Healthscope submission:

Discussion paper on potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia

13 December 2021

Healthscope

Healthscope thanks the Therapeutic Goods Administration (TGA) for the opportunity to provide feedback on the discussion paper on potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia.

Introduction and context

Healthscope operates 42 hospitals across Australia, across all states and territories. We are passionate about providing safe, high-quality care for our patients, and we champion openness and transparency in all aspects of health.

We therefore appreciate the Australian Government's undertaking of reform to improve the safety, performance and quality of medical devices and to improve health outcomes for patients.

Our submission below wishes to make the following points:

- We support transparency
- We think a broad reporting regime as is proposed will impose undue burden with limited upside relative to the current reporting regime
- If the Therapeutic Goods Association (TGA) decides to go ahead with mandatory reporting, there should be a significant materiality threshold, similar to other mandatory reporting regimes (such as the Mandatory Data Breach Reporting for Privacy), and limit to:
    - incidents resulting in an unexpected death or serious injury to a patient, and
    - incidents where the medical device has been demonstrated or is highly suspected to have caused the death or serious injury.

We also ask the TGA to note the current fiscal and operating environment of private hospitals. There are a number of concurrent regulatory and policy reforms underway directly affecting private hospitals. These include the Medicare Benefits Schedule review, private health insurance reform and Prostheses List reform, all of which are adding risk and administrative burden to private hospitals. Australia is also living through a once-in-a-lifetime pandemic. All of these factors make another level of onerous regulation difficult and costly to implement at this time.

Discussion paper questions

Below, we have addressed the consultation questions where appropriate. Where Healthscope is not providing a response, the question has been omitted.

Should Australia introduce mandatory reporting for medical device related adverse events by healthcare facilities? – Why/why not?

Healthscope does not agree Australia should introduce mandatory reporting for healthcare facilities on device-related adverse events. The reasons for this position are;

- Mandatory reporting by healthcare facilities is not commonly required around the world and is not necessarily best practice
- Mandatory reporting by healthcare facilities is not in our view the most efficient way to address adverse events caused by medical devices
- Mandatory reporting by healthcare facilities adds unnecessary administrative and financial burden to healthcare facilities.

As noted in the discussion paper, most other Organisation for Economic Co-operation and Development (OECD) countries do not implement similar reporting standards, apart from Canada

and the United States, where 'suspicious' events need to be reported. In fact, the current reporting structure in Australia relies on the device manufacturer/ supplier to report adverse events. Most other countries have not moved to introducing mandatory reporting for healthcare facilities.

However, the discussion paper outlines the limitations of the Australian system and notes:

> 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. (p7)

Healthscope contends the primary approach here should therefore be not to widen the mandatory reporting, but to improve the existing system in Australia.

Manufacturers/ suppliers have existing reporting structures in place, and we contend it would also be in their interest to know when adverse events have happened as a result of one of their products in a timely manner. In other words, the focus should be on how to ensure manufacturers/ suppliers are better informed outcomes and adverse events resulting from their products, and thereby allowing them to report these where necessary to the Therapeutic Goods Association (TGA).

We note the TGA is introducing requirements around Product Information Leaflets (PIL) and Patient Information Cards (PIC) this month (December 2021), and we suggest these could include information for the patient and healthcare provider on what to do in the case of an adverse event. They should describe what an adverse event is, and what steps can be taken to report these, and to whom. Improving the current system will be more efficient than to introduce new requirements into the healthcare system.

We also note additional reporting requirement will be burdensome and costly on our hospitals. At best, we may have one, sometimes two, person(s) on staff who this reporting will fall to, unlike the public sector which has larger teams to track and report these types of compliance and reporting. We therefore believe improving existing reporting structures will be more cost effective than adding new ones.

Can you identify any unintended consequences of introducing mandatory reporting of adverse events by healthcare facilities?

Healthscope can foresee a number of unintended consequences with this suggested change to reporting requirements. Any change in reporting requirements of this nature will have cost implications.

- If the device manufacturer/ supplier is required to provide higher levels of post-implantation support/ follow up to patients to be able to adequately report adverse events, the cost of devices is likely to increase.
- If healthcare facilities are mandated to report, necessary resource allocation will mean higher cost of healthcare. In public hospitals, this will mean higher healthcare costs, which will mean more tax dollars allocated to healthcare provision. In the private sector, this will mean further pressure on private health insurers, which ultimately will lead to higher premiums for consumers.

