Australian Government
Department of Health
Therapeutic Goods Administration

Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

Discussion Paper

TGA Health Safety Regulation

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Background

In late 2016, the Government responded to an independent *Review of Medicines and Medical Devices Regulation* following extensive consultation with stakeholders. Specific agreed recommendations relating to medical devices included more comprehensive 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 effectiveness of medical devices.

Since that time, the TGA has introduced more streamlined processes for electronic reporting of information by product manufacturers, health professionals and consumers; improved timely access to information from overseas regulators; and strengthened post-market risk assessment, signal detection, and device investigation processes. Moreover, annual reporting of adverse events for all new high-risk medical devices are required by product manufacturers. To strengthen patient safety and post-market medical device monitoring, the Government committed to establishing a Unique Device Identification database, which will enable medical devices to be more easily traced and facilitate rapid notification of potential issues to affected patients. It is envisaged that the unique identifiers may be incorporated into patient records, discharge summaries, implant registries, and MyHealth records.

Despite these improvements, 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 devices.

- In Australia, mandatory adverse event reporting requirements exist only for device manufacturers and sponsors.
- Longer term device failures, such as those that have been a recent focus of public attention (for example, urogynaecological mesh, metal-on-metal hip prostheses, and textured breast implants) are more likely to have serious clinical impacts some years after the device implantation, rather than an immediate adverse event, and they may present in a different healthcare setting to the original procedure.

Whilst healthcare facilities, health professionals, and consumers are strongly encouraged to report adverse events, this is done voluntarily. In 2020, the TGA received approximately 6,000 medical device adverse event reports, of which sponsors reported the vast majority, approximately 89% (*Figure 1)*. Although the number of reported medical device incidents has been steadily increasing over the past years, it is evident that a very significant number are not reported to the TGA. This may be because patients or health professionals are unaware that 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.

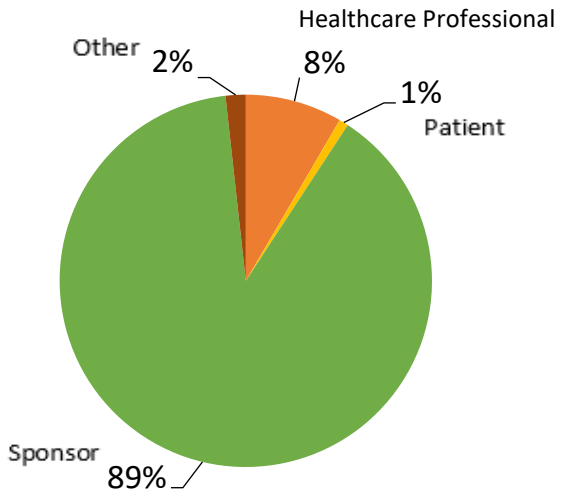

Figure 1. Source of medical device adverse event reports received by the Therapeutic Goods Administration in 2020.

The Senate Inquiry in 2017 into the *Number of women in Australia who have had transvaginal mesh implants and related matters* ('the Senate Inquiry') highlighted that 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 the ability to provide timely information regarding medical devices to consumers and healthcare professionals. Accordingly, the Government has endorsed recommendations made following the Senate Inquiry to work closely with healthcare facilities and state and territory health departments to find ways to increase rapid information sharing about medical device safety and effectiveness (*An Action Plan for Medical Devices: Improving Australia's medical device regulatory framework*, 2019). The Government has endorsed exploring:

- whether it should be mandatory for healthcare facilities to report adverse events/safety problems with medicines and medical devices to the TGA; and
- removing some existing exemptions to require more timely and improved reporting of adverse events by industry to the TGA.

Preliminary consultations

Preliminary consultations with Australian stakeholders and some other OECD regulators occurred in early 2021 to explore the potential benefits and limitations of mandatory reporting for adverse events related to medical devices.

Consultation with Australian stakeholders included representatives from each state and territory departments of health, the Australian Commission for Safety and Quality in Health Care (ACSQHC), and a range of private healthcare organisations and peak bodies.

Our discussions with a number of international regulators confirmed they require mandatory reporting of medical device related adverse events by product manufacturers or sponsors.

