Strengthening Practice - Implantable Medical Devices

Summary  This Information Bulletin summarises key developments in the area of implantable medical devices and outlines expected practice in NSW Health facilities.

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STRENGTHENING PRACTICE - IMPLANTABLE MEDICAL DEVICES

PURPOSE
Implantable medical devices are commonly and increasingly used as part of clinical practice across a wide range of disciplines. While there are important health benefits that can be derived from implantable devices, there are also important patient safety considerations. High profile safety issues associated with implantable devices have prompted a focus on this issue internationally and in Australia.

This Information Bulletin summarises key developments in this area and outlines expected practice in NSW Health facilities.

KEY INFORMATION
The Therapeutic Goods Administration (TGA) defines implantable medical devices as:

any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body, or
- to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.


The following elements of the plan are of immediate relevance to NSW Health services:

1. From 1 December 2018, the TGA began phasing in a requirement for manufacturers of both newly registered and existing permanently implantable medical devices* to provide patient implant cards and have a consumer device information leaflet, as part of new consumer information requirements

2. The TGA will be consulting with stakeholders on opportunities to:
   a. improve the timeliness and completeness of reporting of implantable device-related adverse events from health care providers and facilities
   b. improve the traceability of implantable devices to patients

*note that some implantable devices (eg sutures, staples, screws, wires, dental fillings) are exempt. Exempt devices are listed at https://www.tga.gov.au/publication/medical-device-patient-cards-and-leaflets
Recommended actions by Local Health Districts/Networks

1. Routinely include the product name, type, model and batch number for all implantable devices meeting the above definition in;
   i) the electronic procedure record as entered in theatre or other clinical areas implanting devices such as interventional radiology or cardiology; and
   ii) the patient’s discharge summary.

   This will support patients and general practitioners having easy access to details about the implanted device as in NSW, all discharge summaries are routinely uploaded to My Health Record.

2. Routinely record explantation of devices in the electronic procedure record and discharge summary.

3. Where a relevant device registry exists, support the provision of captured information to the device registry.

4. Discuss information about the implantable device as part of informed consent, and make manufacturer provided consumer information available to patients, in physical or digital format, to support this process.

5. Make manufacturer provided patient implant cards available to patients in physical or digital format.

6. Report any adverse event from an implantable device to the TGA even if the event is a known complication. Information provided to the TGA must be timely and complete.

7. Enter implantable device related incidents, near misses or complaints in the Incident Information Management System (IIMS) even if the event is a known complication.