MINUTE TO DEPUTY SECRETARY CORMACK

To: Mark Cormack

CARDIAC DEVICES REGISTRY

s22

In June 2017, the Performance, Evaluation and Quality Branch engaged HealthConsult Pty Ltd, a member of the Department's evaluation panel, to undertake an independent review of the Australian Breast Device Registry (ABDR) and the CDR. The Review assessed the extent to which each of the registries met or are likely to meet their objectives. The review was required under the Contract for Services between the Department and Monash University, which manages the ABDR, and the ACOR which manages the CDR. The key findings for the CDR include:

- There is a low level of stakeholder engagement because of the perceive value of the CDR.
- Less than five percent of eligible sites are contributing data to the CDR.
- The data collection does not meet the requirements of the Contract for Services.
- The CDR does not include outcomes and procedures data and therefore is unable to analyse device data in a way that is relevant for stakeholders.

s22

If in the intervening time a cardiac device recall failure occurs, the process for a medical recall follows:

- Health practitioners, hospitals and the general public are alerted about problems with implanted medical devices via a Hazard Alert, a type of Recall.
- A Hazard Alert is conducted in accordance with the Uniform Recall Procedure for Therapeutic Goods.
- Sponsors (suppliers) of medical devices are responsible for informing surgeons and healthcare facilities of a Hazard Alert, while the Therapeutic Goods Administration (TGA) oversees the process and will also inform Clinical Colleges and State and Territory Health Departments of a Hazard Alert (and the public via its website).
- It is very rare for it to be either necessary or desirable to retrieve implanted medical devices during an Implant Recall, as the risk of retrieving the implant is almost always greater than the risk associated with having a faulty implant.
- If special patient follow up or removal of the medical device is advised, healthcare facilities and practitioners need to initiate a Patient Recall.
- The aim of a device registry is to collect data about devices and may be able to assist healthcare facilities and practitioners with the required data to identify patients who are affected

The Performance, Evaluation and Quality Branch is currently exploring options for an alternative arrangement for a new CDR. These arrangements will be informed by key learnings from the current CDR to ensure the design and plan for the new CDR is set up with clearly defined the aims and objectives.

s22

Mark Cormack
/ 11 / 17

Attachments:

A Background

B Briefing to the Minister for Health

Contact officer: Nick Hartland

Phone: 02 6289 8776

EA Corro Ref:

TRIM ref: D17-2729333

Attachment A

Background

Clinical Quality Registry

- On 7 October 2016, the COAG Health Council agreed that the Australian Ministers Advisory Council would develop a national Clinical Quality Registry (CQR) policy and funding strategy.
  - The Commonwealth is in partnership with States and Territories, the Australian Commission on Safety and Quality in Health Care, clinicians and other key stakeholders.
  - An expert advisory group has been established to provide guidance on the work and extensive consultation with stakeholders is expected to commence late 2017, with a view to consideration of the strategy by governments in 2017-18.
- The 2017-18 Budget measure, '*Operational Costs for Cardiac and Breast Device Registries*', provided $2.2 million in funding for the Cardiac Devices Registry (CDR) and the Australian Breast Device Registry (ABDR) until 30 June 2018, while a national clinical quality registry policy and funding strategy is developed.
  - This measure will continue to drive improvements in clinical practice, medical devices and patient outcomes for Australians with implanted cardiac or breast devices.
- The CDR and the ABDR aim to provide long term monitoring of implanted cardiac devices and breast devices (respectively) and improve patient safety through timely reporting of adverse events or safety issues.
- In June 2014, the Department engaged Monash University to establish and operate the ABDR. In July 2014, the Department engaged the Australasian Cardiac Outcomes Registry to establish and operate the CDR.

Note: The Budget measure funding for the CDR and ABDR expires on 30 June 2017 and the Performance, Evaluation and Quality Branch will be putting forward a NPP for the 2018-19 Budget.

Cardiac Device Registry

In July 2014, the department engaged the ACOR to establish and operate the CDR. According to the ACOR Contract, the aims of the CDR are:

- To enhance the long term monitoring of implanted cardiac devices and improve patient safety. This is to be achieved by providing participating clinicians, health service providers and other key stakeholders with progressive reporting on adverse events or safety issues associated with these implanted devices.
- The CDR is to provide data to key stakeholders, such as the Therapeutic Goods Administration (TGA) in the case of underperforming devices, which will inform relevant actions by the TGA, including warnings where appropriate and/or removal of the device from the Australian Register of Therapeutic Devices. Patients will directly benefit through the CDR, with safety issues being identified and promptly communicated.
- Devices to be monitored in the CDR include cardiac stents, cardiac valves (whether mechanical or of biological origin) and electrical devices for the regulation of heart rate or intervention for dysrhythmia (i.e. pacemakers and leads, defibrillators and lead, left ventricular and assist devices and cardioverters). The CDR should also have the capability to extend monitoring to new devices as they are introduced into medical and surgical practice for cardiovascular disease.

The Contract for Services requires the ACOR to comply with the following standards and guidelines throughout the Terms of the Contract:

Australian Commission on Safety and Quality in Health Care's Strategic and Operating Principles and Technical Guidelines for a National Approach to Australian Clinical Quality Registries – These principles and guidelines should apply to all aspects of Item A. All principles are to apply, especially principles:

- 6 – sound governance arrangements with strong clinical leadership and a demonstrated framework for quality improvement
- 8 – data governance to be managed as part of the national health information agenda; and
- 10 – meet the requirements of the National Operating Principles for Clinical Quality Registries.