Some European countries also have requirements for health professionals to undertake mandatory reporting of adverse events if there was a suspicion of medical device involvement. A summary of mandatory reporting requirements across different jurisdictions is presented below.

Mandatory reporting arrangements for medical device adverse events across jurisdictions

Jurisdiction	Product manufacturers (or sponsors)	Health professionals	Healthcare facilities
Australia	✓		
Brazil	✓		
Canada	✓		✓
Denmark	✓	✓	
France	✓	✓	
Germany	✓	✓	
Ireland	✓		
Singapore	✓	✓	
Switzerland	✓	✓	
United Kingdom	✓		
USA	✓		✓

Other countries, such as the USA and more recently Canada, have made it mandatory for healthcare facilities to report suspicious events that may be related to medical devices. In these jurisdictions, an organisation-focused approach rather than requirements on individual practitioners was implemented as it 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 regulator, particularly information relating to specific medical devices that may otherwise be unavailable to individual health care professionals at the time of incident notification; and
- 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.

Next steps

This discussion paper provides for broader consultation on the potential benefits and challenges of mandatory reporting of medical device related adverse events by healthcare facilities in Australia. Following this consultation, analysis of the submissions will be provided to the Australian Government for consideration. Updates on the progress of this public consultation will be published on the TGA website at www.tga.gov.au.

This consultation

1. Potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia

Key considerations:

- Signals relating to medical device adverse events can go undetected in Australia.
- Increasing trends of specific medical device incidences can take too long to identify.
- Multiple sources of reporting may facilitate earlier investigation and more timely notification to patients and health professionals regarding the safety of medical devices used in Australia.

In Australia mandatory reporting of medical device adverse events exists only for device manufacturers and sponsors. This has left a gap where patients present to healthcare professionals with harms associated with medical devices, but the manufacturer or sponsor of the medical device is not made aware of the incident. The Senate Inquiry regarding transvaginal mesh implants highlighted this issue. Due to the Senate Inquiry and associated public awareness campaign, patients came forward with reports of adverse events that occurred, some many years after the event initially occurred, leading to a spike in reports to the TGA by patients and then in later years by healthcare professionals (*Figure 2).* The identification of an increasing trend of harm may have occurred earlier if adverse event reporting was required by multiple sources.

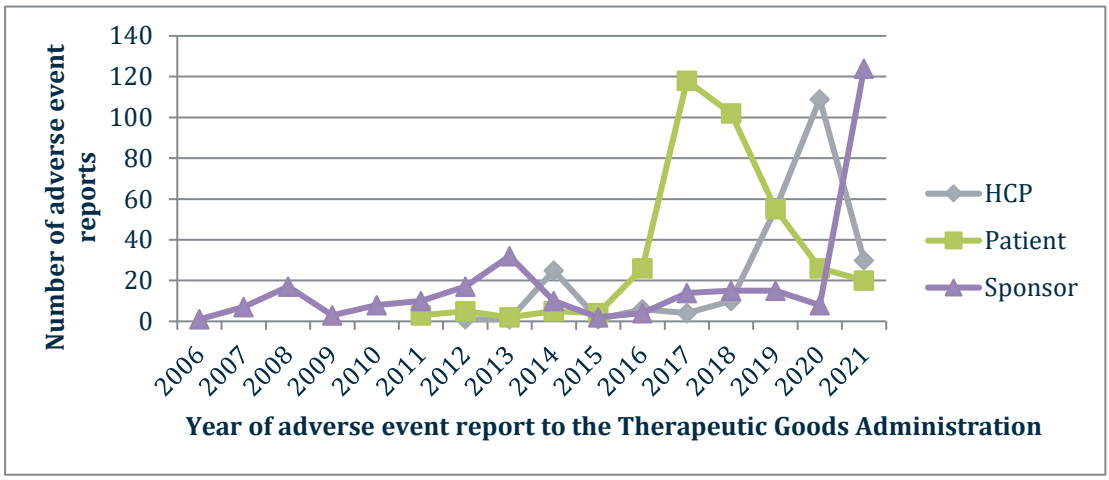

Figure 2. Source of adverse event reports for urogynaecological mesh associated harms, by sponsors fo medical devices, patients or their carers, or healthcare professionals (HCP).

