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

Response

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

Question	Response
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?	Queensland Health gives **in-principle support** to the introduction of mandatory reporting of medical device-related adverse events by Australian healthcare facilities. **Areas requiring further consultation and clarification** However, further consultation and clarification are required in relation to potential barriers to/enablers of sustainable implementation and benefit. These include: • Existence of appropriate thresholds / inclusion and exclusion criteria for reporting, focusing on patient risk and consequences of the adverse event (rather than on medical device classification). • Agreement on core definitions (e.g. differentiation of a 'clinical incident' from a medical device fault/failure). • The potentially significant increase in the number and frequency of reports, and the relative benefit versus administrative burden anticipated from the volume of data. • Strategies to optimise data quality/completeness, while minimising administrative burden on frontline clinicians and health services and avoiding resource-/cost-intensive changes to ICT systems. • Training and resource requirements associated with system/process changes for frontline clinicians and reporting health services. • Whether existing/alternative systems are better suited to reporting certain kinds of adverse event, e.g. whether national device registries are more appropriate for reporting pain/discomfort over time post-implantation of an implantable medical device.

Question	Response
	• Implications of any failure to report, and how non-reporting or under-reporting would be identified and pursued in practice. Compliance-monitoring (for jurisdictions as well as for the TGA) would be a considerable task, and timeframes would need to be practicable for clinicians and health services. It is of use to reflect on the experience of AHPRA and the National Boards, and the reputational risks and patient safety implications of any failure to meet actionable timeframes with potentially litigable outcomes. Resourcing to support such systems must be appropriate. • The extent to which resultant national data will be visible to reporting health services and/or state and territory jurisdictions, e.g. to support trend-identification and comparison with local data; and whether access would be via the existing Database of Adverse Event Notifications - medical devices (DAEN) or an updated system. • Whether healthcare facility staff/clinicians require further information about legal considerations for reporting medical device related events. **Rationale for in-principle support** • Medical device-related adverse clinical events can have significant impact on individuals, communities, and the health system. • Support national post-market surveillance of medical device-related adverse events, with the potential for earlier identification of system-wide device faults/issues and timely information-sharing between states and territories • Provide national data for comparison by state/territory jurisdictions, and for cross-referencing of reports made by healthcare facilities and medical device sponsors/manufacturers. • Provide collateral information to help balance any perceived/actual conflict of interest and potential subjectivity that arises from sponsors'/manufacturers' responsibility to report their own devices.

Question	Response
	• Large numbers of innovative therapeutic devices are entering the market. While TGA assessment and approval processes are robust, the elimination of long-term issues/risks with devices is not certain.
Can you identify any unintended consequences of introducing mandatory reporting of adverse events by healthcare facilities?	Queensland Health has **concerns about the potential for unintended consequences** of introducing mandatory reporting by healthcare facilities of adverse events. These include (but are not limited to): • If not adequately resourced, the system may fail to achieve its principal objective of patient/community protection. • Administrative burden on frontline clinicians, healthcare facilities, and state/territory health systems. While healthcare facilities are proposed to be responsible for TGA reporting, frontline clinicians would remain responsible for local reporting to their facility. • Resource costs (time, funds, personnel, implementation) associated with any functional/technical enhancement of existing systems used by jurisdictions for recording adverse events (e.g. additional data fields or system configuration changes). • Administrative burden on the TGA could affect system capacity to detect issues and respond in a timely manner, in the context of high data volumes and potential variation in data quality/completeness. Without the introduction of a Unique Device Identifier (UDI) database, it will be difficult to triage and trend the volume of incoming information. • Broad/unclear inclusion criteria for reporting, or uncertainty among clinicians and healthcare facilities, could introduce a large volume of irrelevant but burdensome reports that are of low value to post-market surveillance (e.g. reports without likely causal relationship between a medical device and the adverse event; where the event is most attributable to user error; or where key identifying details of the medical device are not known).

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	• Potential inconsistency may arise from jurisdictions using differing adverse event classification systems. • Uncertain delineation of responsibility to investigate adverse events, including potential user error as opposed to device failure. • If resultant national data were made available via the existing DAEN, it may be under-utilised by healthcare facilities/jurisdictions due to challenges with the current DAEN user interface and search functionality. **Areas requiring further consultation and clarification** Further consultation is required to explore the range and detail of such potential consequences, including with reference to the issues flagged in the response above. During initial consultation, stakeholders flagged the need for further discussion about: • How adverse events involving the off-label use of medical devices would be classified/reported • The reporting obligations of healthcare facilities that sub-contract clinical services from an external practice, and the potential for duplication or omission of adverse event reports if this is unclear (E.g. If a residential aged care facility sub-contracts allied health services from a private clinic, would the aged care facility or the allied health practice report an adverse event?)
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

