

Response to TGA Consultation - Medical device cyber security

28 January 2019

Health Consumers Alliance of South Australia (HCA)

HCA is the peak body for health consumers in South Australia. We are a member-based, independent, not-for-profit organisation, funded by SA Health. We work with consumers and health services to position consumers at the centre of care. Health consumers are people who use, or are potential users of health services, including their family and carers.

HCA's mission is to engage consumers and health services to achieve high quality, safe, consumer-centred care for all South Australians. We seek to promote and strengthen the voices, wellbeing, rights and leadership of health consumers.

We advocate that consumer engagement policy and practice is embedded across the SA health care system. This includes public, private and non-government health service providers.

We believe that consumer engagement results in better planning and policy-making. This leads to better health outcomes and community wellbeing.

Specific comments have been provided (tracked) within the draft document (refer second attachment in email). HCA has made two specific recommendations for inclusion in relation to strengthening the health literacy and consumer centred care language and process within the policy (below).

General Comments

HCA supports in principle, any and all practices that provide for increased safety and quality of healthcare for consumers. HCA notes and supports the premise of this document – that the TGA provide further guidance for manufacturers, sponsors, clinicians and consumers (patients) to minimise harm and improve systems that identify and reduce cyber security risk and vulnerability. In achieving this, consumers must be fully informed of the associated risks and safety practices, they should employ to minimise their own cyber vulnerability.

Consumer (patient) engagement has been considered critical to improving the quality of care provided by health care services.ⁱ Consumer complaints provide a valuable source of insight into safety and quality related problems within healthcare organisations.^{ii iii iv}

Consumers' perspectives are unique given their firsthand experience, at every stage of the care pathway. Consumers are legitimately positioned, through this experience, to evaluate the care and services received in terms of whether their care goals, needs and expectations have been met, and their assessment of their outcomes of care.^v

Consumers, providers, leaders, researchers and policy makers now agree that engaging consumers and families is essential to safe care. Fundamentally, consumers (patients) expect to be safe whilst receiving any and all healthcare (include use of medical devices). Evidence and practice increasingly show that consumer engagement is important to prevent patient safety incidents from occurring, respond to incidents, learn from and improve safety and quality of health care.

Consumers are experts in their own care and are experienced healthcare users as they;

- Are highly invested in their own health and wellbeing
- Are highly invested in achieving optimal health outcomes
- Are always present in their own care (even when impaired by factors beyond their control)
- Self-manage their own health and can directly act to improve their own health outcomes
- Are the constant across all health services, processes and care teams
- Know/recognise their own symptoms and how they respond to different treatments
- Are the first to feel when symptoms change
- Directly experience the impact of treatment/s (positive and negative)
- Can directly communicate these changes and outcomes to the care team
- Can articulate the experiences, needs and barriers unique to their community
- Can explain their needs, goals, priorities for their care
- Can inform health providers of their cultural and spiritual and religious customs, beliefs and values relevant to their health, family and care needs

Engaging with, and informing consumers who are recipients of medical devices requiring software and connectivity hardware should include;

- How to use the device safely to minimise risks/vulnerability of cyber security implications
- Clear plain language (and appropriate translated) instructions for connectivity of the device (eg required networks/apps etc)
- Long-term device maintenance (eg software updates, safety and appropriate software/recommended)
- Access to education and information about the device, why and how it manages information online, storing/accessing data online safely, maintaining/complying with updates, use of appropriate/recognised apps etc
- Guidelines and recommendations for creating an account and how to choose a secure passphrase (which may be best supported and facilitated by the clinician)
- Risks associated with use of devices requiring connectively (eg when a device is compromised including breach in patient data etc).

HCA recommends that development of a Consumer Guide - Medical Device Cyber Security, developed in consultation with consumers, that informs and supports consumers to maintain cyber security and minimise risk/vulnerability and include as a minimum;

- Notification/documentation of this information to the consumer (recipient) – at the time of consultation with their clinician
- Information about the device, be provided to the consumer (in a form accessible to them) prior to use/procedure of the;
 - Previous evaluation of risk of patient harm associated with a device
 - In the case of a cyber security risk and/or product alert - related to the device, consumers (recipients) be notified in a timely manner (specifically in relation to

device recalls either immediate or other ie recall, product defect correction, hazard alert, product defect alert).

- Risks associated with use of a specific device including options for alternative devices
- Information about what may constitute a cyber security risk (eg using non-recommended apps) and how to recognise them
- Information about how to access further information
- Public access to information, in a form accessible by consumers (the public) about all types of devices requiring/using online applications (ie plain language, accessible online portals (eg TGA website) and other formats, provision of information at health consultation etc
- Access to a central body for consumers to raise formal concerns, issues or queries (patient reported measures and experiences) in relation to a specific device that has been used in their treatment
- Particular consideration must be given to strategies to support consumers and community groups who may not have the learned skills and knowledge to effectively utilise their medical device technology (eg many older Australians, CALD communities, Aboriginal and Torres Strait Islander peoples and others).

Such a resource should be made available by;

- device manufacturers as part of their instructions and user information (including Consumer information on recommended medical device APPs)
- clinicians, as part of device information and education and decision-making and choices about suitable device
- TGA as part of strategy to inform consumers about medical device cyber security

ⁱ Pomey M-P, Hihat H, Khalifa M, Lebel P, Neron A, Dumez V, Patient partnerships in quality improvement of healthcare services: Patients' inputs and challenges faced (2015) Patient Experience Journal Vol 2 Issue 1 pp 29-42 <https://pxjournal.org/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1064&context=journal>

ⁱⁱ Donaldson L. An organisation with a memory: Learning from adverse events in the NHS. London: Department of Health, (2000)
http://webarchive.nationalarchives.gov.uk/20130105144251/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065086.pdf

ⁱⁱⁱ Bouwman R, Bomhoff M, Robben P, Patients perspectives on the role of their complaints in the regulatory process (2015) Health Expert
https://pure.uvt.nl/ws/portalfiles/portal/9694654/Bouwman_et_al_2015_Health_Expectations.pdf

^{iv} Seelos L, Adamson C, Redefining NHS Complaint Handling – The Real Challenge (1994) International Journal of Health Care Quality Assurance Vol 7 No 6 pp23-31
https://www.researchgate.net/publication/13158999_Redefining_NHS_Complaint_Handling_-_The_Real_Challenge

^v Doyle C, Lennox L, Bell D, A systematic review of evidence on the links between patient experience and clinical safety and effectiveness (2013) British Medical Journal Open
<https://bmjopen.bmj.com/content/bmjopen/3/1/e001570.full.pdf>