A number of OECD countries have introduced mandatory reporting of medical device adverse events by health professionals, or healthcare facilities. However, for many of those countries the responsibility of reporting adverse events by the health professional is commonly undertaken by the healthcare facility that they are associated with, rather than resting with the individual. Mandatory reporting has been expanded beyond product manufacturers or sponsors by these countries in order to achieve the following objectives:

- timely signal detection of medical device adverse events as they occur;
- better identification of rarer events and potentially emerging issues across the country;
- earlier investigations and/or actions to address safety concerns by national regulators; and
- provision of more frequent information to health care providers about possible threats to patient and professional safety.

In addition, several countries actively compare adverse event reports received by health professionals or healthcare facilities with those reported by product manufacturers to monitor compliance with reporting requirements, and to ascertain and address potential gaps in reporting by different stakeholders.

In Australia, the introduction of mandatory reporting by healthcare facilities may enable the TGA to obtain a more rapid representation of issues associated with medical devices; understand a broader range of events that have occurred with specific medical devices (that may not be known or reported by product manufacturers); detect rarer events based upon more systematic reporting across the country; and take earlier actions to inform consumers and health professionals about current or emerging areas of concern.

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Questions:

- Should Australia introduce mandatory reporting for medical device related adverse events by healthcare facilities?
  - Why should Australia introduce mandatory reporting for medical device-related adverse events by healthcare facilities?

    or

  - Why should Australia not introduce mandatory reporting for medical device-related adverse events by healthcare facilities?
- Can you identify any unintended consequences of introducing mandatory reporting of adverse events by healthcare facilities?

2. Facilities that could be included and/or excluded from mandatory reporting

Key considerations:

- Mandatory reporting has been introduced overseas for public, private, and not-for-profit healthcare facilities. The facilities included share similar characteristics:
  - they are frequent users of a range of medical devices;
  - they provide services to highly dependent or vulnerable people (e.g., nursing home residents); and/or
  - they use medical devices that can cause significant harm to patients or other users if they fail or malfunction (e.g., implanted devices, diagnostic equipment, use of ionising radiation).
- In these jurisdictions exclusions from mandatory reporting have been applied to clinical practices (e.g., physicians' rooms) to minimise any additional regulatory burden upon individual health practitioners.
- Australia has differences in clinical practice to some other jurisdictions, such as device procedures being undertaken in physicians' rooms.
- If mandatory reporting for healthcare facilities was to be introduced in Australia, decisions regarding which healthcare facilities are included and those that are excluded would need to be determined.
- If agreed, a legal mechanism to implement mandatory reporting would need to be identified, such as amendments to the *Therapeutic Good Act 1989* and/or licencing or accreditation schemes.

In jurisdictions where mandatory reporting requirements for healthcare facilities have been introduced, there have been clear definitions about who is included and excluded from reporting requirements.

- In the USA, mandatory reporting applies to hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, that are *not physicians' offices*.
- In Canada, mandatory reporting applies to all hospitals and outpatient clinics that are part of a hospital but *excluded private clinics or long-term care facilities (such as nursing homes)*. It is worth noting that the proportion of private healthcare is minimal in Canada.

Currently, the laws in Australia that relate to the mandatory reporting of adverse events by sponsors and manufacturers of medical devices do not extend to healthcare facilities. Therefore, if mandatory reporting by healthcare facilities were to be introduced in Australia, one option would be to amend the *Therapeutic Goods Act 1989*. See further below.

Furthermore, if Australia were to introduce mandatory reporting of adverse events for healthcare facilities, it is critical to define which facilities would be included or made exempt. One proposal might be to include healthcare facilities that are accredited under existing national schemes. For example, hospitals accredited to the National Safety and Quality Health Service Standards, or residential aged care services accredited by the Aged Care Quality and Safety Commission. Consideration may also need to be given to relevant state and territory legislation and health service registration and/or licencing requirements that may assist in defining relevant healthcare facilities[1].

