for data transfer. However, other methods, such as web portal, online forms, email and electronic transfer of data files will also be maintained while the systems are upgraded to ensure a smooth transition.

Table 25 - Cost of IT upgrades to prepare for the new reporting requirements

Item	Value	Basis
Hours of IT upgrades required	56	Estimate provided by IT vendor and based on information from the interjurisdictional steering committee representatives, on the basis of updates to add additional fields to incumbent reporting systems.
Cost per hour	\$200	
Frequency	1 (per facility)	

Average annual regulatory costs for each option over the ten-year default period

Table 26 – Summary of regulatory cost calculation over the ten-year default period

Components of average annual administration costs (10 year avg. \$)			Option 1	Option 2a	Option 2b	Option 3a	Option 3b	Option 4a	Option 4b
Private Hospitals	Review Regulations			5,367	5,367	5,367	5,367	5,367	5,367
	IT upgrade for new reporting			720,160	720,160	720,160	720,160	720,160	720,160
	Class III	Batch		463,878		463,878		463,878	
		On-Occurrence			470,201		470,201		470,201
	Class IIa and IIb	Batch				422,495		422,495	
		On-Occurrence					470,201		470,201
	Sub-Total		-	1,189,405	1,195,729	1,611,900	1,665,930	1,611,900	1,665,930
Aged Care Facilities (Residential Care)	Review Regulations							22,037	22,037
	IT upgrade for new reporting							2,956,800	2,956,800
	Class III	Batch						484,706	
		On-Occurrence							484,706
	Class IIa and IIb	Batch						484,706	
		On-Occurrence							484,706
	Sub-Total		-	-	-	-	-	3,948,248	3,948,248
Total		-	1,189,405	1,195,729	1,611,900	1,665,930	5,560,149	5,614,178	

Option 2A Measures 1, 2, 3, 4 and 5	Total regulatory burden estimates for all private healthcare facilities (businesses): \$1.19 million / year
	Total regulatory burden estimates for community organisations and individuals: \$0
	Total administrative costs: \$0.46 million / year
	Total substantive compliance costs: \$0.725 million / year
	Total cost per facility over ten years: \$18,507
Option 2B Measures 1, 2, 3, 4 and 6	Total regulatory burden estimates for all private healthcare facilities (businesses): \$1.20 million / year
	Total regulatory burden estimates for community organisations and individuals: \$0
	Total administrative costs: \$0.47 million / year
	Total substantive compliance costs: \$0.725 million / year
	Total cost per facility over ten years: \$18,662

<u>Option 3A</u> Measures 1, 2, 3, 4, 5 and 7	Total regulatory burden estimates for all healthcare facilities (businesses): \$1.62 million / year Total regulatory burden estimates for individuals and community organisations: \$0 Total administrative costs: \$0.89 million / year Total substantive compliance costs: \$0.725 million / year Total cost per facility over ten years: \$ 25,194
<u>Option 3B</u> Measures 1, 2, 3, 4, 6 and 7	Total regulatory burden estimates for all healthcare facilities (businesses): \$ 1.67 million / year Total regulatory burden estimates for individuals and community organisations: \$0 Total administrative costs: \$0.94 million / year Total substantive compliance costs: \$0.725 million / year Total cost per facility over ten years: \$25,972

<u>Option 4A</u> Measures 1, 2, 3, 4, 5, 7 and 8	Total regulatory burden estimates for all healthcare facilities and residential aged care facilities (excluding MPS facilities): \$5.56 million / year Total regulatory burden estimates for individuals and community organisations: \$0 Total administrative costs: \$1.86 million / year Total substantive compliance costs: \$3.70 million / year Total cost per facility over ten years: \$16,936
<u>Option 4B</u> Measures 1, 2, 3, 4, 6, 7 and 8	Total regulatory burden estimates for all health care facilities and residential aged care facilities (excluding MPS facilities): \$5.61 million / year Total regulatory burden estimates for individuals and community organisations: \$0 Total administrative costs: \$1.91 million / year Total substantive compliance costs: \$3.70 million / year Total cost per facility over ten years: \$ 17,100