In the private sector, other complicated scenarios could also occur;

- An admission for a patient with private health insurance who has a medical device implanted in one location, yet adverse events are discovered at another hospital:
    - Who will be the mandatory party to report?

- Will private health insurers refuse payment to the second hospital, who then needs to seek payment from the first hospital/ healthcare provider?

Overall, the added administrative and financial burden will be disproportionate in the private sector.

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?

While we do not agree the mandatory reporting requirement should be expanded, the Australian National Safety and Quality Health Service Standards (National Standards) and our contractual arrangements with private health insurers require private hospitals to report appropriately to existing regulation and legislation. No further bodies will be required to mandate reporting.

We also note the Prostheses List Advisory Committee (PLAC) has a role in approving medical devices in Australia, and reporting (by manufacturers/ suppliers) could be managed though them.

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

Further to the above, in New South Wales we are also required to report to the TGA under their regulation of the health sector, see the *Private Health Facilities Regulation 2017*.

What type of medical device-related incidents or events do you consider should be reported through to the TGA?

As noted, Healthscope maintains manufacturers/ suppliers should be enabled to improve their reporting to the TGA, rather than extending the current requirement for mandatory reporting.

Should the TGA extend mandatory reporting to healthcare facilities, we believe the type of incidents necessitating mandatory reporting should be limited to:

- incidents resulting in unexpected death of or resulting in serious injury to a patient, and
- incidents where the medical device has been demonstrated or is highly suspected to have caused the death or serious injury.

The TGA may wish to consider facilitating voluntary reporting of other types of incidences under this reporting structure.

Should the TGA extend mandatory reporting to healthcare facilities, we also suggest the onus of reporting should be equally on the device manufacturer as the healthcare facility.

If you work in a healthcare facility, will the harm metrics that your healthcare facility utilises allow for identification of reportable incidents?

All our hospitals manage harm metrics through a software called RiskMan.

Further to the software, we also have an up to date reportable events policy by which all of our hospitals are required to adhere.

When an adverse event occurs, what medical device-related information is collected by facilities through incident or other information management systems?

Healthscope stores information on all medical devices used within our facilities. These data include

- name of device
- name of manufacturer
- serial and batch number of the device.

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?

Healthscope already has processes in place to record adverse outcomes, and typically, incident management systems would include information on injuries and complications.

What level of patient symptoms should be flagged by healthcare facilities?

As mentioned above, we do not support expansion of mandatory reporting.

Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions?

- Issues identified during routine maintenance where the device is fixed or replaced prior to use:

Yes, all reports of maintenance highlight issues to be fixed with a device. These reports are collected and kept by biomedical engineering.

It is worth noting biomedical engineering across our network are provided by a combination of the device manufacturer and ourselves, and at some sites, these are contracted services.

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

There is capability of recording and reporting these issues through incident management systems.

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

There are circumstances where another hospital or a healthcare provider might tell us about an adverse event.

However, if an incident takes place outside of a healthcare setting, we may never find out, or only if it resulted in death or a serious injury.

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?

RiskMan

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?

We can produce reports in validated PDF only.

If a healthcare facility, do you already submit data to the TGA for COVID-19 vaccine reaction reporting?

We do not administer a large amount of COVID-19 vaccines, apart from at Knox Private Hospital in Victoria. We are aware, and comply with, our responsibility of reporting COVID reactions.

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?

Locally within Healthscope we have a standardised reporting requirements for all 42 of our hospitals, including local policies outlining incidence reporting requirements. This is a multi-tier review process of incidents.

Please note, however, this is not standardised across the private sector, nor is there a national minimum data set for this reporting.

Within healthcare facilities, which health professionals are responsible for reporting adverse events as part of their accreditation requirements?

At Healthcsope, all clinicians working within our hospitals have the responsibility to report adverse events to our hospital administration.

What existing legislative, accreditation or other mechanisms should be explored in relation to potential mandatory reporting and why?

Until the TGA reach a position on mandatory reporting on medical device-related adverse events for healthcare facilities, it is difficult to determine which legislation, accreditation or other mechanisms would be suitable to apply.

Summary

In summary, Healthscope supports transparency, so long as the cost of the transparency is reasonable. We think a broad reporting regime will impose undue burden with limited upside relative to current regime.

If the TGA proceeds to implement mandatory reporting of medical device-related adverse events for healthcare settings, there should be a significant materiality threshold, limit mandatory reporting to:

- incidents resulting in an unexpected death or in serious injury to a patient, and
- incidents where the medical device has been demonstrated or is highly suspected to have caused the death or serious injury.