Healthcare facilities that may be accredited through national schemes include:

- Public hospitals
- Private hospitals
- Day hospitals
- Diagnostic imaging services
- Day procedure clinics
- Pathology services
- Radiation oncology services
- Public/private residential aged care facilities

Further consideration is required to determine the inclusion of other healthcare services who are frequent users of medical devices, and where potential mandatory reporting of medical device-related adverse events would be a benefit to public health. Exemptions to mandatory reporting of medical device-related adverse events might apply to general practices, specialist medical practices, allied health practices, community-based ambulatory care clinics and community nursing services.

1. Other relevant State and Territory legislation, registration or licencing arrangements may include (subject to further consultation): the NSW *Health Services Act 1997*, *Private Health Facilities Act 2007* and *Private Health Facilities Regulation 2010*; the Victorian *Ambulance Service Act 1986*, *Health Services Act 1988* and *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002*; the Queensland *Ambulance Service Act 1991* and *Private Health Facilities Act 1999*; the South Australian *Health Care Act 2008* and *Health Care Regulations 2008*; the Western Australia *Hospitals and Health Services Act 1927*, the *Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987*, the *Hospitals and Health Services (Day Hospital Facility) Determination 2005*, and the *Hospitals and Health Services (Day Hospital Facility) Determination (No. 2) 2005*; the Tasmanian *Ambulance Service Act 1982*, *Health Organisations Act 2011* and *Health Service Act 2018*; the Northern Territory *Private Hospitals Act 2011* and *Private Hospitals and Nursing Homes Amendment Act 2011*; and the ACT *Public Health Act 1997* and *Emergencies Act 2004.*

Questions:

- Are there any healthcare facilities licensed/accredited through national schemes (listed in the discussion paper) that should not be included in any proposed mandatory reporting of medical device adverse event reports?
  - If so, why?
- Are there any other frequent users of medical devices that could potentially be included? Please select from the provided list or provide examples of other types of services:
  - Public and private ambulance services
  - Dental and orthodontic practices
  - Chiropractic practices (who conduct diagnostic imaging)
  - Pharmacy practices (who supply medical devices)
  - Non-medical specialist cosmetic procedure centres
  - Other residential care providers
  - General practices
  - Specialist medical practices
  - Allied health practices
  - Community-based health services (e.g., district nursing services)
  - Other (Please provide)
- Are you aware of a reporting, accreditation or licencing body that would be able to mandate potential mandatory reporting of medical device-related adverse events?
- Are you aware of any specific state and territory legislation, health service licencing or other requirements that would **prevent** potential mandatory reporting?

3. The type of medical device-related incidents or events that could be reported to the TGA

Key considerations:

- There are approximately 1.4 million medical devices approved for use across Australia.
- The TGA classifies and regulates devices according to the potential level of risk to consumers – with higher risk devices subject to more stringent levels of regulation (including monitoring and reporting of adverse events).
- Consumers and health professionals are largely unaware of specific TGA risk classifications assigned to different medical devices. They tend to focus on the impact of medical device-related problems upon patients or staff.
- In Australian healthcare facilities, there are multiple classification metrics applied to describe the severity and impact of adverse events.
- Whilst the different adverse event classification metrics are broadly comparable, further detail about the nature of medical devices may be required for any mandatory reporting.

Public and private healthcare facilities across Australia already collect detailed information about serious adverse events that occur to patients during their clinical care. Depending upon the private sector facility or the relevant state or territory government, these events are assigned an Incident Severity Rating (ISR), Harm Score (HS), or Severity Assessment Code (SAC) and are subject to detailed investigation and reporting.

The level of information relating to these events is comparable to the mandatory reporting requirements in overseas jurisdictions, which typically require:

- notification of any adverse event that has resulted in death or serious injury to consumers, professionals, or other individuals;
- reasonable grounds to suspect involvement of a medical device failure or deterioration in effectiveness (without the need for a reporter to demonstrate causality between the medical device and the adverse event).

Differences between information currently collected by Australian healthcare facilities and information required for medical device adverse event reporting for the TGA may relate to the level of detail about any suspected medical device.

