AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | ama@ama.com.au
W | www.ama.com.au
39 Brisbane Ave Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission to the Therapeutic Goods Administration – Potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia

devicereforms@health.gov.au

Introduction

The AMA supports a comprehensive product vigilance system in line with international best practice, and the development of proactive product vigilance strategies that improve data linkage and enhance the robustness of post market surveillance processes.

Adverse medical device events are in themselves significant public health problems. The AMA supports improvements to adverse medical device event reporting systems. To reduce the risk of adverse events associated with medical devices, post-market monitoring must occur from the time a medicine or medical device first comes to market, complemented by the TGA's early warning system.

The TGA needs to be appropriately funded and resourced to ensure the safety of the system is maintained.

Introducing mandatory reporting by healthcare facilities

The AMA supports in principle mandatory reporting by healthcare facilities.

The AMA agrees that certain healthcare facilities should be excluded from mandatory reporting. Characteristics of healthcare facilities who are subject to mandatory reporting should include facilities that are frequent users of medical devices. Mandatory reporting for residential aged care facilities (RACFs) may provide no or only marginal benefit given the lack of clinical involvement and because aged care providers are not set up to do this. This would require the establishment of new systems and processes. This must be considered in the context of a report already being made through another avenue. The AMA agrees that medical practices in Australia would not have the capacity or resources to conduct mandatory reporting and should be excluded. The most appropriate healthcare facility for mandatory reporting would be private and public hospitals.

A phased approach may be warranted to introduce mandatory reporting by healthcare facilities. It could be trialled by public and private hospitals and then if appropriate move to include facilities such as day hospitals, diagnostic imaging, and pathology services. The TGA should review the success of adverse event reporting within a specified timeframe after its implementation to ensure it is fit for purpose.

The exclusions and inclusions for mandatory reporting must be clear. State, Territory, and Federal governments should consider a scoping review before implementation to ensure appropriate resources are available to included healthcare facilities to carry out this important work.

While there may be exclusions for mandatory reporting, it is still important for the TGA to encourage voluntary reporting. Reporting needs to be as clear and simple as possible to reduce administrative burden on healthcare facilities and patients. It may be useful to publicly campaign again to raise awareness of the TGA's adverse event reporting, including examples of adverse events, due to the last campaign's success in increasing reporting.

Types of medical device incidents to report

The AMA understands that the TGA has recently consulted on proposed enhancements to adverse event reporting in 2020. One problem identified by the TGA was that definitions could be misinterpreted and that there was international inconsistency of definitions. The AMA agrees that Australia should change its definitions for various adverse events to align with the European Union Regulation on Medical Devices (2017/745). This will ensure definitions are clear and consistent. The AMA understands that current reporting exemption rules for sponsors can be misinterpreted,[1] potentially resulting in a lower quantity of reports to the TGA.

The AMA considers that mandatory reporting should include incidents resulting in death, serious injury, and near misses that could result in death or serious injury. This would include anything picked up during routine maintenance. The location where the incident occurred (e.g. outside a hospital setting) should not influence the decision to report – if there is an incident that is picked up by the healthcare facility, it should be reported.

Reducing duplication of data entry

The AMA supports interoperability between software systems so data are not duplicated and administrative burden is reduced. There are several examples where clinical software systems sync with government systems to automatically upload patient data, such as the National Cancer Screening Register and the My Health Record. Where appropriate, a similar approach should be considered for reporting adverse events to the TGA. There should be space available for additional comments to ensure reporting does not become a tick-box exercise and all important information is captured. Patient privacy and informed consent will be important for healthcare facilities to establish before reporting to the TGA.

[1] Therapeutic Goods Administration (2020) *Proposed enhancements to adverse event reporting for medical devices: consultation paper.*

In addition to the scoping review to identify appropriate resources for included healthcare facilities, the levels of jurisdiction should also review what data are already collected by healthcare facilities and how this varies across jurisdictions and facilities to identify gaps.

The government-funded Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) assesses prosthesis performance and may refer issues to the TGA. It will be important for the TGA to consult with the AOANJRR to determine important data collection points and also to ensure that there is no duplication of reporting that will increase administrative burden on healthcare facilities unnecessarily.

Quality assurance of the incident information

The TGA will need to review the kind of information that is currently collected at the facility level with public and private healthcare facilities to determine current information gaps.

Accountability for mandatory reporting

The TGA will need to consider the following:

- Timeframes for reporting that are in line with the seriousness of the adverse event, that are reasonable based on the complexity of the administrative task. This includes timing for initial and final adverse event reporting such as those required of sponsors.
- Any consequences for failing to report should be phased in with adequate communication to healthcare facilities.
- Depending on the amount of information required by the TGA, healthcare facilities may need to hire an additional staff member. This should be reflected in government funding to ensure that the costs of hiring an additional staff member are not passed on to patients.

The AMA believes that mandatory reporting should only be regulated once through the TGA. Healthcare facilities will certainly require governance processes to be able to monitor and report adverse events. This is already mentioned in the Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service (NSQHS), however the focus is currently on medication safety when medical devices should also be mentioned.[2]

Conclusion

The AMA supports, in principle, the mandatory reporting of medical device adverse events by those healthcare facilities that are capable of doing so and where a demonstrable benefit exists. Healthcare facilities that are frequent users of medical devices, such as hospitals, should be included in mandatory reporting, while medical practices and RACFs should be exempt. The TGA must ensure that adverse event reporting comes with clear definitions, and that regulatory and administrative burden is minimised. Included healthcare facilities must be adequately resourced and supported to carry out mandatory reporting.

[2] Australian Commission on Safety and Quality in Health Care (2021) *The NSQHS Standards.*

December 2021

Contact

Hannah Wigley
Senior Policy Adviser
hwigley@ama.com.au