Submission to the Therapeutic Goods Administration Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia Discussion Paper

The Royal Australian and New Zealand College of Radiologists (RANZCR) is committed to improving health outcomes for all, by educating and supporting clinical radiologists and radiation oncologists. RANZCR is dedicated to setting standards, professional training, assessment and accreditation, and advocating access to quality care in both professions to create healthier communities.
RANZCR creates a positive impact by driving change, focusing on the professional development of its members and advancing best practice health policy and advocacy, to enable better patient outcomes.
RANZCR members are critical to health services: radiation oncology is a vital component in the treatment of cancer; clinical radiology is central to the diagnosis and treatment of disease and injury.

RANZCR welcomes the opportunity to provide feedback on the potential for mandatory reporting by healthcare facilities. Overall, the College supports this proposal. Safe medication, devices and technology are necessary to ensure the best possible care for health consumers in Australia.

When considering adverse medical events, RANZCR considers it crucial to consider emerging as well as established technologies. Of particular note is the advancement of artificial intelligence devices in healthcare. Software devices are rapidly scalable (i.e. they can be deployed quickly across multiple systems), with the potential to impact the care of a large population of patients in a short space of time. This is particularly relevant for devices that are intended for screening for common conditions, due to the disproportionate effect they can have at the population level.

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

RANZCR supports the implementation of mandatory reporting for medical device related adverse events by healthcare facilities. Individual practitioners may not hold the necessary perspective to alert them to an adverse event, and thus reporting by an individual may not be plausible.

Mandatory reporting should also be implemented in a fashion that is as minimally disruptive as possible for clinicians and allied health professionals. Where possible, implementation should also limit impact and administrative burden upon the healthcare facility.

While mandatory reporting would provide a more accurate view of the performance of medical devices, it may prove difficult to determine if an adverse event is the direct result of a device malfunction, or if other factors have contributed. The potential multifactorial nature of adverse events is an additional reason why healthcare facilities with a range of internal expertise are best placed to undertake mandatory reporting, rather than individual healthcare workers.

Mandatory reporting may have unintended consequences if appropriate and robust investigative process are not applied. Some device manufactures may perceive a risk associated with unfounded device malfunctions and be dissuaded from developing and releasing devices in Australia.

Software as a Medical Device (SaMD) showcases the complexity in correctly diagnosing a device malfunction. Medical imaging AI applications are regulated under this category and if a misdiagnosis occurs, consideration needs to be undertaken as to whether this needs to be a reportable event.

Healthcare facilities that could be included or excluded

RANZCR believes that the strength of a mandatory reporting system relies on it being universal across different healthcare entities including public and private practice. Consideration must be given to a process that is deliverable by healthcare facilities of different sizes and complexity.

Types of medical device incidents to report

RANZCR supports the reporting of any device approved for use by the TGA.

Accountability for mandatory reporting

RANZCR supports an accountability framework for reporting of medical device adverse events. Appropriate standards such as those set by the National Safety and Quality Health Service (NSQHS) may represent an important component of this framework to support accountability of healthcare facilities. RANZCR has concerns regarding linking mandatory reporting to practitioner registration, as clinicians may not be aware of adverse events and therefore be are unable to report on them.

Yours sincerely

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