Annex A – Acronyms and Abbreviations

Acronym / Abbreviation	Description
ACQSC	Aged Care Quality and Safety Commission
AIMDs	Active Implantable Medical Devices
API	Application Programming Interface
ARGMD	Australian Regulatory Guidelines for Medical Devices
ARTG	Australian Register of Therapeutic Goods
CAP	Conformity Assessment Procedures
CEO	Chief Executive Officer
COI	Cost of Inclusion
DAEN	Database of Adverse Event Notifications
ERIC	Events, Risk, Improvements, and Compliance
FTE	Full-Time Equivalent
IMDRG	International Medical Devices Regulators Forum
IMS	Incident Management System
IMS+	Incident Management System Plus
IRIS	Incident Reporting and Investigation Scheme
IVDs	In Vitro Diagnostics
MDIR	Medical Device Incident Report
MPS	Multi-Purpose Services
NSQHS Standards	National Safety and Quality Health Service Standards
OIA	Office of Impact Analysis
OBPR	Office of Best Practice Regulation
OECD	Organisation for Economic Co-operation and Development
RBE	Regulatory Burden Estimate
RMG 130	Resource Management Guide 130
ROGS	Report on Government Services
TBS portal	TGA Business Services portal
TGA	Therapeutic Goods Administration
The Commission	Australian Commission on Safety and Quality in Health Care
The Framework	Regulatory Burden Measurement Framework
The Patient Safety Company	TPSC
The Program	IRIS InSite Program
VHIMS	Victorian Health Information Management System

Annex B – Impact on Healthcare Facilities

Purpose of this annexure

The purpose of Annex B is to explore, in further detail, the key impacts on healthcare facilities as a result of imposing mandatory reporting of medical device adverse events. This will cover:

- reporting populations (i.e., public and private hospitals, and approved residential aged care facilities (excluding MPS facilities))
- impacted individuals (i.e., medical/clinical practitioners and hospital clerks/administrative employees)
- reporting functionality
- data fields
- incident management guidance
- awareness activities
- follow-up activities.

Current population - hospitals

Part 4-8A of the *Therapeutic Goods Act 1989* relates to the mandatory reporting of adverse events involving medical devices by healthcare facilities.⁹⁴ Reporting responsibilities are specifically assigned to the chief executive officer of a 'healthcare facility'. Section 3(1) of the Act (as amended) defines a healthcare facility as:

- a public hospital
- a private hospital
- any other facility prescribed by regulations made for the purposes of this paragraph.

Furthermore, this section further defines public and private hospitals as those declared by the Minister for Health and Aged Care under s.121-5(5)⁹⁵ of the *Private Health Insurance Act 2007*. The department periodically publishes a consolidated listing of declared hospitals.⁹⁶

While the *Therapeutic Goods Act 1989* does not currently differentiate between types of private hospitals; the published list of declared hospitals assigns private hospitals against 7 categories based on clinical services offered and the number of licenced beds. Category G relates to 'private hospitals that provide episodes of hospital treatment only for periods of not more than 24 hours'. Roundtable consultation activities for the proposed regulatory changes referenced public and private hospitals and day procedure (Category G referenced above). This taxonomy has been carried forward into the IA.

The current (January 2024) population of impacted facilities is detailed in the table below.

⁹⁴ As amended via the *Therapeutic Goods Amendment (2022 Measures No.1) Act 2023*.

⁹⁵ The legislated authority for the Minister to make the declaration is under s.121-5(6). Section 121-5(8) requires a statement categorising the hospital as either public or private.

⁹⁶ State and territory governments license and regulate all facilities that have been declared as hospitals for health insurance business. Hospitals must also be accredited against the National Safety and Quality Health Service Standards. Facilities must supply supporting evidence to help the Minister decide whether to declare them a hospital for private health insurance business. This evidence includes a copy of their state or territory hospital licence and a copy of their accreditation certificate, or evidence that they have applied for accreditation.

Table 26 - Number of impacted facilities by the proposed regulatory changes (as of 23 January 2024)

Hospital categorisation	Number
Public	686
Private (Not Day Procedure Centres)	293
Private (Day Procedure Centres)	346
Total	1,325

Source: List of declared hospitals published 15 December 2023 (updated 23 January 2024), see <[List of declared hospitals | Australian Government Department of Health, Disability and Ageing](#)>.

