Response to TGA Consultation - Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

22 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

This consultation paper advocates that the UDI system is acknowledged by the industry and regulators as an effective means of ensuring timely access to complete, accurate and consistent information about medical devices. Given the benefits listed in the Consultation paper on pages 6 and 7, and the potential flow-on benefits to health consumers with medical devices, HCA agrees with the proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements.

It is noted that this system is already in place in the US (since 2013) and is progressing in the European Union (since 2017).

HCA supports in principle, any and all practices that provide for increased safety and quality of healthcare for consumers. HCA notes and supports the proposal to implement a system of UDI that is based on internationally harmonised principles as outlined in the IMDRF UDI Guidance and informed by the work done by the EU, the US FDA and other regulatory authorities (Consultation paper, page 8), to contribute to a higher level of safety protection worldwide.

Ideally, HCA supports the Australian UDI System be used for all medical devices, regardless of whether they are custom-made, and regardless of Class. The proposal acknowledges that, in the interests of patient safety, a rigorous and unambiguous system of device identification is essential.

HCA does not have a specific view on whether such a system would be best established and maintained by the TGA or another body but consumers would expect and require that the regulatory body and issuing Agencies should meet internationally agreed and accredited guidelines.

What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

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 a symptom changes
- 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

Therefore, informing consumers more about medical devices, including providing them with clear information about UDI systems, and robust evidence-based information about risks, benefits, incidents and adverse events, will ensure consumers are able to contribute effectively in informing the identified benefits of implementing a Udi system in Australia (as outlined in the proposal page 6).

HCA notes the identified benefits of implementing an UDI system in Australia and strongly emphasises that these benefits, whilst significant, fail to recognise (or include) the importance of, or requirement to, ensure consumers with medical devices are appropriately informed about their device.

To that end HCA recommends that establishment of an UDI System by the TGA should include the provision of mandatory;

- Notification/documentation of the device UDI to the consumer (recipient)
- Information about the device, be provided to the consumer (in a form accessible to them) prior to use/procedure of the;
    - Evidence of incidents/adverse events associated with the device (eg vaginal mesh) In the case of an incident or adverse event related to the medical device, consumers can be notified in a timely manner.
    - Risks associated with use of the specific device (eg evidence-based date on surgical errors) including options for alternative devices
    - Open disclosure by health practitioners/services of any 'kick-backs' or incentives received by the practitioner/service by using the device
    - Access to current research information
    - Public access to information, in a form accessible by consumers (the public) about all devices (ie plan language, accessible online portals (eg TGA website) and other formats, provision of information at health consultation etc
    - Access to a central body 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 (eg the UDI regulatory body).

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[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