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

Question	Response
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?	Queensland Health has not identified any healthcare facilities accredited through national schemes that should not be included in the proposed reform for mandatory reporting. **Area requiring further consideration** • There is the potential for patients to present to healthcare facilities (e.g. General Practices) for an issue potentially related to a medical device (especially an implantable), key identifiers of which are not known to the facility. A two-tiered approach to reporting might be considered, e.g. incorporating efficient referral pathways to a facility that could confirm the issue and report to the TGA.
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 – **Consider including** beauty salons that provide laser treatments ☒Other residential care providers – **E.g.** residential aged care facilities; supported accommodation for people with a disability

Question	Response
	☒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?	**Mandatory national accreditation bodies for healthcare facilities** 1. Australian Commission for Safety and Quality in Health Care (ACSQHC), via a. National Safety and Quality Health Service (NSQHS) Standards b. National Safety and Quality Primary and Community Healthcare Standards 2. NDIS Quality and Safeguards Commission, e.g. via a. NDIS Practice Standards **Optional reporting/accreditation bodies for healthcare facilities**, e.g. 3. Australian Council on Healthcare Standards (ACHS) (accreditation), via a. EQuIP standards 4. Planetree (certification) 5. Magnet (hospital recognition) 6. DIAS accreditation (diagnostic imaging) Further investigation would be required to determine whether the regulatory functions of Radiation Health (Queensland), and requirements of the *Radiation Safety*

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	Act 1999 and the *Radiation Safety Regulation 2021*, may be able to mandate potential mandatory reporting of medical device-related adverse events (if relevant). Given that National Boards and the Australian Health Practitioner Regulation Agency (AHPRA) regulate individual health practitioners rather than healthcare facilities, it would be duplicative and less appropriate to involve such bodies in mandating actions at facility level.
Are you aware of any specific state and territory legislation, health service licencing or other requirements that would **prevent** potential mandatory reporting?	**Further consultation and clarification required** Before potential mandatory reporting could be considered in Queensland Health, it would be necessary to further investigate privacy and ICT requirements. Initial consultation has identified a need for changes to the state-wide incident reporting system, including: • De-identification, such as the removal of patient identifiers and reporter identifiers before exporting any data to the TGA • Data-linkage between medical device inventory systems and the incident reporting system. In its present configuration, the state-wide incident reporting system (potential source of data for exporting mandatory adverse event information to the TGA) would not contain sufficient medical device details.

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

Question	Response
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

Question	Response
	☒ 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)?	Queensland Health uses risk/harm metrics that define reportable incidents in accordance with current Hospital and Health Service and state-wide requirements. Using these metrics allows for the identification of incidents including the types mentioned in the preceding question. **Areas requiring further consultation and clarification** Initial consideration has identified a need for further consultation, including on (but not limited to) the points below. • The reporting system/data repository for device-related issues may vary according to context (e.g. whether a medical device issue was identified during patient care, detected via preventative maintenance, or identified during long-term patient follow-up and documented in a device registry). Information is recorded differently in each system. Further understanding of this complexity is required if data may potentially be exported to the TGA. • It would be necessary to clearly define near-miss inclusion/exclusion criteria, to maximise data quality/relevance and practicability of reporting. • Clear definition of each reporting criterion is required, including for consistency between medical device sponsor/manufacturer quality systems and healthcare facility systems.

Question	Response
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 – Level of detail varies in different systems ☐ Where the medical device came from (e.g. facility/health professional) ☐ The current location of the medical device ☒ Other (please specify) Identified/suspected harm attributed to the medical device and remedial action taken.

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

Question	Response
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?	A broad-ranging enhancement has been scoped and specified to augment the existing clinical incident reporting system. Queensland Health expects that it will include the essential content that would be required in a mandatory report. **Areas requiring further consultation and clarification** Initial consideration has identified a need for further consultation, including on (but not limited to) the points below. • Reporting longer-term symptoms following implantation of an implantable medical device requires further discussion, e.g. whether pain/discomfort associated with surgical mesh would be defined as a reportable symptom/adverse event for the purposes of the proposed scheme. • Consider linking to existing device registries, to avoid duplication. E.g. Clinicians/facilities would not be expected to report poor outcomes of a total hip replacement in the clinical incident reporting system, as this information is captured in the relevant device registry.

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What level of patient symptoms should be flagged by healthcare facilities?	☒Symptoms causing pain or discomfort – please see comment above ☒Symptoms that cause impairment of function ☒Symptoms that require additional medical care Other comments As above, consideration should be given to excluding implantable medical devices for which device registries already record patient outcomes. Consider mandatory reporting of implantable devices into relevant device registries.
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 the information recorded? • Is this information **reported**? If so, Who or where is this information reported to?	Given health system complexity, **further consultation is required** to confirm all details. Healthcare facilities' collection of information about potential or actual device malfunctions varies, depending on the role of the reporter and that of the personnel responding to the problem (e.g. biomedical engineer or clinician). The system in which the device details/issue is recorded also varies accordingly (e.g. clinicians reporting via the clinical incident reporting system, and engineers reporting via the medical equipment management system). This information is recorded by biomedical engineering and technical/medical device maintenance services, but in volumes that are too large to be feasibly reported and which would contribute only noise.