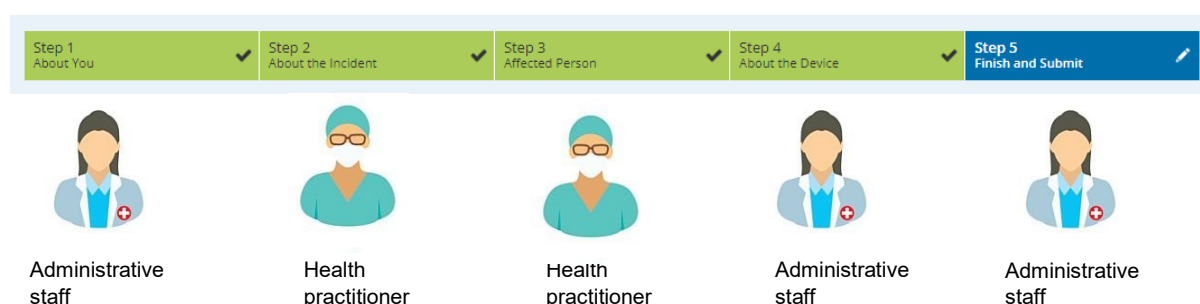
Projected population - hospitals

Noting the definitional elements detailed above, the number of regulated entities encompassed by mandatory reporting obligations will change over time as facilities are closed, opened, repurposed or consolidated. An analysis of the overall number of declared hospitals over the past five years has not revealed a material change in overall number or clear growth trajectory. The current population (detailed above) has therefore been carried forward as the base population across the default ten-year period for the regulatory costing.

Impacted individuals

There are likely to be a range of individuals involved in the compilation, review and submission of medical device adverse event report. Stakeholder consultations revealed that there is likely to be an internal review process, cognisant of potential legal liabilities, to determine whether the reported event arose from operator error as opposed to medical device failure or malfunction. While it is assumed that once a mature state is reached for adverse event reporting that a number of data fields will be automatically completed (likely pertaining to address and potentially personal information).⁹⁷ It is likely that an initial report will be raised by a health practitioner with the submitted report being compiled by hospital administrative staff (such as an admissions clerk, procurement specialist etc.)⁹⁸

Figure 22 - Likely individuals compiling separate elements of the report

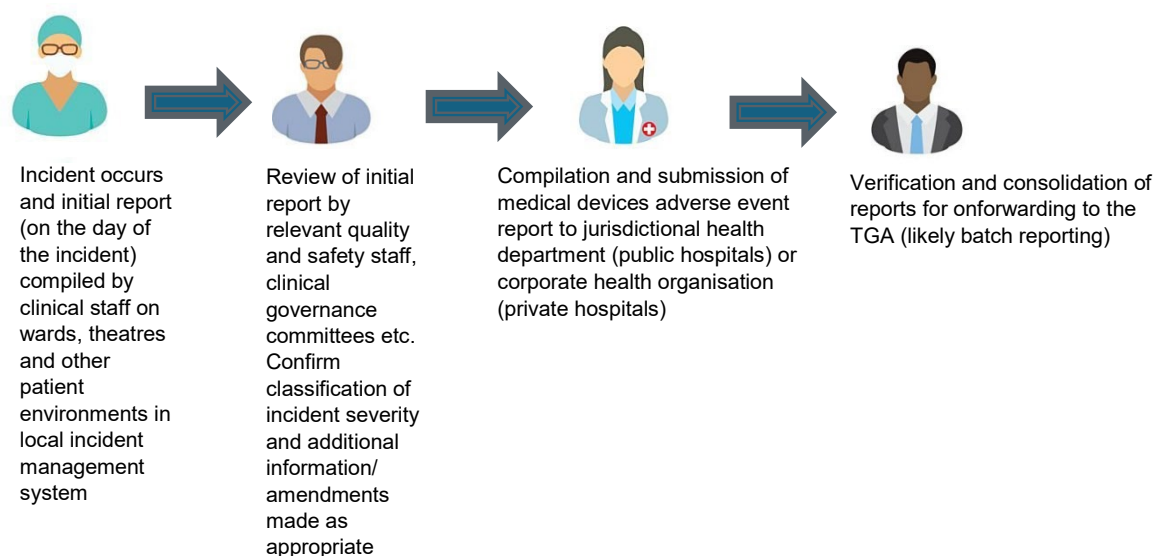


The envisaged process flow is detailed in the figure below. Jurisdictional health departments normally require notification of serious adverse events within two days of becoming aware that an event has occurred. This is not the case for near misses, and thus a local level investigation may be necessary to ensure the appropriate balance between quick information versus good information, specifically to determine causality except in the rare instances where it was clearly evident that device was associated with serious harm. As such, it is proposed that stratified reporting be implemented (i.e., quicker for death and serious harm and slower for near misses which are more complicated and require further time for investigation of causation). This is to alleviate concerns raised in consultation regarding the potential legal and reputational impacts if a healthcare facility were to report early only to find through further investigation to be user error.