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.

Questions:

- What type of medical device-related incidents or events do you consider should be reported through to the TGA?
  - Incidents resulting in death
  - Incidents resulting in serious injury
  - Near misses that could have resulted in death or serious injury
  - Issues identified during routine maintenance where the device is fixed or replaced prior to use
  - Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility
  - Other (please specify and provide reason)
- If you work in a healthcare facility, will the harm metrics that your healthcare facility utilises allow for identification of reportable incidents (including the types mentioned in the preceding question)?
- When an adverse event occurs, what medical device-related information is collected by facilities through incident or other information management systems?
  - The suspected involvement of a medical device
  - The brand/trade name of the medical device
  - Where the medical device came from (e.g. facility/health professional)
  - The current location of the medical device
  - Other (please specify)

4. Recognising and reporting events that might cause (or be causing) harm to consumers

Key considerations:

- Any potential mandatory reporting of medical device-related adverse events may need to include:
  - Patient symptoms that might have been caused by a medical device (and a reason for seeking medical attention)
  - Malfunctions that are identified before a device is used
  - Other problems with devices or consumables identified by clinical or maintenance staff.
- Information about potential or actual device malfunction may not be routinely collected by the current healthcare facility incident management systems. There may be a need to look more broadly across the facility for input into reporting.
- State and territory governments, healthcare facilities and health services may need to revise and update local incident management policies, procedures, and data management systems to collect information for any future mandatory reporting to the TGA.

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:

- incidents that have occurred outside of a hospital setting (e.g. malfunctioning of an implant);
- 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, faulty syringes, 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.

Questions:

- Do current reporting systems need to be improved to incorporate patient symptoms that might have been caused by a medical device?
  - If so, what needs to be improved?
- What level of patient symptoms should be flagged by healthcare facilities?
  - symptoms causing pain or discomfort
  - symptoms that cause impairment of function
  - symptoms that require additional medical care
- Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions?
  a. Issues identified during routine maintenance where the device is fixed or replaced prior to use:
     - Is this information recorded? If so,

       Where is this information recorded?
     - Is this information reported? If so,

       Who or where is this information reported to?

  b. Issues successfully managed by clinical staff e.g. near misses:
     - Is this information recorded? If so,

       Where is this information recorded?
     - Is this information reported? If so,

       Who is this information reported to?

  c. Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility:
     - Is this information recorded? If so,

       Where is this information recorded?
     - Is this information reported? If so,

       Who is this information reported to?

5. Reducing duplication of data entry and/or analysis by healthcare facilities

Key considerations:

- Any potential mandatory reporting should use existing IT systems that healthcare facilities currently have to collect patient, treatment, device, and incident information.
- In healthcare facilities, information, or data, currently collected across multiple systems may need to be integrated to facilitate potential mandatory reporting.
- Improved data integration would also enable more efficient information management, clinical workflows, and clinical governance activities within healthcare facilities.
- The TGA would need to develop a secure system for the transfer of information from healthcare facilities, in addition to maintaining ways for individual online reporting.

The potential mandatory capture and reporting of medical device-related adverse event information would assist healthcare facilities and jurisdictional health authorities in detecting early trends of concern regarding medical device safety. However, it is important that the systems used to report this data do not add additional unreasonable burden to facilities and avoids, where possible, duplication of data entry and/or analysis.

The least burdensome approach to potential mandatory reporting would be to make the best use of existing patient, treatment, device and incident data already collected by healthcare facilities, exploiting information captured in local incident information management systems, and in clinical management and other systems where convenient.

Preliminary consultations with Australian stakeholders identified that in the public health system, incident information management is dominated by three main software platforms, and private healthcare facilities may use a range of incident information systems. Whilst a diverse range of clinical systems are used to hold patient and treatment information, these systems commonly upload claims and other treatment information in standard formats. As such, it is possible that these standards and capabilities could be adapted and extended to meet potential mandatory reporting requirements. Additional device and incident information may also be available in other systems such as purchasing, inventory and maintenance systems, and workplace health and safety systems.