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b. Issues successfully managed by clinical staff e.g. near misses: • Is this information **recorded**? If so, Where is the information recorded? • Is this information **reported**? If so, Who or where is this information reported to?	There is scope for basic equipment information involved in near-miss incidents to be reported in the integrated incident management system. This functionality will be expanded via the planned clinical incident management system enhancement. **Areas requiring further consultation and clarification** As above, it would be necessary to clearly define near-miss inclusion/exclusion criteria, to maximise data quality/relevance and practicability of reporting.
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 the information recorded? • Is this information **reported**? If so, Who or where is this information reported to?	For medical device malfunctions that occur outside a hospital setting, there may be variation in the level of medical device detail recorded the incident reporting system. Further consultation is required to develop a comprehensive understanding of processes across the state. There is scope for basic device information to be reported in the integrated incident management system. This functionality will be expanded with the clinical incident management system enhancement.

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

Question	Response
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 as shown)?	☒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?	It is anticipated that the current integrated incident reporting system can handle any of these formats (FHIR, XML or JSON). The preferred format is JSON.
If you have more than one platform that records device incidents, are there issues with integrating current information systems?	Technical issues with information system-integration are inevitable, but can normally be resolved with consultation.
Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?	It is feasible that functionality could be added to the existing clinical incident reporting system, to format and send a subset of data. Such enhancement should not be at the cost of the State. **Further consultation required**

Question	Response
• 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?	Further consultation would be required to identify potential costs, timeframes, and barriers to implementation.
• If so, please outline which information systems would benefit from an adaptor, the potential costs and timeframes, and any potential blockers.	As above, it is feasible that the RiskMan clinical incident reporting system could be augmented with the functionality to format and export a subset of data. **Further consultation required** Further consultation would be required to identify potential costs, timeframes, and barriers to implementation.
• If not, why?	**Further consultation required** Consideration of a system adaptor has not been in scope for system enhancements already planned. It is a change that would need the vendor (RL-Datix) to implement. Cost is unknown at this time.

Topic 6: Quality assurance of the incident information

Question	Response
Is there a current minimum data set that is collected for adverse event/incident reporting?	There is a current minimum data set that is collected for adverse event/incident reporting.

Question	Response
• 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?	Each Hospital and Health Service is responsible for reporting, escalation and clinical governance processes that apply to information collected in the incident reporting system. The allocation of responsibilities to specific roles will vary according to the structure and reporting lines in different services.
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) Further investigation would be required to confirm professional accreditation requirements. All Hospital and Health Services are required to have a system for recording and managing clinical and staff/workplace-related adverse events. All currently use the State-purchased RiskMan system. All healthcare staff in Queensland have a mandatory responsibility to report SAC 1 clinical events. Other level events (SAC 2,3,4) are encouraged but not mandated, and may fall to the discretion of the clinician and the requirements of the Hospital and Health Service

Question	Response

Topic 7: Accountability for reporting of medical devices adverse events

Question	Response
What existing legislative, accreditation or other mechanisms should be explored in relation to potential mandatory reporting and why?	The National Safety and Quality Health Service (NSQHS) Standards drive the implementation of safety and quality systems and improvements in the quality of health care in Queensland Health services. Queensland Health Quality Improvement Frameworks could be used to support changes in practice around mandatory reporting if these were necessary. **Areas requiring further consideration** • In relation to dental healthcare facilities: While all public oral health services in Queensland are accredited, there is no mandatory requirement for accreditation of private dental practices. Accreditation-related requirements may therefore not achieve the level of compliance required. Should private dental practices be included in the mandatory scheme, an alternative leverage point would be required. The *Therapeutic Goods Act 1989* (Cwth) or jurisdictional legislative options may prove more applicable. • Accreditation requirements for other private services/disciplines would require further investigation to confirm. • Clearly articulating the benefit to patients, clinicians and healthcare facilities, and avoiding any duplicated/unnecessary administrative burden, would be central to implementation and ongoing engagement. If the reporting system were difficult or time-consuming to use, this would pose a barrier to consistent adoption.

Question	Response
What type of compliance schemes do you consider would be appropriate to reinforce mandatory reporting?	☒Modification to current accreditation schemes – Consider whether requiring a standardised approach to reporting processes/frameworks would be feasible and appropriate ☐Organisational recognition and reward schemes ☐Risk-adjusted funding arrangements ☐Other incentives or penalties