HealthCare Consumers

[redacted]

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

Background

The Health Care Consumers' Association (HCCA) is a health promotion agency and the peak consumer advocacy organisation in the Canberra region. HCCA provides a voice for consumers on local health issues and provides opportunities for health care consumers to participate in all levels of health service planning, policy development and decision making.

HCCA involves consumers through:

- consumer representation and consumer and community consultations;
- training in health rights and navigating the health system;
- community forums and information sessions about health services; and
- research into consumer experience of human services.

Thank you for the opportunity for HCCA to provide comment to the Therapeutic Goods Administration (TGA) on the *Discussion paper on potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia*. In developing this submission, we contacted a number of HCCA's consumer reference groups to seek consumer input.

1. General Comments

Overall HCCA supports the TGA's proposal for mandatory reporting of medical device adverse events by healthcare facilities in Australia. We support a culture of reporting and accountability for patient care throughout our health care services. The National Safety and Quality Health Service Standards outline in Action 1.11 that:

> *Incident reporting can improve safety (especially when it is based on a cycle of quality improvement), improve care processes, change the way clinicians think about risk and raise awareness of good practice. The nature of the risks faced by organisations varies according to the type of organisation and the context of service delivery. This highlights the importance of evaluating the effectiveness of incident management and investigation systems at the local level[1].*

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Reporting of adverse events, including through clinical incident management systems, forms part of continuous quality improvement processes in our health services.

In terms of the Australian Charter for Health Care Rights, this proposal relates specifically to the consumer rights of safety, information and giving feedback[2]. This includes for consumers to:

- Receive safe and high-quality health care that meets national standards
- Be told if something has gone wrong during my health care, how it happened, how it may affect me and what is being done to make care safe
- Share my experience and participate to improve the quality of care and health services

In this submission we have addressed consultation questions 1, 2, 3 and 4 from the Discussion paper. Consumer feedback on these issues appears in the sections below.

2. Specific Feedback

Consultation Question 1 - Potential introduction of mandatory reporting

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

Overall, the consumers we spoke with thought that mandating reporting by healthcare facilities was good, but not sufficient, in dealing medical device related adverse events. As the TGA website suggests, we can all play an important role in monitoring the safety and quality of therapeutic goods in Australia by reporting suspected adverse events[3].

There were suggestions that beyond healthcare facilities, individual practitioners should also be required to report. For instance, we know that:

> *"some of the specialty groups keep data on the different implants on registries, so that should be another group of people with a duty to report [medical device related adverse events"].*

In terms of the particular kinds of healthcare facilities that should report, this might depend on how 'medical devices' are defined, as well as what is considered to be a 'medical device related adverse event'. The definitions are very important and need to be well understood by stakeholders if mandatory reporting is to be introduced.

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

Consumers were concerned about the concept of obliging reporting and that it may result in less timely reporting:

"I think… it may result in late reporting. Most of the failures I am aware of aren't known until some time after eg vaginal mesh, the hip joints that caused a form of poisoning for people".

A number of COVID mandates have demonstrated there can be lessons to be learnt from mandates, and they can lead to unintended consequences. However, in the case of medical devices, it is also important not to allow unsafe procedures using medical devices that are unsafe.

Consumers also highlight the need for consumers to be able to report, in a similar way to being able to report adverse medicine events:

"It also seems to me, if we have late reporting then we probably need consumer reporting and we also need primary care and specialist to report, as people are likely either be aware of an issue first, then to a GP or a specialist, which given appointment delays can be quite a long time later... SO I don't think one single obligated source is sufficient - they need several sources all reporting"

"My other experience is that consumers must be able to report, because often doctors are too busy and don't, or they disregard the complaints of the consumer thinking that their concerns are in their mind".

Consultation Question 2 - Healthcare facilities that could be included or excluded

Consumers were pleased to see the suggestion for non-medical specialist cosmetic procedure centres to be included in the types of healthcare facilities. There is concern from consumers about limited regulation and the extent to which compliance is monitored and evaluated with safety and quality measures in these facilities.

It is also important to consider the role General Practitioners (GP) play as gate keepers of specialist health care. While mandatory reporting is an additional burden on already under-resourced GPs, they may be best placed to report on non-catastrophic device failure in a timely way. This also applies to specialist practices where consumers may be referred after presenting to their GP.

The opportunity to identify issues in a timely way to allow action to be taken to protect consumers may be lost if reporting is limited only to hospital style health services. It is possible that smaller health services may benefit from funding support for any additional administrative burden.

It is also important to include dentistry in any mandatory reporting regime. Oral health is vital to general health and dental devices (including implants) present some of the same risks as general medical devices.

Consultation Question 3 - Types of medical device incidents to report

Consumer feedback suggested a range of medical device incident reporting would be useful for identifying safety issues and trends. If the types of incidents that are required to be reported is too limited, then mandatory reporting may not be as useful for monitoring safety and quality of devices as it could be.

HCCA is of the view that all incidents which impact negatively on a consumers' quality of life or their health and safety should be included in any reporting mechanisms. However, it may be appropriate to differentiate the level of detail required for certain risk profiles.

Consultation Question 4 - Recognising and reporting events that might cause (or be causing) harm

As above, a range of patient symptoms should be flagged by healthcare facilities if there is a possibility that these might be caused by a medical device. This would include symptoms causing pain or discomfort, symptoms that cause impairment of function, and symptoms that require additional medical care.

A consumer mentioned the TGA's system for medicines and adverse event reporting:

> *"There is a system in place for reporting of medicine adverse events, but the reasoning is not well understood and it is likely well-underutilised and therefore not as effective as it could be for identifying trends in adverse events that need to be acted upon".*

We know that the reporting of adverse medicine events is likely under-reported, where events are documented in a patient's record but never report externally[4]. This could be due to time constraints, including the duplication of documentation, where technology has not yet made for a seamless workflow in this area. We would assume that the same reporting issues exist for reporting adverse events with medical devices as for medicines.

Consumers also asked:

> *"How closely will new technologies be monitored? It is important that these are monitored thoroughly. The governance at health facilities needs particular attention in relation to adherence to reporting".*

There need to be systems in place to ensure reporting does really happen in practice, with sanctions established for individual providers and for health services if the system is to be effective. It may be possible to achieve this, to some degree, through amendments to current health service accreditation processes.

3. Concluding Remarks

HCCA broadly supports the proposal to implement a mandatory reporting requirement for health services. The value of the program will lie in the ability of the TGA to harness the information received to act on device-based risks to consumers. The *Discussion paper on potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia* does not address the investigation and compliance activities the TGA may undertake in response to information obtained through mandatory reporting. There is value in collating this information only if there is scope to act decisively on red flags.

We are happy to discuss our submission further. Please contact me if you have any questions or require clarification.

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Policy Officer

Health Care Consumers' Association
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[1] ACSQHC – National Safety and Quality Health Service Standards https://www.safetyandquality.gov.au/sites/default/files/2021-05/national_safety_and_quality_health_service_nsqhs_standards_second_edition_-_updated_may_2021.pdf

[2] ACSQHC – Australian Charter for Healthcare Rights https://www.safetyandquality.gov.au/consumers/working-your-healthcare-provider/australian-charter-healthcare-rights

[3] TGA – Reporting Adverse Events https://www.tga.gov.au/reporting-adverse-events

[4] Hohl, Corinne M et al. "Why Clinicians Don't Report Adverse Drug Events: Qualitative Study." *JMIR public health and surveillance* vol. 4,1 e21. 27 Feb. 2018, doi:10.2196/publichealth.9282