Whilst some facilities may need to integrate data from clinical, incident, or other separate systems, these changes may coincide with other initiatives and investments occurring to deliver health services in a digital economy including those being led by the Australian Digital Health Agency.

Reporting to the TGA could be facilitated using existing healthcare facilities' platforms to push selected data to the TGA. Alternatively, or in combination with, an electronic reporting mechanism developed within the TGA's existing adverse event reporting system that could

securely extract de-identified incident and other device-related information from existing healthcare facility information management systems. This approach could build upon data transfer arrangements developed between the TGA and state and territory health departments that are being used to report adverse reactions to COVID-19 vaccinations.

Consultation between the TGA, healthcare organisations, and with vendors regarding the ability to periodically batch-transmit adverse incidents in suitable standards and formats such as FHIR, XML or JSON, along with confirmation that authentication, privacy, confirmation and exception handling would need to occur.

In cases where legacy systems cannot easily upload in modern electronic formats, third party providers of system adaptors, currently in use for claims and clinical interoperability, could be consulted with to identify viable options and potential re-use of those system adapters.

At the same time, the TGA could maintain access to online web forms 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.

Questions:

- What platform/s does your organisation currently use (or provide, if you are a software vendor) to record medical device-related incidents, adverse events, potential incidents, or device failures (examples below)?
    - Patient 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
    - Other (please specify)
- Does the platform include the capability to generate or send reports or summaries of the incidents in standards and formats such as FHIR, XML or JSON?
- If a healthcare facility, do you already submit data to the TGA for COVID-19 vaccine reaction reporting?
- If you have more than one platform that records device incidents, are there issues with integrating current information systems?
- Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?
    - If so, please outline how this integration could occur, the potential costs and timeframes, and any potential blockers.
    - If not, could a system adaptor be utilised?
- If so, please outline which information systems would benefit from an adaptor, the potential costs and timeframes, and any potential blockers.
- If not, why?

6. Quality assurance of the incident information

Key considerations:

- Quality assurance of incident information may need to occur where minimum data requirements have not been completed (i.e. gaps in data).
- Mandatory reporting of medical device adverse events by healthcare facilities using integrated information management systems would streamline reporting processes.
- The time taken to follow up data gaps needs to be balanced with the burden and relative importance of the actual data gap to minimise the need for additional follow-up.
- There is potential to leverage existing staff for quality assurance activities who currently have reporting responsibilities as required by healthcare facility accreditation standards.

Reporting of incidents and adverse events, with quality assurance checks on minimum data sets, already occurs within many healthcare facilities. This reporting could be leveraged to minimise the burden of any potential mandatory reporting, with addition of jurisdictional and facility policy and procedures to integrate incident information with other sources of data relating to medical device failures and potentially suspicious patient symptoms.

Several European countries have staff in each healthcare facility who are responsible for co-ordinating and submitting medical device-related incident reports to the national regulator. Overseas regulators consider that this approach is one of the most significant facilitators of effective reporting by facilities and is similar to the role of the chief pharmacist within many Australian hospitals who reports medicine-related adverse events to the TGA.

In Australia, in addition to possible amendments to the *Therapeutic Goods Act 1989* to mandate medical device adverse event reporting, national accreditation standards might also be considered as a way of facilitating reporting of medical device adverse events. However, this action would require a number of steps in advance, including the states and territories establishing policies, agreements or regulation for health services to require submission of this information, and the TGA establishing the mechanisms for the collection and monitoring of the information. If an assessment of these actions indicated that implementation had not been successful or further measures were required, this could be a trigger for inclusion of requirements relating to medical devices in the National Safety and Quality Health Service (NSQHS) Standards, in a similar way to organisations being required to have reporting systems in place for adverse reactions in relation to medicines (Standard 4.09).

If this process occurred, the timing for the next version of the NSQHS Standards is for planning to commence in 2024, the standards to be released by 2027, with accreditation to a revised set of standards from 2029. However, the Australian Commission on Safety and Quality in Health Care (which sets the NSQHS Standards) could continue to work with the states and territories and the TGA, in the interim, to progress the underlying objective.