⁹⁷ The current online report provides the ability to pre-fill fields by entering a TGA-assigned Reporter Number and the associated surname.

⁹⁸ This multi-stage report compilation is envisaged in the online report where one of the questions is 'Are you reporting the incident on behalf of something else (the initial reporter)?'.

Figure 23 - Medical device adverse event reporting process flow



Current population – aged care facilities

Public/private residential aged care facilities, while not currently subject to mandatory reporting of medical devices adverse events, could be so prescribed via the Therapeutic Goods regulations. Aged care providers are ‘approved’ by the sector regulator (the Aged Care Quality and Safety Commission (an Australian Government agency)). Approved facilities are accredited to provide specific services.

Within Australia, aged care services are categorised as ‘residential care’ (services provided in the agency’s facilities) and ‘home services’ (services provided at the homes of recipients). There is not always a clear delimitation between hospital and aged care facilities. For example, the Australian Government’s MPS Program provides integrated health and aged care services for older people living in small communities in regional and remote areas, where the demand on services is not sufficient to support both a hospital and a separate aged care home. The 181 MPS facilities (as at 30 June 2023)⁹⁹ are all declared hospitals (as detailed above). It is considered that, given the nature of the envisaged reporting functionality, that potential extension of the scope for mandatory reporting of medical devices adverse events would be limited to residential care providers (noting that there is likely some crossover at the entity level between service categories).

Table 27 - Number of approved aged care services providers (as at 30 June 2023)

Aged Care Services	Number
Residential care providers	2,640
Home services providers	2,263
Total	4,903

⁹⁹Figure titled ‘Aged care services in Australia’, Aged Care Quality and Safety Commission – Sector performance report April – June 2023, available at:

Sector Performance April – June 2023 (agedcarequality.gov.au) and GEN Aged care data

Reporting Volumes (projected)

TGA currently experiences around 10,000 medical device incident reports per year, with ~88% coming from sponsors. When Canada and the US introduced their regulations around mandatory reporting by hospitals, this not only saw an increase in reporting by hospitals, but also a material increase in reports by manufacturers who were already subject to mandatory reporting requirements. Specifically, there was a 5.9x increase in reports by US manufacturers before and after 1991, and a 14.2x corresponding increase for manufacturers in Canada around 2018.

Hence (for now), we've assumed a 10x increase in reported incidents of adverse effects relating to medical devices across the board for the Australian scenario. This assumption would mean 100,000 reports annually going forward rather than the current 10,000 per year. This is akin to assuming that only 10% of true incidents are being currently reported, so while the numbers appear large, they are relatively conservative in comparison to the 5% or 0.5% figures suggested by some of the literature (which would correspond to a 20x and 200x respectively in reporting volumes).

Focusing on hospitals, in the US and Canadian data there is large variation in the impact of regulation on the number of incidents reported by hospitals, and in the US the hospitals can report directly to manufacturers to satisfy their regulatory requirement which also muddies the waters. Hence, we'll assume that 10% of the new total incident reporting is at least made by hospitals, i.e., 10,000 reports across public and private (noting there can be double counting across hospitals and manufacturers). This will mean around 5,000 new reports being submitted by private hospitals given the relative split of public and private hospitals.

We then split this number 4:2:1 across private hospitals with High:Medium:Low exposure to incidents, meaning we're assuming ~2 incidents to report each month for the high exposure hospitals, and 2 per year for the low exposure hospitals, with these amounts then split 50:50 across high and medium risk devices.

Figure 24 - Estimated reports per hospital (public and private hospitals)

Type of facility	Reports	Number of hospitals	Reports per hospital / year
Private Hospitals – High exposure	2,858	101	28
Private Hospitals – Medium exposure	1,429	110	13
Private Hospitals – Low exposure	713	432	2
Aged Care	<i>explained below</i>		
Public Hospitals	5,000	686	7

Batch reporting calculations for all classes of reportable medical devices reflect the maximum reporting frequency (i.e., 1 per month, 12 annually). E.g., for Options 3A and 4A:

- for high exposure hospitals, the total incidents per year is assumed to be 28 across all classes of devices, however, they will only produce a maximum of 12 batch reports.
- for medium exposure hospitals, the total incidents per year is assumed to be 13 across all classes of devices. Similarly, a maximum of 12 batch reports will be produced.

