Consumers Health Forum of Australia

SUBMISSION

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

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Consumers Health Forum of Australia (2021) *Submission to the TGA Consultation: Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia.* Canberra, Australia

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Overview

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA conducted this consultation as part of the reform program.

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.

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.

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. This consultation looked to investigate the potential benefits and challenges of mandatory reporting of medical device related adverse events by healthcare facilities in Australia.

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs, including health-based research. We have over 250 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community. We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest. CHF is pleased to make this submission in response to this TGA Consultation on enhancing medical device adverse event reporting.

Note that this consultation was administered as an online survey and this document has been adapted from the CHF submission to that survey.

CHF Submission to online questions

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

1. Should Australia introduce mandatory reporting for medical device related adverse events by healthcare facilities?

Yes.

As articulated in the consultation paper the current system is not ensuring that adverse events are reported to the TGA, with many consumers suffering from adverse events that do not reach the regulator. This means the TGA does not have accurate or complete information regarding the effects of medical devices in order to properly assess whether the device is safe and effective for usage in Australia. Not having strong certainty that the vast majority of adverse events are reported to the TGA fundamentally undercuts the entire basis of our current post-market surveillance system. Given this, mandatory reporting is clearly a long overdue function that should be implemented.

Additionally, while beyond the scope of this paper, this mandatory reporting of adverse events should be extended to all therapeutic goods; not just medical devices.

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

One unintended consequence could be duplicate reporting for the same adverse event where a person has to see multiple health professionals to get treatment and they all report the same device's adverse event. However on balance, we view overreporting to be the lesser evil compared to the current underreporting and believe a well-designed reporting tool could minimise this occurring. Additionally these 'duplicate" reports will allow for the impact and effects of the faulty device to be more precisely gauged and for any non-reporting to be detected.

We note that one concern around mandatory reporting could be that health facilities have to divert resources from treating patients to completing this additional administration. We would counter this by observing that more reporting of adverse events would lead to adverse event causing devices being removed from market sooner, leading to a reduction of people needing medical attention for this purpose.

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

3. 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?

- ○ Yes
- ◉ No

4. 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)

Any healthcare provider/facility who will or might encounter an adverse event that is caused or is plausibly caused by a medical device should be required to report that adverse event to the TGA.

5. 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?

- ○ Yes
- ◉ No

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

- ○ Yes
- ◉ No

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

7. What type of medical device-related incidents or events do you consider should be reported through to the TGA? Select all that apply

- ☑ 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)

Notable negative effects or side effects that are not known to be caused by the medical device as per the ARTG listing, so that the TGA can include this information in its post-market surveillance of the medical device.

8. 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)?

N/A

9. When an adverse event occurs, what medical device-related information is collected by facilities through incident or other information management systems? Select all that apply Regulations? If yes, what definition do you propose for the meaning of this term?

- ☑ 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)

Additionally we would add:

1) How long the medical device has been in use.
2) If the person has seen other health providers who may /should have also reported the adverse event caused by the device

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

10. Do current reporting systems need to be improved to incorporate patient symptoms that might have been caused by a medical device?

- (•) Yes
- ( ) No

If 'Yes', what needs to be improved?

If the current reporting systems don't include patient symptoms, as implied by this question, then those systems need to be improved to include reporting on the symptoms. Patient symptoms would seem to be self-evidently required to understand what the adverse event was.

11. What level of patient symptoms should be flagged by healthcare facilities? Select all that apply

- [x] symptoms causing pain or discomfort
- [x] symptoms that cause impairment of function
- [x] symptoms that require additional medical care

12.

a. 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
- ( ) No

N/A

Is this information recorded?

- Yes
- No

N/A

Where is this information recorded?

N/A

Is this information reported?

- Yes
- No

N/A

Who or where is this information reported to?

N/A

b. Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions? - Issues successfully managed by clinical staff e.g. near misses:

- Yes
- No

N/A

Is this information recorded?

- Yes
- No

N/A

Where is this information recorded?

N/A

Is this information reported?

- Yes
- No

N/A

Who or where is this information reported to?

N/A

c. Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions? - Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility:

- Yes
- No

N/A

Is this information recorded?

- Yes
- No

N/A

Where is this information recorded?

N/A

Is this information reported?

- Yes
- No

N/A

Who or where is this information reported to?

N/A

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

13. 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)? Select all that apply

- [ ] 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)

N/A

14. 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?

- ( ) Yes
- ( ) No

N/A

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

- Yes
- No

N/A

16. If you have more than one platform that records device incidents, are there issues with integrating current information systems?

- Yes
- No

N/A

17. Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?

- Yes
- No

N/A

If 'Yes', please outline how this integration could occur, the potential costs and timeframes, and any potential blockers.
N/A

If 'Yes', please outline how this integration could occur, the potential costs and timeframes, and any potential blockers.
N/A

If 'No', could a system adaptor be utilised?

- Yes
- No

N/A

If 'Yes', please outline which information systems would benefit from an adaptor, the potential costs and timeframes, and any potential blockers.

N/A

If 'No', why?

N/A

Section 6- Quality assurance of the incident information

18. Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?

- ○ Yes
- ○ No

If 'Yes', what does this data set consist of?

Not to our knowledge, but we imagine that the current minimum dataset would be dictated by what the current TGA Adverse Event Reporting form is on the TGA website.

Does this currently undergo quality assurance checks?

- ○ Yes
- ○ No

If 'Yes', who is responsible for undertaking this check?

Again, not to our knowledge beyond whatever investigation processes the TGA follow when responding to adverse event reports it receives.

19. Within healthcare facilities, which health professionals are responsible for reporting adverse events as part of their accreditation requirements? Select all that apply

- ☐ Nurse manager
- ☐ Quality and safety consultant
- ☐ Clinical nurse specialist
- ☐ Biomedical engineer
- ☐ Clinician
- ☐ Other (please specify)

N/A

Section 7- Accountability for reporting of medical devices adverse events

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

We are not sure which ones exist currently, but in our view any that do our could exist should be leveraged to ensure the TGA can be certain the overwhelming majority of adverse events are reported to it.

Broadly this question appears to be asking "What tool should we be using to make healthcare facilities do this", in which case we would presume it varies depending on what the specific facility is e.g. State Accreditation process for hospitals/secondary health facilities, Commonwealth funding agreements for primary care facilities, professional body qualification/accreditation for individual profession types, AHPRA regulations etc.

21. What type of compliance schemes do you consider would be appropriate to reinforce mandatory reporting? Select all that apply

- ☑ Modification to current accreditation schemes
- ☑ Organisational recognition and reward schemes
- ☑ Risk-adjusted funding arrangements