Questions:

- Is there a current minimum data set that is collected for adverse event/incident reporting?
  - If so, what does this data set consist of?
  - Does this currently undergo quality assurance checks?
  - If so, who is responsible for undertaking this check?
- Within healthcare facilities, which health professionals are responsible for reporting adverse events as part of their accreditation requirements?
  - Nurse manager
  - Quality and safety consultant
  - Clinical nurse specialist
  - Biomedical engineer
  - Clinician
  - Other (please specify)

7. Accountability for reporting of medical devices adverse events

Key considerations:

- In order to be meaningful, 'mandatory' reporting must have consequences for participants.
- There may be one or more existing regulatory frameworks that could be amended to implement mandatory reporting and provide sanctions for non-compliance. For example, the *Therapeutic Goods Act 1989*, national standards or accreditation schemes that provide a framework for accountability and compliance.
- Healthcare facilities could also promote their own participation in any potential mandatory reporting scheme as a measure of quality assurance for consumers or funding bodies.

Currently, the laws that relate to the mandatory reporting of adverse events by sponsors of medical devices do not extend to healthcare facilities. Without ruling out the possibility of other options, if mandatory reporting were to be introduced in Australia, one option could be to explore potential amendments to the *Therapeutic Goods Act 1989*. State or territory legislation/schemes may also require consideration.

In addition to legislation amendments, the NSQHS Standards could be leveraged in their next review to consider the potential inclusion of standards relating to mandatory reporting of medical device-related adverse events. This would be considered following any state and territory changes to regulation. This would be a way of utilising an existing framework to ensure accountability and ongoing participation by facilities in meeting their reporting obligations and failure to comply with standards could be addressed in the context of a facility seeking to maintain ongoing accreditation with respect to the standards.

In addition, individual healthcare facilities may wish to publicise their compliance with mandatory reporting as a testament of their ongoing commitment to quality assurance and patient safety.

Non-participation in future potential mandatory reporting could be subject to a range of measures applied by the relevant regulator consistent with their powers. Some overseas jurisdictions have published league tables outlining the level of participation or non-participation in mandatory reporting of medical devices (based upon case-mix adjusted, peer group comparisons over time). Others have implemented penalties or graded sanctions for under-reporting.

Questions:

- What existing legislative, accreditation or other mechanisms should be explored in relation to potential mandatory reporting and why?
- What type of compliance schemes do you consider would be appropriate to reinforce mandatory reporting?
  - Modification to current accreditation schemes
  - Organisational recognition and reward schemes
  - Risk-adjusted funding arrangements
  - Other incentives or penalties

What we invite you to do

In your submission, we ask you to consider the questions outlined above, and gathered below, and provide comments to those questions that you consider are relevant to your needs or interests.

CONSULTATION QUESTIONS (as listed above)

1. Potential introduction of mandatory reporting

- Should Australia introduce mandatory reporting for medical device-related adverse events by healthcare facilities?
  - Why should Australia introduce mandatory reporting for medical device-related adverse events by healthcare facilities?
  - Why should Australia not introduce mandatory reporting for medical device-related adverse events by healthcare facilities?
- Can you identify any unintended consequences of introducing mandatory reporting of adverse events by healthcare facilities?

2. Healthcare facilities that could be included or excluded

- Are there any healthcare facilities licensed/accredited through national schemes (listed in the discussion paper) that should not be included in any proposed mandatory reporting of medical device adverse event reports?
  - If so, why?
- Are there any other frequent users of medical devices that could potentially be included? Please select from the provided list or provide examples of other:
  - Public and private ambulance services
  - Dental and orthodontic practices
  - Chiropractic practices (who conduct diagnostic imaging)
  - Pharmacy practices (who supply medical devices)
  - Non-medical specialist cosmetic procedure centres
  - Other residential care providers
  - General practices
  - Specialist medical practices
  - Allied health practices
  - Community-based health services (e.g., district nursing services)
  - Other (Please provide)
- Are you aware of a reporting, accreditation or licencing body that would be able to mandate potential mandatory reporting of medical device- related adverse events?

- Are you aware of any specific state and territory legislation, health service licencing or other requirements that would **prevent** potential mandatory reporting?