For Aged care we have assumed 2 per year in line with Low exposure hospitals for now, and for Public Hospitals the calculated rate is akin to a blended rate for the private hospitals and is approximately 7 per year. The private hospitals have been split into three groups reflecting high, medium and low exposure to potential incidents with the split being based on their size and the nature of their activities.

Figure 25 - Private hospital categories

Private Hospital Categories		
Description	Category	Count
High exposure to incidents		
Over 100 beds - with A&E or SCCU or ICU	F	82
Over 100 beds - no A&E or SCCU or ICU	E	19
Subtotal		101
Medium exposure to incidents		
51-100 beds	D	49
Up to 50 beds	C	61
Subtotal		110
Low exposure to incidents		
Psychiatric Care	A	48
Rehabilitation Care	B	35
Day Surgeries	G	349
Subtotal		432
Total		643

*A&E = Accident & Emergency Unit,
SCCU = Specialised Care Cardiac Unit,
ICU = Intensive Care Unit

Reporting functionality

A key design consideration is to avoid, as much as is practical, the duplication of data entry and/or analysis in relation to incident reporting. It is assumed that each reporting entity has some form of incident management system. Leveraging the data captured in such systems would likely reduce the arising regulatory burden of mandatory reporting.

All Australian public and private hospitals, day procedure services and public dental practices are required to be accredited to the NSQHS Standards. Under the Clinical Governance Standard (one of eight standards that collectively comprise the NSQHS Standards), in the 'Patient safety and quality systems' criteria, health service organisations are to have 'organisation-wide incident management and investigation systems'. The listed elements for incident management systems are detailed in the figure below.

Figure 26 - Standards requirements for incident management systems¹⁰⁰

Item	Action
Incident management systems and open disclosure	<p>1.11 The health service organisation has organisation-wide incident management and investigation systems, and:</p> <ul style="list-style-type: none"> a. Supports the workforce to recognise and report incidents b. Supports patients, carers and families to communicate concerns or incidents c. Involves the workforce and consumers in the review of incidents d. Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers e. Uses the information from the analysis of incidents to improve safety and quality f. Incorporates risks identified in the analysis of incidents into the risk management system g. Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems

¹⁰⁰ Source: Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2nd edition, 2021, available at:

https://www.safetyandquality.gov.au/sites/default/files/2021-05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf

A variety of incident management systems are utilised across the sector. These mostly cloud-based systems range from those in widespread use across both public and private hospitals to likely bespoke systems (including paper-based reporting) utilised by smaller providers. Amongst those with widespread use are commercial systems utilising RL Datix platforms (such as RiskMan) and those developed inhouse, such as NSW Health's Incident Management System (IMS+), and the Victorian Health Incident Management System (VHIMS). These changes will need to be negotiated by jurisdictions with vendors. At the same time, the TGA would maintain access to online web forms, portal and email attachment provisions to allow individual case reporting by smaller organisations which may not have the systems or volume of medical device-related adverse events to support electronic data transfer.

Once the TGA has determined the data transmission format(s)¹⁰¹ and specifications for the minimum dataset, then all software vendors will then be able to develop/modify their systems to the agreed standard, to accommodate the necessary data transfer. It is anticipated that systems managed by the TGA and those managed by jurisdictions/corporations would be configured to enable batch processing of incident notifications at agreed time intervals (e.g., daily or monthly).

The TGA notes there is a variety of taxonomies¹⁰² for classifying incidents for public hospital reporting across jurisdictions. While there is a significant correlation between the continuum of outcomes (from death to no harm) and the level of incident, there are definitional differences and variance in how near misses are treated. The TGA also notes that there are multiple data repositories, including:

- electronic and paper-based medical records (for symptom related data)
- incident management systems (for events that impact upon patients)
- workplace health and safety systems (for incidents that impact upon staff)
- equipment maintenance records or databases
- hospital purchasing records (e.g. for returned products)
- patient/staff complaints data.

These systems and associated data repositories have limited integration and often limited scope for generating and exporting data in a standard format. In particular, stakeholders noted during roundtable discussions that adverse events arising from previous use of a medical device or for near misses would not usually be captured in existing hospital incident management systems, though could be captured in patient medical records or systems. Additionally, the security and integrity of the interfaces between this system, particular in relation to the handling of sensitive personal data, will be a critical design consideration for the implementation of mandatory reporting. Based on stakeholder consultations, the data fields proposed for reporting will be structured to ensure that only de-identified information is required. Minimal free text data will be collected, and personal details will not be requested as part of the reporting process.

Incident notifications are routinely screened within 5 working days of submission and undergo an initial triaging to assign an initial level of urgency for follow-up activities. A key consideration here is the potential severity of the impact associated with an adverse event with the required information to enable the TGA to make a rapid initial determination of the likelihood of a broader public health threat or preventable deaths or serious impairments. Noting this, the current TGA 'Users Medical Device Incident Report' requires compilers to categorise the health consequences¹⁰³ but also requires a free form text description of the event (incident) and outcome. Currently, received adverse events reports are 'coded' by TGA staff against the relevant adverse event reporting terminologies defined by the

¹⁰¹ Widespread data transmission formats include Extensible Markup Language (XML), JavaScript Object Notation (JSON), Health Level Seven (HL7) and Fast Health Interoperability Resources (FHIR).

¹⁰² The ACT and NSW uses Harm Scores, Incident Severity Ratings are used in the NT, SA and Vic., while Severity Assessment Codes are utilised in Qld, Tas and WA.

¹⁰³ Categories are: 'No Injury, Near Miss, Temporary Injury, Serious Injury, Permanent Disability, Death, Unknown and Other'.

International Medical Devices Regulators Forum (IMDRF). This coding is required for internationally harmonised trend analysis of adverse event reports. The current version was published in March 2020 and incorporate three levels of categorisation that allow the capturing of the problem encountered at the device level from an observational rather than diagnostic (describing possible reasons for causes for the problem or failures observed) basis. These terms are listed in Annex A to *IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes*. Level 1 identifies 23 specific problem categories, and these constitute the minimum level of coding by national jurisdictions. These categories are detailed in the table below.

Table 28 - Level 1 Term for classification of medical device problems¹⁰⁴

- Patient Device Interaction Problem
- Manufacturing, Packaging or Shipping Problem
- Chemical Problem
- Material Integrity Problem
- Mechanical Problem
- Optical Problem
- Electrical /Electronic Property Problem
- Calibration Problem
- Output Problem
- Temperature Problem
- Computer Software Problem
- Connection Problem
- Communication or Transmission Problem
- Infusion or Flow Problem
- Activation, Positioning or Separation Problem
- Protective Measures Problem
- Compatibility Problem
- Contamination / Decontamination Problem
- Environmental Compatibility Problem
- Installation-Related Problem
- Labelling, Instructions for Use or Training Problem
- Human-Device Interface Problem
- Use of Device Problem

There are 175 Level 2 Terms and 279 Level 3 Terms (an example of the interrelationship between terms is shown in the table below).

Table 29 - Level 1 Term for classification of medical device problems

Level 1 Term	Level 2 Term	Level 3 Term	Code	Definition
Patient Device Interaction Problem			A01	Problem related to the interaction between the patient and the device.
	Patient-Device Incompatibility		A0101	Problem associated with the interaction between the patient's physiology or anatomy and the device that affects the patient and/or the device.
		Biocompatibility	A010101	Problem associated with undesirable local or systemic effects due to exposure to medical device materials or leachates from those materials by a patient who has an implant or is receiving treatment with a device made from them.
		Device Appears to Trigger Rejection	A010102	The device appears to elicit undesired response in the patient to the presence of an implanted or invasive device, without inherent device failure, e.g. fibrous encapsulation, or inflammation of the tissue around the device, or extrusion of the device.
		Inadequacy of Device Shape and/or Size	A010103	The physical size and/or shape of the device was inadequate with regard to the patient's anatomy.

¹⁰⁴ International Medical Device Regulators Form, IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes, Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem, published 16 February 2023, available at:

<https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes>

Level 1 Term	Level 2 Term	Level 3 Term	Code	Definition
	Osseointegration Problem		A0102	Problem associated with interconnection between the bone tissue and the implanted device.
		Failure to integrate	A010201	Problem associated with the failure to see direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface.
		Loss of Osseointegration	A010202	Problem associated with weakened integration of the device at the bone-implant interface due to loss of fibrous and/or bony tissue and leading to compromised anchorage of the device. i.e. Loosening/Lysis
	Loosening of Implant Not Related to Bone-Ingrowth		A0103	Problem associated with the loss of direct anchorage of an implanted device over time or due to an injury.
	Migration or Expulsion of Device		A0104	Problem with an implanted or invasive device moving within the body or being completely expelled from the body.
		Expulsion	A010401	Problem with all or part of an implanted or invasive device being completely expelled from its intended location within the body.
		Migration	A010402	Problem with all or part of an implanted or invasive device moving from its intended location within the body.
	Lack of Effect		A0105	Problems associated with a product having less efficacy than expected. No other malfunctions could be identified.
	Device Stenosis		A0106	Problem associated with the narrowing or obstruction of the device (e.g. prosthetic heart valves, stents, etc.).

It is assumed that clinical incident taxonomies will not be standardised nationally and the TGA will continue to provide a coding harmonisation function for received reports. It is further assumed that the TGA will require at least sufficient information to accurately assign a Level 1 category.

It is further assumed that specific individual events requiring mandatory medical device adverse event reporting will have a very high correlation with events already required to be reported under existing incident management governance arrangements. The key questions, from a regulatory costing perspective, is therefore the extent of currently entered information that can be repurposed to satisfy the data elements for the TGA's reporting requirements and additional data fields specifically generated by the proposed regulatory changes.

Data Fields

Sentinel Events are preventable adverse events that result in death or serious harm to a patient. The original list of eight National Sentinel Events was agreed by Australian health ministers in 2002 and reported nationally by all Australian states and territories between 2004 and June 2019. From 2007, Sentinel Events have been reported by each Australian jurisdiction for inclusion in the Productivity Commission's Report on Government Services (ROGS). A revised list (2.0) was endorsed by Australian Health Ministers in December 2018, with reporting against this list commencing 1 July 2019. While both public and private hospitals are required to report against the Australian sentinel events (listed below) there is likely a low correlation with a medical device adverse event.

Table 30 - Australian sentinel events (version 2.0)¹⁰⁵

1	Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death
2	Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death
3	Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death
4.	Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death
5.	Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death
6.	Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward
7.	Medication error resulting in serious harm or death
8.	Use of physical or mechanical restraint resulting in serious harm or death
9.	Discharge or release of an infant or child to an unauthorised person
10.	Use of an incorrectly positioned oro- or naso- gastric tube resulting in serious harm or death

One jurisdiction (Victoria) includes an 11th sentinel event being 'All other adverse patient safety events resulting in serious harm or death'. This additional event aims to help Victorian health services manage adverse *patient* safety events that fall outside the 10 national sentinel event categories, 10 sub-categories are included including one titled 'medical device or equipment'. This sub-category covers errors associated with medical devices or equipment resulting in serious harm or death. Examples provided include 'malfunction of a product'.¹⁰⁶

Information concerning medical device-related adverse events that occur outside a hospital setting will be more challenging to collect on a routine basis. Other information about medical device failures that is more challenging to collect on a routine basis, but is equally important for the purposes of detecting current or emerging safety signals include:

- near misses identified and managed successfully within a healthcare facility (e.g. unreliable performance of an infusion device which is replaced by clinical staff); and
- device or consumable failures identified prior to use or during routine maintenance (e.g. broken prostheses, defibrillator not working when tested at the beginning of a shift).

Medical device failures in these areas have the potential to cause harm to other members of the public and are of particular concern to the TGA. Whilst medical device and consumable failures, and near misses may be routinely documented by healthcare facilities, this information is largely disconnected from patient safety information systems and may not be aggregated or reported to state and territory, or national authorities including the TGA. Additionally, current information systems would need to integrate information about incidents when a device failure has not caused immediate patient harm, and where a device may be causing symptoms underlying a patient presentation for treatment. If mandatory reporting were introduced, healthcare facilities may need to revise and update local incident management policies, procedures, and data management systems to integrate a range of different sources of adverse event information.

The data collected as part of potential mandatory reporting requirements would need to be determined. At a minimum it may include device brand/trade name, where the device came from (e.g., the healthcare facility, or a treating health professional), and the current location of the device (particularly if the device remains implanted). Whilst some of this information may be available from patient medical records, it may not be entered into existing healthcare facility incident reporting systems. 10-12 data items are currently being considered.

¹⁰⁵ Australian Commission on Safety and Quality in Health Care, Incident management and sentinel events, available at:

<https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/incident-management-and-sentinel-events>

¹⁰⁶ Safer Care Victoria, *Victorian sentinel event guide: Essential information for health services about managing sentinel events in Victoria*, June 2019, p.15, available at: https://www.safercare.vic.gov.au/sites/default/files/2019-06/Victorian%20sentinel%20events%20guide_0.pdf

Figure 27 - Data Fields Currently Being Considered for reporting

FIELD	FORMAT	DEFINITION (TBC)	VALUES
1. State/Territory Name	String	METEOR	Select one option only AA[A]
2. Facility/Site Name	List	Declared Hospitals	Select one option only
3. Facility Identifier (auto generated)	String	METEOR	Hospital identifier XXXXX
4. Date/Time of Incident	Date	Date (day, month, year) and time (hours and minutes) of incident	DDMMYYYY:HHMM
5. De-identified Patient Details	String	Family name letters 2, 3, 5 Given name letters 2, 3 Date of birth (day, month, year) Sex (1-male, 2-female, 3- unknown)	SLK-581 XXXXXDDMMYYYN.
6. Incident Narrative*	Text	What happened? What was actions were taken?	Up to 100 words Up to 100 words
7. TGA incident classification*	List	Death Serious injury or deterioration in health or major harm Treatment for a serious injury or deterioration in health related to a medical device Prevention of a serious injury or deterioration in health (near miss)	Select all that apply
8. Device Description*	Text	Where was (is) device located? Describe type of device? Describe purpose of device?	Up to 20 words Up to 20 words Up to 100 words
9. Incident reported to state/Territory government	List	Yes No	Select one option only
10. Device Name*	Text	State device name if known	Up to 20 words
11. Unique Device Identifier (UDI) (when available)	Text	State the UDI if known	
12. Device manufacturer (if known)	Text	State device sponsor if known	Up to 20 words
13. Incident reported to device sponsor?	List	Yes No	Select one option only

*Mandatory fields as per the requirements in the Act

Often events are not reported to the medical device sponsor/manufacturer either. Images of the device or the actual device, including the product information such as reference number, lot or serial number, expiry date, are also recommended to be part of reporting.

Incident Management Guidance

The Commission defines an incident as ‘an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may be a near miss. Incidents may also be associated with omissions where patients are not provided with a medical intervention from which they would have likely benefited.’¹⁰⁷

¹⁰⁷ Australian Commission on Safety and Quality in Healthcare, *Incident Management Guide*, November 2021, p.2, available at: https://www.safetyandquality.gov.au/sites/default/files/2021-12/incident_management_guide_november_2021.pdf

The Commission produced an incident management guide (latest edition is November 2021) and provides an overview of the incident management process and its underlying principles and consolidates best practice approaches based on literature reviews and the jurisdictional incident management policies. The guide applies only to clinical incidents and not to staff or work health and safety incidents. Each state and territory have an Incident Management Policy/Procedure to guide publicly funded healthcare facilities¹⁰⁸ in their roles and responsibilities for reporting and managing critical incidents and this guidance is hyperlinked within the guide.

The phases of incident management are detailed in the figure below.

Figure 28 - Incident management phases¹⁰⁹



In general, there is consistency in the aims of incident management policies and procedures across all jurisdictions as all policies align with the Commission's *Incident Management Guide*.

Awareness

External awareness will be provided via updates to the Commission's Policies and Procedures, National Advisory Guidance Documents, Examples of Issues to Report, other education documents. In addition, TGA will produce and socialise guidance material and educational resources to support health facilities on any changes required to reporting serious adverse events. Further education at the health facility level may be required to understand the range of potential problems with medical devices that are likely to occur. The TGA and the Commission will provide a range of communication and information material as part of the implementation process, noting, however, that they may be modified in accordance with the approaches to implementation preferred by individual jurisdictions.

¹⁰⁸ Victorian and Western Australia have explicitly extended these policies to include all private hospitals.

¹⁰⁹ Australian Commission on Safety and Quality in Health Care, Incident Management Guide, November 2021, p.5, available at:

https://www.safetyandquality.gov.au/sites/default/files/2021-12/incident_management_guide_november_2021.pdf

Follow-up activities

Under the TGA's current procedures, there is minimal burden of additional data collection placed upon individual healthcare facilities. Rather, following the reporting of an adverse incident, the TGA usually contacts the product sponsor or manufacturer for follow-up knowledge and information about specific adverse events. Most issues associated with medical device-related adverse events are previously known to occur under specific circumstances and are resolved through routine investigations undertaken by product sponsors/manufacturers, which are in turn reviewed by the TGA.