3. Types of medical device incidents to report

- What type of medical device-related incidents or events do you consider should be reported through to the TGA?
  - Incidents resulting in death
  - Incidents resulting in serious injury
  - Near misses that could have resulted in death or serious injury
  - Issues identified during routine maintenance where the device is fixed or replaced prior to use
  - Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility
  - Other (please specify and provide reason)
- If you work in a healthcare facility, will the harm metrics that your healthcare facility utilises allow for identification of reportable incidents (including the types mentioned in the preceding question)?
- When an adverse event occurs, what medical device related information is collected by facilities through incident or other information management systems?
  - The suspected involvement of a medical device
  - The brand/trade name of the medical device
  - Where the medical device came from (e.g. facility/health professional)
  - The current location of the medical device
  - Other (please specify)

4. Recognising and reporting events that might cause (or be causing) harm

- Do current reporting systems need to be improved to incorporate patient symptoms that might have been caused by a medical device?
  - If so, what needs to be improved?
- What level of patient symptoms should be flagged by healthcare facilities?
  - symptoms causing pain or discomfort
  - symptoms that cause impairment of function
  - symptoms that require additional medical care
- Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions?
  a. Issues identified during routine maintenance where the device is fixed or replaced prior to use:
     - Is this information recorded? If so,

Where is this information recorded?

- Is this information reported? If so,

  Who or where is this information reported to?

b. Issues successfully managed by clinical staff e.g. near misses:

- Is this information recorded? If so,

  Where is this information recorded?

- Is this information reported? If so,

  Who is this information reported to?

c. Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility:

- Is this information recorded? If so,

  Where is this information recorded?

- Is this information reported? If so,

  Who is this information reported to?

5. Reducing duplication of data entry

- What platform/s does your organisation currently use (or provide, if you are a software vendor) to record medical device-related incidents, adverse events, potential incidents, or device failures (examples below)?
  - Patient 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
  - Other (please specify)
- Does the platform include the capability to generate or send reports or summaries of the incidents in standards and formats such as FHIR, XML or JSON?
- If a healthcare facility, do you already submit data to the TGA for COVID-19 vaccine reaction reporting?
- If you have more than one platform that records device incidents, are there issues with integrating current information systems?
- Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?
  - If so, please outline how this integration could occur, the potential costs and timeframes, and any potential blockers.
  - If not, could a system adaptor be utilised?

- If so, please outline which information systems would benefit from an adaptor, the potential costs and timeframes, and any potential blockers.
- If not, why?

6. Quality assurance of the incident information

- Is there a current minimum data set that is collected for adverse event/incident reporting?
  - If so, what does this data set consist of?
  - Does this currently undergo quality assurance checks?
  - If so, who is responsible for undertaking this check?
- Within healthcare facilities, which health professionals are responsible for reporting adverse events as part of their accreditation requirements?
  - Nurse manager
  - Quality and safety consultant
  - Clinical nurse specialist
  - Bio-medical engineer
  - Clinician
- Other (please specify)

7. Accountability for mandatory reporting

- What existing legislative, accreditation or other mechanisms should be explored in relation to potential mandatory reporting and why?
- What type of compliance schemes could be implemented to reinforce potential mandatory reporting?
  - Modification to current accreditation schemes
  - Organisational recognition and reward schemes
  - Risk-adjusted funding arrangements

How to submit

We invite you to complete our online survey for this consultation, addressing the questions posed in this paper, at the Department of Health's consultation hub (consultations.health.gov.au).

You can also submit feedback, whether this addresses the consultation questions, broader comments or both, directly to the TGA by email at: DeviceReforms@health.gov.au. If emailing your submission, **please ensure your submission is accompanied by a completed cover sheet** (template available on the consultation landing page).

This consultation closes on **December 13, 2021**

Enquiries

If you have any questions relating to this consultation or submissions please direct them to: DeviceReforms@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	MDPQD MDS Device Post Market Reform and Reviews Section	September 2021
V1.2	Updated to correct grammar and terms	MDPQD MDS Device Post Market Reform and Reviews Section	October 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #