



**Australian Government**  

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**Department of Health and Ageing**

**Regulation Impact Statement**

**CLINICAL REGISTERS FOR HIGH RISK  
IMPLANTABLE MEDICAL DEVICES**

**18 February 2013**

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## 1. Introduction

This Regulation Impact Statement (RIS) has been prepared by the Commonwealth Department of Health and Ageing in response to the Government's commitment to work further with stakeholders to identify the most effective ways to track use and performance of high risk implantable medical devices.

An initial *Regulation Impact Statement (RIS) for Clinical Registers for High Risk Implantable Medical Devices* (the preliminary RIS) was released on 2 October 2012. This RIS considered three options to address the problem: (1) maintaining the status quo, (2) one or more quality registers and/or a national contact register; and (3) registers managed by individual hospitals. The preliminary RIS identified the second option and its subcomponents as suitable for further exploration, noting that a number of areas including structure, governance, funding, privacy, data and costs would need to be addressed in more detail. The preliminary RIS also noted that an implementation RIS would be prepared should the Government choose to affirm its support for a preferred register model.

The purpose of this implementation RIS is to assist the Australian Government in deciding how to best implement the decision to support registers. This next stage of development draws on consultation with industry, clinicians and consumers in identifying the most effective ways to establish national registers to track the use and performance of high risk implantable medical devices (including the number, nature and priority of possible registers), balancing benefits and costs to patients, providers and the wider community.

Three options to support the establishment of national registers are identified. Consideration of each of these options includes their anticipated impact on consumers, the medical devices industry, the health care sector and government agencies. Consideration of costs and benefits of the three options are also discussed.

These options are considered as mechanisms to facilitate patient contact where the Therapeutic Goods Administration (TGA) has identified performance issues with a high risk implantable device and to enhance the TGA's post market surveillance capability. The need to strengthen this capability is driven by the potential risks to patients' safety with certain medical devices.

The RIS concludes with a recommendation for implementation for the Government's consideration.

### 1.1 What is a high risk implantable medical device?

All therapeutic goods have risks, some of which are insignificant, and some serious. The TGA approves and regulates products based on an assessment of risks against benefits. The TGA applies scientific and clinical expertise to ensure that the benefits of a product outweigh any risks. In assessing the level of risk, factors such as potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.

The TGA's classification of devices is:

Class I	Low risk devices
Class IIa	Low-medium risk devices
Class IIb	Medium-high risk devices
Class III	High risk medical devices
Class AIMD	Active Implantable Medical Devices, which are treated in a similar way to Class III medical devices.

Medical devices are classified by the TGA according to the degree of risk involved in their use, based on the degree of invasiveness in the human body, duration of use, location of use and whether or not the device is powered. Assessment of medical devices is conducted against the specified criteria for safety and performance (the 'Essential Principles') with which devices must conform, adopted in Australia via the Global Harmonisation Task Force with which Australia was a participant. Pre-market assessment of medical devices seeks to ensure the safety and efficacy of devices. However, the nature of implantable devices means specific, long term clinical data may not generally be available before these devices are placed on the market. For this reason, post-market monitoring is particularly critical for the effective regulation of high risk implantable medical devices.

Some of the most common surgically implanted devices are vascular catheters (Class IIb), cardiac stents (Class III), breast implants (Class III) and cardiac pacemakers (Class AIMD).

## 2. The Problem

### (2.1) What is the problem being addressed?

There are two separate but related problems being addressed.

The first problem is that Australia (along with most other countries) lacks the ability, consistently and comprehensively, to identify patients who have received a specific model of a device from a particular lot or batch, for example in circumstances where there is evidence that the device presents a potential risk to the patient. Given that many types of high risk implantable devices have substantial life spans (for example implantable cardioverter defibrillators have a life span of up to eight years<sup>1</sup>), the ability to keep track of patients and contact them when necessary is a long term requirement.

The second problem is the need to strengthen the post-market monitoring of high risk implantable medical devices. Under current arrangements, the TGA uses a number of different data sources to monitor the safety and effectiveness of medical devices, including reports provided under the Medical Device Incident Report Investigation Scheme<sup>2</sup>, annual

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<sup>1</sup> Sousa, P. J., Cavaco, D. et al (2010). 'Subcutaneous ICD implantation', *Rev Port Cardiol*, 29 (3), 451-457.

<sup>2</sup> Manufacturers and sponsors have a statutory obligation to report to the TGA known serious adverse events associated with the use of their devices in Australia.

reports for AIMDs, Class III and implantable Class IIb medical devices<sup>3</sup> and other sources of information about device performance provided on a voluntary basis through clinicians and consumers.

However, a more multi-faceted approach based on a consistent and rigorous source of data on the performance of high risk medical devices that have been implanted in patients would enable the TGA to conduct more active surveillance on the safety and performance of high risk implanted devices once they have reached the market.

The community is seeking greater assurance that any unforeseen hazards in relation to the performance of high risk implantable medical devices can be identified early as part of post-market monitoring and that where there is evidence that an implantable device may pose an unforeseen risk to their health, patients can be contacted.

## 2.2 Background

The underperformance of particular groups of implantable medical devices can put patients' health at risk with associated increases in morbidity and mortality. This can result in substantial economic loss to the individual and the community, and additional expense to the health care system.

Recent examples include the Poly Implant Prothese (PIP) silicone breast implants affecting up to 6000 Australian women, with 438 of those implants now having been reported to the TGA as having ruptured.<sup>4</sup> Metal on metal hip implants, that have been identified as having higher revision rates than other similar products, have been recalled. This particular model had been implanted in around 5,500 Australians.<sup>5</sup>

Investigation and consultation on the assessment and regulation of high-risk implantable medical devices has been underway for a number of years. This has produced a significant body of work around the classification, risk management and long term performance of a selected range of devices. These reports include: the *Review of Health Technology Assessment in Australia* (The HTA report released in February 2010), the Senate Standing Committee on Community Affairs inquiry into *The Regulatory Standards for the Approval of Medical Devices in Australia* (report released November 2011) and the Senate Standing Committee on Community Affairs inquiry into *The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothèse (PIP) breast implants* (report released May 2012).

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<sup>3</sup> It is a condition of inclusion on the Australian Register of Therapeutic Goods, that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb, provides three consecutive annual reports to the TGA.

<sup>4</sup> PIP Breast Implants - TGA Update, September 2012, Therapeutic Goods Administration, Australian Government, 2012, accessed on 11 January 2013 at <http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120914.htm>.

<sup>5</sup> Recall of DePuy Orthopaedics ASR hip replacement device, Therapeutic Goods Administration, 16 May 2011, accessed on 11 January 2013 at <http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm>

While a number of these reports and inquiries have also emphasised the need to increase the rigour of the TGA's premarket assessment process for high risk medical devices, any changes to premarket assessment requirements are being considered separately by TGA<sup>6</sup>. The scope of this RIS is limited to post-market surveillance of high risk implantable medical devices.

Work has also been undertaken by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and its predecessor on the need for and value of clinical registers. Clinical quality registers are essentially databases of identifiable persons containing clearly defined sets of health and demographic information. They can range widely in scope and function and may or may not be legislatively based (refer Glossary for further details).

### **The Government's policy decision**

Recommendations 13, 14 and 15 of the 2010 HTA report highlighted the need to improve post-market surveillance, including the establishment of registers for high-risk implantable devices. Recommendation 7 and 15 of the report on *The Regulatory Standards for the Approval of Medical Devices in Australia* also reiterated support for implementing the above-mentioned HTA recommendations and strengthening the current arrangements for communicating with the public in the event of adverse events.

In response to these reviews, the Australian Government has publically confirmed its support for clinical registers for procedures associated with high risk implantable medical devices and committed to exploring ways in which to track the use and performance of high risk implantable medical devices including through clinical registers. The Government also undertook to consider funding options for the establishment of these registers, including the feasibility of the use of cost recovery from industry through the TGA cost recovery arrangements.

This RIS reflects the next concrete step towards realising the Australian Government's policy decision.

Further details of the reviews and inquiries relevant to this body of work is in the preliminary RIS which also noted that issues related to implantable medical devices are set to expand on a number of fronts. The number of people undergoing a procedure involving a high risk implant is expected to increase as Australia's population ages, becomes more affluent, has greater access to medical services, and as the number of devices on the market increases.

### *Current gaps*

The combination of these pressures has highlighted significant gaps in managing the risk to the patient and associated economic, social and health care costs.

The first gap is a lack of capacity at local and national levels to quickly identify and contact patients who have been the recipients of certain high risk implantable medical devices in

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<sup>6</sup> *Changes to premarket assessment requirements for medical devices* Therapeutic Goods Administration, January 2013.

the event of a recall. This was highlighted and criticised by health consumer groups during the recall of breast and hip implants.<sup>7</sup> Recent consultations undertaken by the ACSQHC with health consumer representatives indicated that a contact register is viewed as a high priority, alongside clinical registers capable of detecting emerging risks with certain categories of medical devices over the longer term.<sup>8</sup>

The table below includes the number of hazard alerts for implantable medical devices that the TGA has found to be defective after implantation from 2009-2012. It is not possible to confirm the number of patients involved in these hazard alerts, as the treating clinician is responsible for contacting and providing appropriate advice to patients implanted with the affected device. The TGA's role extends only to co-ordinating the issuing of the hazard alert, in consultation with the sponsor, to those hospitals where the device has been distributed.

Year	Number of hazard alerts
2011 - 2012	20
2010 - 2011	13
2009 - 2010	21

*Source: TGA Report Recalls Jan-June 2012: Table 78b*

The second gap pertains to the need to enhance the post-market surveillance capacity of the TGA.

There have been a number of reviews looking at the role of the TGA and where its processes should be adapted and expanded to approve and monitor a range of medical devices in the context of an increasingly complex marketing and medical environment.

The gap in post-market monitoring capability was the subject of specific recommendations arising from the 2009 HTA review. That report suggested that there was a need to take a stronger 'life cycle' approach to the performance of implantable medical devices.<sup>9</sup> While the TGA currently has a strong front-end pre-market assessment and monitoring process for medical devices to be included on the Australian Register of Therapeutic Goods (ARTG)<sup>10</sup>, the review identified the need to monitor the performance of devices more systematically once they were approved for supply to the market.<sup>11</sup>

Both in Australia and overseas, groups of clinicians have recognised the importance of being able to monitor the use and long-term performance of specific implantable medical devices, patient attributes and clinical setting and training around implantation<sup>12</sup>.

<sup>7</sup> Refer submissions to the Senate Community Affairs Committee Inquiry into the role of Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants (2012)

<sup>8</sup> Unpublished ACSQHC consultations November 2012.

<sup>9</sup> Report of the Review of Health Technology Assessment in Australia, pp 98-99 , Australian Government, 2010

<sup>10</sup> Information held in the ARTG includes information about the manufacturer and the kind of product that can be supplied in Australia. Further information on the ARTG is available at [TGA website](#).

<sup>11</sup> Report of the Review of Health Technology Assessment in Australia, p100 , Australian Government, 2010

<sup>12</sup> Hip and Knee Arthroplasty Annual Report 2012, pp4-5, 204, National Joint Replacement Registry, Australian Orthopaedic Association, 2012 , US FDA *Strengthening our National System for Medical Device Postmarket*



### 2.3 Significance and magnitude of problem

At 1 July 2012, the numbers of ARTG entries for Class IIb, Class III or Active Implantable Medical Devices (AIMD) classifications (noting that non-implantable devices will also be included within some of these classification groupings) were: Class IIb 4521, Class III 2254 and AIMD 312.

In 2009, the ACSQHC estimated that approximately 350,000 high risk devices would be supplied in that year.<sup>13</sup> These included cardiac devices and valves, breast implants, stents, joint prostheses and implanted neurological stimulators. The ACSQHC report comments that the number of medical device implants is likely to increase over time, particularly given the potential for miniaturisation and nanotechnology to drive further device development. The report also notes that consumers may be concerned about the employment of nanotechnology (functional systems on a molecular scale) in implantable devices and may seek increased regulation and monitoring as a result.<sup>14</sup>

As an example of one particular type of device, the Department of Health and Ageing's submission to the recent Senate Community Affairs References Committee's *Inquiry into the role of the Government and the TGA regarding medical devices, particularly PIP breast implants* stated that 'in the two calendar years (2008 and 2009) immediately prior to the recall of PIP implants, a total of approximately 50,200 silicone gel-filled breast implants were supplied in Australia....'.<sup>15</sup>

The potential consequences can be severe when high-risk implantable medical devices do not perform as expected. By definition, failure or malfunction of a life sustaining device, such as cardiac devices, will threaten life and may cause death. Problems with other devices such as hip implants can severely affect a patient's quality of life, and lead to significant morbidity. Evidence presented to the recent Senate committee inquiry on PIP breast implants asserted that severe emotional stress can result for patients who have reason to doubt the integrity of an implanted device, even where its risk to health has not been fully established or is not significantly increased.<sup>16</sup>

The Senate Community Affairs References Committee's report on the *Inquiry into the role of the Government and the TGA regarding medical devices, particularly PIP breast implants* noted that several submitters had raised concerns about the lack of record keeping and limited notification of the recall. According to the report, many women were not contacted and advised about the recall due to poor record keeping practices by surgeons, or due to absence of a centralised database. One submitter stated in her submission to the inquiry:

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*Surveillance* (Sept 2012), Australian Medical Association submission to the Senate Community Affairs Committee Inquiry into the role of Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants (April 2012)

<sup>13</sup> Australian Commission on Safety and Quality in Health Care, p.9.

<sup>14</sup> Australian Commission on Safety and Quality in Health Care, p.2.

<sup>15</sup> Department of Health and Ageing, *Submission to the Senate Community Affairs References Committee Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants*, 20 April 2012, p.11.

<sup>16</sup> Submissions by affected individuals to the Senate Standing Committee on Community Affairs Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants, April 2012,

*...they have failed us by not having adequate record keeping requirements in place, neither in the local surgeries or at a mandatory centralised reporting agency so that if this does happen, individuals affected can be informed as matter of course and make their own judgments with appropriate medical advice as to the course of action from there.*

## 2.4 Current arrangements for clinical quality registers and contacting patients

### 2.4.1 Clinical Quality Registers

There are a number of clinical quality style registers in Australia<sup>17</sup>, only some of which collect information on procedures involving implantable devices. Clinical quality registers in their most developed form collect a range of information that provides a full picture of the effectiveness of a particular procedure. In addition to recording attributes of the patient such as name, age, sex, comorbidities and other factors that may impact on clinical decisions, they can also record information about the type of device that may be implanted in a patient and provide indications of the longer term performance of the device. Registers of this type play an important role in improving clinical performance and contribute information that might lead to a decision to recall a device. The medical device industry is also able to draw on data from national clinical quality registers to aid the development of new devices and new uses of existing devices.

There is no standard approach to data collection, reporting, governance or the funding of clinical quality registers. A 2011 report on a survey of Australian Clinical Registries<sup>18</sup> found that of a total of 28 registries identified, the majority required modifications to their procedures in order to provide useful and reliable information and that the approach to dissemination of information was highly variable.

Only five national registers encompassing joint replacement, renal dialysis and various forms of organ transplantation have national coverage. The range of arrangements applying to an existing national register for joint replacements, a Victorian register for cardiac outcomes and a planned pilot register for breast implants are outlined in the following table.

Clinical register	Data collected	Governance	Funding
<b>The National Joint Replacement Registry (NJRR).</b>	The register is covered by statutory protections limiting what information can be accessed and by whom. <sup>19</sup> The NJRR is very well supported by clinicians. This type of register is also capable of providing information on the relative performance of medical	The NJRR is owned by the membership of the AOA and governed by a committee comprising orthopaedic surgeons and the chief executive officer of the AOA, with	The NJRR was established by the Australian Orthopaedic Association (AOA) in 1998 with the support of Australian Government funding. Since 2009-10, the NJRR

<sup>17</sup> A 2006-07 survey identified 28 clinical registers operating in Australia, although only a small number had national coverage. (Evans SM, Bihensky M, Cameron PA, McNeil J. *A survey of Australian clinical registries: can quality of care be measured?* Intern Med J. 2011 Jan;41(1a):42-8)

<sup>18</sup> Ibid.

<sup>19</sup> Qualified privilege legislation operates at Commonwealth, state and territory level and stops the release of information to patients and others including government departments, researchers and lawyers. For example the NJRR is subject to the Health Insurance Regulations 1975, 23C, (2) where information must not identify an individual if the sole source of the information was enrolment on the register.

Clinical register	Data collected	Governance	Funding
	<p>practitioners as well as the long term performance of particular implants.</p> <p>The NJRR provides regular reports to TGA to enhance post-market monitoring of implantable joint replacements.</p>	<p>advice from a more broadly-based consultative committee.</p>	<p>has been funded through a legislated levy on the devices industry.</p>
<b>The Victorian Cardiac Outcomes Registry (VCOR)</b>	<p>This Registry will include patient-specific clinical, procedural and outcome data, establishing a basis for monitoring device, clinician and unit performance. However, coverage is limited to procedures which take place in Victoria.</p> <p>The initial data to be collected will focus on percutaneous coronary interventions (which often involve the implanting of coronary stents). Work is scheduled in 2013 to develop further modules related to pacemakers and defibrillators.</p>	<p>This registry is being coordinated by Monash University School of Public Health &amp; Preventive Medicine and has the support of the Cardiac Society of Australia and New Zealand.</p>	<p>Under development with funding sourced from the Victorian Department of Health and Medibank Private.</p>
<b>Breast Device Registry (BDR)</b>	<p>The Registry will include patient specific data, implant details, surgeon details, operation notes and if applicable revision details (removal/replacement).</p> <p>The BDR has been approved by the Human Research Ethics Committee at the Alfred Hospital.</p>	<p>The register is to be governed by a consortium of stakeholders including specialist associations, Government, regulators of medical devices and manufacturers and suppliers of implants.</p>	<p>The Australasian Society of Plastic Surgeons, together with the Australasian College of Cosmetic Surgery have committed to establishing this registry as a pilot in the first instance to be operated by Monash University.</p>

The ACSQHC *Strategic and Operating Principles for Australian Clinical Quality Registries* provide a framework for the minimum requirements for Clinical Quality Registers. They were developed by the ACSQHC in collaboration with the National Health and Medical Research Council (NHMRC) Centre for Research Excellence in Patient Safety (CREPS) at Monash University and the National E-Health Transition Authority (NEHTA). The ACSQHC also consulted a range of clinicians, speciality groups and registry custodians.

The ACSQHC has developed this framework based on the recognition that *“for registers to meet their full potential in informing the state of health care in Australia, confidence is needed in the quality and relevance of the data”*<sup>20</sup>.

These Principles (refer in full at **Appendix A**) were endorsed by Health Ministers in November 2010 and cover issues of data collection, security and custodianship, and ethics

<sup>20</sup> Australian Commission on Safety and Quality in Health Care, *Operating Principles and Technical Standards for Australian Clinical Quality Registries*, 2008.

and privacy. They include directions that the following principles be observed where data collection has been mandated or enabled through legislation or regulation:

- Institutional Ethics Committee [IEC] approval must be obtained to establish ... [an] Australian Clinical Quality Registry (except where legally mandated or legally authorised);
- Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*;
- Participants or their next of kin should be made aware of the collection of registry data. They should be provided with information about the ... Registry, the purpose for which their data will be put and provided with the option not to participate. This should be at no cost to the registry participant.
- Where projects are undertaken using register data, Institutional Ethics Committee approval must be sought unless the project falls within the scope of an institution's quality assurance activity.<sup>21</sup>

Any options to support registers should be guided by these principles.

#### 2.4.2. Contacting patients – linking patients and implanted high risk devices

Once a hazard alert for an implanted medical device has been issued, the TGA is responsible for working with the relevant sponsor to provide appropriate information to implanting surgeons. However, as the sponsor does not normally deal directly with those implanted with the device, or have access to the relevant personal information, they are not in a position to contact patients with implanted devices.

The TGA has no power to require surgeons to contact their patients with implanted devices of the kind recalled to either advise them of the recall or to ensure that all patients consult the surgeon if they have any concerns about the implanted device. However, in appropriate cases, the TGA will directly contact relevant professional associations and provide public information on the TGA website directed to those who have the implanted device, to encourage appropriate clinical review. There is no requirement for health providers to report back to TGA on the number of patients identified and contacted, or the patients who could not be contacted.

Under the current arrangements there is no single mechanism which would enable patients with specific high risk implantable medical devices to be identified and contacted following an alert about the performance of a particular type/brand/model/batch/lot of device.

In general, each hospital relies on its own data collection systems to identify and contact patients, where necessary. Information about hospital procedures is collected in a number of ways. There is no consistent means of quickly identifying recipients of specific high risk implantable medical devices. In addition, patients are not consistently provided with details of high risk implanted devices, or if they are, the level of detail may not be specific enough to identify particular devices in the event of a recall.

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<sup>21</sup> Australian Commission on Safety and Quality in Health Care, Australian Clinical Quality Registries, Operating Principles, 2010, p.56.

Hospitals routinely collect and provide uniform data on procedures but this data is often only held at the hospital or local health area level. Some de-identified information is aggregated at a national level.

For example, the State Records Authority of NSW<sup>22</sup> requires that hospitals maintain a register of surgically implanted devices which are to be retained indefinitely. However, each local health district is able to develop its own procedures to comply with this requirement and there is no standardised protocol for responding to a hazard alert. In complying with this requirement it appears that some hospitals already have procedures in place to capture details of an implanted prosthesis or device<sup>23</sup> as part of a patient's medical record, including the lot number.

Certain de-identified data is uploaded from hospital systems to populate the National Minimum Data Set (NMDS) but this data only provides details of implantable devices for patients covered by private health insurance. The prostheses charge code, which is included on the NMDS for the purposes of identifying the benefit payable under private health insurance arrangements, is linked to the device manufacturer, product, model and size. The billing code does not incorporate batch/lot/serial numbers and there is currently no requirement for a unique device identifier (UDI) to be included on the product label<sup>24</sup>. International standards for standardised device labelling are being considered by the USA and the EU.

## **2.5 Why is government action needed?**

The community expects that in the event of a safety risk relating to an implantable device, any person whose health may be affected will be contacted and appropriate information / support provided. While every hospital has a duty of care to establish a system to identify and contact patients where there are public health concerns, there is currently no consistent approach to achieving this objective, with information about hospital procedures collected in a number of ways.

Government leadership will facilitate a nationally consistent means of quickly identifying recipients of high risk implantable medical devices which will enhance patient safety and reduce the burden on hospitals to maintain individual systems and the challenges of maintaining the currency of contact details.

Although existing clinical quality registers are supported by a range of funding models and sources, not all have achieved a stable and sustainable footing. They operate under diverse data collection, governance and reporting arrangements without standardisation of data security and health information standards, often through a series of relationships with healthcare providers. Further, the Government has no control or influence over priorities or

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<sup>22</sup> State Records Authority of NSW – 2.0.0 Patient/Client Registration and Identification (GDA17)  
<http://records.nsw.gov/recordkeeping/government-recordkeeping-manual/rules/general>

<sup>23</sup> NSW Health Northern Sydney Local Health District *Procedure – Implantable Prosthesis or Devices – Perioperative Documentation NSLHD* (June 2012)

<sup>24</sup> While this RIS does not propose that a UDI be mandated as a regulatory requirement, this concept would further streamline post-market surveillance and recall action. Should the benefits of a UDI be explored in a more considered way in the future, a separate RIS may be required.

timeframes for new registers, their scope, compliance with best practice, or geographic coverage.

### **3: Objectives of Government Action**

The primary objective of Government action is to protect the health and safety of patients implanted with high risk medical devices, while balancing this with the need for timely access to medical devices which offer significant health benefits to the public.

The secondary objectives are to:

- a) Implement a national system which will provide for effective contact with patients where there is evidence that a high risk implantable device may pose an unforeseen risk to their health; and
- b) Build early evidence of the performance of high risk implantable medical devices and identify any unforeseen hazards (following TGA approval for supply in Australia).

When considering the funding arrangements for clinical registers the guiding principles are that the arrangements must be sustainable, effective and fair.

### **4: Options to achieve objectives**

The preliminary RIS made the case for, and established the validity of, the options to establish clinical registers and/or a national contact register. Therefore this implementation RIS only addresses the approach to establishing such registers and does not consider a status quo option.

This RIS considers the following options for establishing specific clinical quality registers and/or a national contact register:

- **Option 1** – Establish one or more specific national clinical quality registers.
- **Option 2** – Contacting patients - establish a national patient contact register or build national capability for contacting patients
- **Option 3** – Establish one or more specific national clinical quality registers and build national capability for contacting patients with data held at the hospital level.

#### **4.1 Consideration of the options**

##### *4.1.1 Option 1: Establish specific national clinical quality registers*

The key procedures involving implantable devices which could be covered by clinical quality registers include cardiac surgery, vascular surgery, breast implant surgery, neurosurgery and joint replacement surgery. Hip, knee and spinal devices are already covered by the National

Joint Replacement Register (NJRR), which is funded through a levy imposed on each joint replacement prosthesis sponsor for each relevant item on the Prostheses List<sup>25</sup>.

There are several ways in which clinical quality registers for the remaining types of procedures could be established.

- *Establishing a national clinical quality register for cardiac surgery, vascular surgery, breast implant surgery and neurosurgery under the auspices of a single organization through a Government funding agreement.*

This option would provide a single new national clinical quality register for all procedures associated with high risk implantable medical devices not currently covered by a national register. The defined minimum data set would need to cover all prostheses types and features, methods of prostheses fixation and surgical techniques used (other than those associated with joint replacements). The feasibility of this option from a technical perspective has not been investigated.

The way in which each medical craft group took responsibility for their “part” of a single register would also require further consideration, noting that the success of any clinical quality register is dependent on the level of support from the relevant medical craft group.

- *Enhancing existing separate registers for cardiac surgery, vascular surgery, breast implant surgery and neurosurgery through Government funding agreements.*

This option acknowledges that there are already a number of clinical quality registers which exist or are in an advanced stage of development for surgical procedures involving implantable high risk devices (refer Section 2.4.1).

Prioritisation of support for specific clinical quality registers should be based on Principle 7 of the ACSQHC Principles (refer [Appendix A](#)), namely: gaps in existing data flows; the significance of the national burden of disease and the cost of interventions; the existence of variation in practice and outcomes; the ability to improve quality of care including reduction in practice variation; availability of national clinical leadership and consideration of existing data; and cost/benefit analysis of the options.

- *Voluntary or mandated participation*

While it would be possible for Government to develop legislation mandating that certain data be collected and input to national quality register/s, this is not considered to be necessary or appropriate. The NJRR operates as a very successful national registry without being prescribed in Commonwealth legislation. Further legislative mandating of a clinical quality register would diminish a sense of ownership by relevant medical craft groups. For those reasons all options canvassed in this RIS for national clinical quality registers are based on the principle of voluntary participation.

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<sup>25</sup> The Prostheses List contains all of the prostheses that have been approved by the Commonwealth Minister for Health for the payment of benefits by Private Health Insurers. The list also states the benefit that must be paid by the insurer.

#### *4.1.2 Option 2: Contacting patients - establish a national patient contact register or building national capability at the hospital level*

The key to being able to identify and contact patients when the need arises is the data collected at the hospital level. Consistent, national arrangements for hospitals and other health facilities are needed to record relevant information to link a patient with the implantable device they have received as part of the facility's patient administration system<sup>26</sup> (PAS) and to have in place processes which reflect best practice when a hazard alert is issued. The minimum additional data required to ensure that relevant patients can be readily identified in the case of a hazard alert is a unique device identifier information (including the batch/lot number), implant date and, where appropriate, removal date.

A fundamental requirement is to expand hospital patient administration systems to collect this data. This standard expanded dataset would need to be negotiated with states/territories and the private hospital sector. Once this data is collected there are then 2 main approaches which could be taken – transfer the data to a central database or retain the data at the hospital level.

##### ***Option 2a – A national patient contact register with data held centrally***

This sub-option is to develop a single national patient contact register to receive and maintain relevant patient and implantable medical device information with hazard alerts facilitated through the development of a national protocol for a rapid patient identification and notification system.

A national patient contact register would contain only a small subset of the data typically contained in a clinical quality register including the date of implantation and identifiers for the patient, the device, the health care provider and the health care facility. The primary purpose of improving patient identification and contact capability in the Australian health care system would be to support the TGA in ensuring that the information about a hazard alert had reached all affected parties and that appropriate action in response to the hazard alert has been taken.

There are essentially two ways in which this data could be incorporated into a single patient contact register centrally operated and governed by a single Government or non-Government body:

- Patient and device data transferred from the PAS of each hospital to the central register; or
- Patient and device data extracted from the National Minimum Data Set (NMDS) which is drawn from PAS data.

##### ***Patient Administration Systems***

Device details would become a routine data item in hospital admission data collections and arrangements would be established to upload this data together with the patient-identifying

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<sup>26</sup> Every hospital is required to keep records of patient details, a PAS typically records patient demographics and details of all patient contact with that hospital.



information directly to the central register. If DHS were to operate this central register it would be possible to continuously update patient contact details by linking to Medicare data. Detailed specifications of the changes to the PAS would need to be developed and agreed by states/territories and the private hospital sector. PAS vendors would need to provide the additional device fields specified for that purpose.

#### *The National Minimum Data Set*

Alternatively data could be uploaded from the National Minimum Data Set (NMDS) to the central register. The NMDS for health is a minimum set of data elements agreed for mandatory collection and reporting at a national level. A NMDS is contingent upon a national agreement to collect uniform data and to supply it as part of the national collection, but does not preclude agencies and service providers from collecting additional data to meet their own specific needs. Agreement between all relevant parties to a NMDS is essential, including agreed specified data elements as well as the scope of the application of those data elements.

The NMDS does not currently contain identified patient details or details of high risk implantable devices (other than the Prostheses List Billing Code which links to details of the device manufacturer/product/model and size for the purposes of private health insurance reimbursement). The option of using an extract from the NMDS as the basis for a single patient contact register would require that policy aspects of the NMDS be renegotiated with states/territories.

#### *The operational and governing body*

Many existing Australian health information datasets are operated by public statutory authorities (e.g. AIHW), health care provider organisations, government departments and non-government organisations (e.g. cancer councils). Many are underpinned by legislation and/or are the subject of national agreements.

The Department of Human Services (DHS) maintains a number of national registers including the Australian Childhood Immunisation Register (ACIR), the Australian Organ Donor Register (AODR), and the Bowel Cancer Screening Register (BCSR). The DHS is a regular recipient, via secure transfer, of data sent by general practitioners, specialists and hospitals. The DHS hosts the Public Key Infrastructure (PKI), an information technology infrastructure incorporating software tools and hardware, network services and management techniques (policy and procedures) that work together to allow the secure exchange of data.

The DHS manages substantial supporting infrastructure including data validation functions and 1800 telephone inquiry lines and for some registers has a direct patient contact function (e.g. DHS sends reminder letters and employs nurses to contact patients in some jurisdictions when there is no evidence of patient follow up following a positive faecal occult blood test). Further, the extensive, distributed community-facing infrastructure that the Department has in place to support a number of other government programs may establish a useful interface with consumers wishing to interact with a patient contact register.

DHS or the DoHA could be the business owner of and governance entity for the register. Alternatively, another organisation such as a university which is experienced in establishing, maintaining and governing clinical quality registers could be the operating body. A steering group committee could support the governance arrangements.

If the operational body were DHS, the funding arrangements would need to be covered through the usual Business Practice Agreements between DoHA and DHS for specific services. Otherwise a standard funding agreement with the non-Government body would need to be developed.

***Option 2b – Building national capability to identify and contact patients with data retained at hospital level***

An alternative to a central patient contact register is to retain the patient and device data at the hospital level but build national capability to put in place consistent systems and protocols for hospitals to identify and contact patients, where necessary.

The hospital or health service would need to record patient and implantable device information as a routine data item in their relevant PAS. Under this arrangement, device details would still become a routine data item in hospital admission data collections and a national protocol for identifying and notifying patients would be developed to support best practice in the event of a hazard alert. This process, including stakeholder consultation, could be developed by the ACSQHC with support from Government funding.

Mechanisms for capturing data would need to be developed and the same issues about automating data collection would need to be addressed.

The likelihood of delays in contacting patients (where contact details are not current) in the event of a hazard alert could be addressed through implementing a process to verify patient contact details against Medicare data with DHS where initial efforts by the hospital to contact the patient have failed. DoHA would be best placed to liaise with DHS in developing this process. Government funding would be required to establish and support the patient contact verification process.

***4.1.3 Option 3: Establish specific national clinical quality registers (as per option 1) and build national capability to identify and contact patients with data retained at hospital level (option 2b)***

Option 3 essentially incorporates option 1 and option 2b.

Following implementation of option 2b, the feasibility and cost-effectiveness of hospitals feeding data to a central database (potentially hosted by DHS) could be examined in detail and further advice provided. A more detailed assessment of the cost-effectiveness of a national contact register would inform any decision to implement a national patient contact register. This option would allow for further investigation and consultation with states/territories and the private hospital sector on the merits of the DHS, or another agency being responsible for a national dataset.

## 5: Impact Analysis, including costs and benefits

Key stakeholders affected by this proposal include:

- Consumers/patients (i.e. persons who are implanted with a high risk medical device);
- health care services / professionals (who treat such people);
- the medical device industry (i.e. persons or organisations who sponsor or manufacture high risk implantable medical devices)

*[Medical device manufacturers are not considered as a separate set of stakeholders as high risk implantable medical devices are generally manufactured overseas and imported by the Australian sponsor].*

- the private health insurance industry (which pays the costs of certain implanted medical devices for patients covered by private health insurance); and
- governments (as the regulators and the funders) .

### *Funding and cost recovery*

The costs of any of the three options described could be either fully or partially recovered from stakeholders based on:

- the principle that funding should relate primarily to the potential for the funder to realise the costs and/or the benefits related to the work being undertaken; and
- consistency with the *Australian Commonwealth Cost Recovery Guidelines* (July 2005).

Clinical quality registers have characteristics consistent with public goods<sup>27</sup>. Non-identifying information collected and stored in a clinical quality register would be expected to be made available to the industry, particularly sponsors, healthcare professionals, and to the public. Medical device sponsors can access both general and specific information about their products which enables them to assess the effectiveness and usage of their products. While sponsors would have access to this information, other stakeholders may continue to access information, subject to privacy constraints.

The main options for funding are:

- a. the Government fully funds all activities;
- b. full or partial cost recovery from the medical device industry; or
- c. full or partial cost recovery from a broad range of stakeholders including health insurers, governments, health service providers and relevant device manufacturers.

The Commonwealth Cost Recovery Guidelines establish that cost recovery arrangements may apply to two categories of activities undertaken by agencies in the provision of goods and services, including regulatory and information activities. The collection of data on

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<sup>27</sup> According to the *Australian Commonwealth Cost Recovery Guidelines* (July 2005), a public good exists where provisions for one person means the good or service is available to all people at no additional cost. Public goods are non-rivalrous (in the case of information this means that once it is collected and compiled, it can be used by many people without affecting the cost of collection and compilation) ; and they are non-excludable (that is, it is difficult to exclude anyone from benefiting from the good).

surgical procedures associated with high risk implantable medical devices is primarily an information based activity (ie they involve collecting, compiling and disseminating information). However, the TGA may also use clinical quality registers for regulatory purposes related to monitoring ongoing safety and quality issues with devices.

Possible models for cost recovery would need to be explored in further detail through a Cost Recovery Impact Statement, including models which are based on increases to TGA annual charges or a new levy.

### **5.1 Option 1: Establish specific national clinical quality registers**

Option 1 is to establish specific clinical quality registers, either as a single register covering a number of different surgical procedures or as individual clinical quality registers. Medical device registers have been identified as a cost-effective tool for reducing adverse events and disease burden associated with device failures<sup>28</sup>.

#### *A single register or multiple registers*

Given differing data and reporting requirements and that the success of any clinical quality register relies on the co-operation and support of the relevant medical craft group<sup>29</sup>, a single register covering multiple types of surgical procedures is considered to be a high risk option. Further it is likely to be complex and would result in higher costs to develop and maintain than separate registers. However, it would be reasonable to expect that the capacity and expertise developed in setting up any initial national clinical quality registers would be leveraged in establishing any further registers.

During the consultation period<sup>30</sup>, some stakeholders expressed a strong view that existing data collections should be utilised where possible to capture the device- and patient-specific data necessary to support the effective implementation of hazard alerts. There was also very strong support for development of a systematised electronic data collection process for capturing device-level data in routine admitted patient datasets which already incorporate patient-, clinician-, procedure- and organisation-level data (refer Section 6 Consultation).

There are a number of existing registers which are run by non-Government bodies (such as universities). Enhancing existing registers for procedures associated with certain high risk implantable devices (such as cardiac and breast devices) would build on existing infrastructure. Under this option the national coverage of specific registers, which are already supported by relevant craft groups, would be accelerated with regular reports to be provided to the TGA to support post-market surveillance activities. The selection of a non-Government provider to administer any national register function should be based on their expertise and available infrastructure.

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<sup>28</sup> Paxton E et al. Evaluation of total hip arthroplasty devices using a total joint replacement registry. *Pharmacopoeidemiol Drug Saf* 2012;21;s53-9.

<sup>29</sup> Data input to a register is on a voluntary basis, noting that the Commonwealth does not have the jurisdiction to oblige health care providers to participate

<sup>30</sup> As drawn from unpublished ACSQHC consultations November 2012 (refer also Section 6)

### *Estimated costs and choices of register*

The ACSQHC estimates the annual ongoing costs of clinical quality registers to be between \$0.99 million and \$1.4 million per register, based on the costs of existing clinical registers. The levy on industry to support the NJRR (as a relatively large register) in 2012-13 is \$1.7 million. According to the Australian Society of Plastic Surgeons president, Mr Rod Cooter<sup>31</sup>, it would cost \$1.2 million a year to run a national breast implant register. However, as existing registers receive funds from various sources<sup>32</sup>, the funding needed to support enhanced reporting and national rollout is likely to vary depending on the size of the register to be supported and how well established it is.

The specific type and number of registers to receive support funding should be decided in consultation with the Australian Commission on Safety and Quality in Health Care. This decision should be based on the criteria for prioritising support for registers<sup>33</sup> and previous advice from the former TGA Medical Devices Evaluation Committee (now the Advisory Committee for Safety of Medical Devices) which recommended tracking five types of implantable devices<sup>34</sup> – implantable drug delivery devices, vascular grafts, silicone breast implants, those involving emerging technology (e.g. drug coated stents) and devices of biological origin.

Any funded registers would be expected to comply with the *Operating Principles for Australian Clinical Quality Registries* which were endorsed by Health Ministers in 2010. National standards to implement these principles are being developed.

An assessment is made below of the costs and benefits that option 1 can be expected to have on each stakeholder group, noting that the potential impact on each stakeholder group will depend on which funding option is to be implemented. Improved information provided by national clinical quality registers is of general benefit to the medical device industry, consumers, healthcare services, the private health insurance sector and Governments.

#### *5.1.1 Consumers*

A key purpose of a clinical quality register is to improve the safety and quality of health care provided to patients by collecting information that can then be used to improve clinical performance and improve health outcomes for patients<sup>35</sup>. Option 1 would provide benefits to consumers in allowing the TGA to use the register data to assess the real-world performance of medical devices and procedures, to determine the clinical effectiveness and safety of a medical device or procedure. The American Food and Drug Administration (FDA)

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<sup>31</sup> As reported in The West Australian, *Wanted: breast implant register* 21 Jan 2013

<sup>32</sup> For example, Monash University is currently funded by Medibank Private (\$1.2 million over three years) and the Victorian Government (\$200,000 ) to operate the Victorian Cardiac Outcomes Register

<sup>33</sup> These criteria are ‘gaps in existing data flows, the significance of the national burden of disease and the cost of interventions, the existence of variation in practice and outcomes, the ability to improve quality of care including reduction in practice variation, availability of clinical leadership and consideration of existing data, and cost/benefit options’. Australian Commission on Safety and Quality in Health Care, *Strategic Principles for a National Approach to Australian Clinical Quality Registries*, Principle 7

<sup>34</sup> In addition to cardiac life supporting implants, implanted neurological stimulators, diaphragmatic/phrenic nerve stimulators

<sup>35</sup> ACSQHC (Nov 2008) *Operating Principles and Technical Standards for Clinical Quality Registries*.

notes that “well-designed registries provide valuable insights into device performance and device-associated clinical benefits and risks”<sup>36</sup>.

Knee replacement operations in public hospitals typically cost in the order of \$23,600, while a hip replacement is about \$24,800. In the case of joint replacement, there is good evidence that the procedures may benefit the community, by being cost-effective by preventing older people moving in to residential care, and promoting physical activity and its associated benefits<sup>37</sup>. However, there are additional informal care costs associated with hip or knee surgery and particularly during the recuperation period where people may need assistance with activities of daily living such as driving, shopping, showering and cleaning. Frequently these costs are assumed by families and members of the community performing support tasks on a voluntary basis.

The average recovery time is around three months (with short term recovery usually achieved in around 4 to 6 weeks; however the window may be as short as one month or more than six months)<sup>38</sup>. However, due to the complexity of revision surgery (in particular where an existing implant needs to be removed before the new one is fitted), recovery times can be much longer and the time for which patients require assistance is also likely to increase.

Based on the evidence which shows that clinical quality registers can contribute to reduced revision rates for previous surgery, consumers are likely to benefit by avoiding long recuperation times and (where the person is of working age) being able to remain in the workforce rather than experiencing longer and unproductive periods of absence. While the potential costs associated with this are not quantified, they are likely to be significant. The National Joint Replacement Register estimates that around 15% of revisions are undertaken on people under the age of 65<sup>39</sup>.

There are challenges in using clinical quality registers for the parallel purpose of contacting patients, where necessary, as the release of information from such registers is often protected under qualified privilege legislation. Qualified privilege legislation operates at Commonwealth, state and territory level and stops the release of information to patients and others including government departments, researchers and lawyers. For example the NJRR is subject to the *Health Insurance Regulations 1975*, 23C, (2) where information must not identify an individual if the sole source of the information was enrolment on the register. The effectiveness of this option would also rely on patients maintaining the currency of their contact details.

The range of clinical registers is unlikely to cover the full range of surgical procedures associated with high risk implantable medical devices.

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<sup>36</sup> FDA *Strengthening our National System for Medical Device Postmarket Surveillance* (Sept 2012)

<sup>37</sup> Adam Cresswell, *Health editor, The Australian*, Jan 28, 2010.

<sup>38</sup> Jeremy Reither ‘ *How long does it take to recover from total hip replacement surgery, Hip and Knee*, 11/06/2009.

<sup>39</sup> NJRR , *Hip and Knee Arthroplasty*, Annual Report 2012, p149

Given data protection issues and relatively narrow coverage, clinical registers are considered to have some limitations in facilitating patient identification and notification further to an implanted device recall.

There may be some concern that any levy or increase in charges to the medical device industry would be passed onto consumers through increases in the cost of medical devices.

#### *5.1.2 Health care professionals and medical craft groups*

Clinical quality registers are of benefit to healthcare professionals as they assist the clinical community to:

- compare patterns of care with best practice guidelines to determine compliance and build the evidence base for patient outcomes;
- compare their own outcomes from surgical procedures with those of other practitioners, enabling self-identifying modification of practice; and
- change clinical practice where there is evidence that such changes lead to better patient outcomes.

Registers typically involve the relevant national professional associations, for instance in the areas of data custodianship and clinical practice advice.

The health service providers most likely to be directly affected are the hospitals, day surgeries or other facilities, where surgery is undertaken.

Some health care facilities may be concerned that registers will impose an additional burden on collecting and reporting of data. Given that participation is not proposed to be legally mandated, the success of any register will rely on the design and mechanism for data collection minimising any burden on health care service providers. For this reason it is critical that relevant medical craft groups are involved in developing design specifications.

As a matter of good record keeping much of this information should already be held in an individual patient's records. Further, there are a number of schemes for pilot or state-based clinical registers which have already demonstrated that any additional impost on health care professionals or service providers is not a barrier to uptake of voluntary participation.

#### *5.1.3 Private health insurers*

Clinical quality registers are generally of benefit to private health insurers as the higher the revision rates of high risk implantable devices, the higher the cost to the private health insurance sector.

The NJRR captures information on revision rates following hip and knee surgery. The Australian Orthopaedic Association (AOA) National Joint Replacement Register Annual Report 2011 noted that there had been a decline in the number of hip and knee revisions between 2003 and 2010 due to better monitoring enabled by the register<sup>40</sup>. Based on the average cost of a revision being \$25,000 this equates to around \$110 million in savings from

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<sup>40</sup> National Joint Replacement Register Annual Report 2011 - Australian Orthopaedic Association (AOA)

avoided procedures. This figure does not take into account other additional costs such as loss of income, care needs or ongoing medical costs.

Under the *Private Health Insurance Act 2007*, private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service. The Prosthesis List contains over 9,000 prostheses for which insurers are required to pay such a benefit. For example, in 2011-12, over \$244 million was paid in benefits by insurers for some 292 types of implantable cardiac devices on the Prostheses List. Generally most suppliers of these prostheses accept the benefit as full payment and do not charge a gap.

The benefits to private health insurers of any specific clinical quality register will depend on the nature of the surgery to be covered. For example, cosmetic procedures associated with breast implants are usually not covered by private health insurance.

#### 5.1.4 Medical Device Industry

The medical device industry is comprised of a diverse range of manufacturers and suppliers from small family operated businesses to large multi-national companies. In 2010-11, the Australian medical device industry included over 500 medical technology companies in Australia and had total annual revenue in the order of \$10 billion<sup>41</sup>. The Australian medical technology market is largely dependent on imports. In 2010 the value of Australian medical technology exports was over \$1.89 billion and the value of imports was over \$4.5 billion (Australian Bureau of Statistics, Customised Statistical Report 2011)<sup>42</sup>.

There is no additional administrative burden (such as data collection or recording) on the medical device industry to establish national clinical quality registers.

The medical device industry will benefit in having reliable performance information on existing products and design to draw from in facilitating the development of new technologies, new devices and new uses of currently marketed devices through evidence generation and analysis.

Enhanced post-market surveillance of the performance of prostheses also provides considerable benefits to the industry by improving consumer confidence in the safety and quality of high risk implantable medical devices. Any devices showing high failure rates can be identified quickly and promptly removed from the market.

Depending on a decision about cost recovery, the medical device industry would potentially bear the cost of establishing national clinical registers associated with procedures for high risk implantable registers through either a new industry levy or an increase in TGA annual charges. If two national clinical quality registers were fully supported, up to \$1.7 million per register would need to be cost recovered through the increase in annual charges.

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<sup>41</sup> Medical Technology Association of Australia (MTAA) – industry statistics (<http://www.mtaa.org.au>)

<sup>42</sup> <http://www.innovation.gov.au/>



The DLA Phillips Fox paper<sup>43</sup>, *Funding for Clinical Quality Registries – the Australian Cardiac Procedures Registry* (2010) notes that ‘*Procedures for the Management of cardiovascular disease are some of the highest cost, highest volume and relatively higher risk components of health care*’. Without pre-empting the specific types of clinical registers which would be established, by way of an example, there are over 20,000 cardiac procedures<sup>44</sup> performed per year. The cost to the medical device industry to recover \$1.7 million for a cardiac procedures register would therefore be in the order of \$85 for each procedure. There is a wide range of prosthetic devices used in surgery and this is reflected in the variation in benefits for different kinds of prostheses. For example the Prostheses List benefit for a cardiac defibrillator is \$52,000 compared to around \$1,000 for a breast implant.

Ideally, any cost-recovery model would take into account the volume/value of each relevant implanted high risk medical device supplied into the market.

### 5.1.5 Government

Option 1 would benefit the Government through:

- Improved and more comprehensive information to monitor device performance, to allow systematic evaluation and take regulatory action where appropriate;
- Enhanced post-market surveillance of devices, to inform ongoing assessment including pre-market assessment and to protect public health and safety in the face of unforeseen risks; and
- More targeted reimbursement of cost effective medical procedures and associated devices.

Reductions in device revisions and improvements in public health and safety ultimately lead to reduced demand for public health resources. Given the potential savings to the public health system, a shared funding arrangement between the Government and the medical device industry could be considered. For example, the Government could consider funding the initial cost to establish capabilities for select national clinical quality registers and industry could fund the ongoing maintenance costs.

Under this arrangement Government would need to provide one-off funding of between \$1 million to \$1.7 million per register. Alternatively, if the Government were to contribute 50% in funding (with the other 50% to be raised through the medical device industry and medical groups), the amount of funding required would be \$500,000 to \$850,000 annually for each register.

Additional Government resources to identify priority clinical quality registers for funding and establish and manage appropriate funding arrangements will be required.

## 5.2 Option 2: Contacting patients - establishing a national patient contact register or building national capability at the hospital level

### Option 2a

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<sup>43</sup> [http://www.crepatientsafety.org.au/registries/funding\\_for\\_clinical\\_registries\\_acpr\\_experience.pdf](http://www.crepatientsafety.org.au/registries/funding_for_clinical_registries_acpr_experience.pdf)

<sup>44</sup> MTAA quotes 21,223 implantable cardiac devices implanted in 2007-08 ( [MTAA website](#) )

Option 2a is to establish a centralised national system for the coordination of patient identification and contact associated with high risk implantable medical devices. Any proposal for a national patient contact register for high risk implantable medical devices would need to be developed through standard business case and project processes, including clarification of purpose and specification of requirements (expected functions) and scope.

A detailed costing would need to be developed once these elements, particularly the architecture and the operational model for a single patient contact register, are defined.

Indicative development costs for an electronic system in 2009 were estimated at \$2.3m and annual operating costs were estimated at between \$1.16m and \$1.32m<sup>45</sup>. Based on these figures and subject to register design, the preliminary estimates of establishment costs provided by the ACSQHC range from approximately \$2.5 million to \$3.5 million with ongoing costs of around \$1.5 million. More recent estimates from the Department of Human Services (February 2013) cost establishment of a national patient contact register at \$2.5 million with \$630,000 ongoing annual maintenance costs.

Given the complexity of this proposal it is estimated that it may take 2-3 years to develop and fully implement. A more detailed analysis of the cost-effectiveness of implementing such a system for up to 20 hazard alerts for implanted medical devices annually is required.

#### *Option 2b*

Option 2b is to build national capability to identify and contact patients when necessary, including the development of a national protocol for identifying and contacting patients to reflect best practice and streamline processes in individual healthcare facilities. The protocol would aim to ensure that plans are in place at the hospital level to readily identify, when there has been a hazard alert, whether the device has been implanted and trigger communication with affected patients in a timely and efficient manner.

However, the key challenge for hospitals is maintaining the currency of patient contact details. Option 2b provides for the Department of Human Services (DHS) to cross-check the contact details for select patients with Medicare data. The estimated cost of developing the national protocol and an agreed process for cross-checking patient contact details is up to \$650,000, including developing the specifications for the additional PAS data fields. The estimated ongoing cost is \$50,000 annually (noting that this may vary slightly from year to year dependent upon the number of hazard alerts and the number of Medicare records to be accessed). It is estimated that these improved arrangements could be in place within 1 year.

Once these improved processes are in place, the need for, and cost-effectiveness of, establishing a single national contact register could be considered.

Option 2b would have more immediate results in strengthening the existing disparate hospital arrangements than option 2a and be less costly for Government.

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<sup>45</sup> ACSQHC unpublished report November 2012

An assessment is made below of the costs and benefits that options 2a and 2b can be expected to have on each stakeholder group.

### *5.2.1 Consumers*

In every instance in which a hazard alert is issued for a high risk implanted medical device, identifying and providing appropriate care and advice to the patient is the first priority. Option 2a would provide benefits to consumers through the rapid identification of individuals who have received devices that may need intervention or close observation. Option 2b would provide similar benefits to consumers but would be reliant on hospitals to comply with the best practice national protocol. As option 2b is a decentralised option, it may also take longer for all affected patients to be contacted by individual hospitals.

Given the narrow dataset collected to assist in contacting patients, options 2a and 2b provide only limited benefit to consumers in strengthening post-market monitoring of the clinical effectiveness and safety of a medical device or the safety of the surgical procedure. The only information which may be of some use in this context is the data on how many particular devices have been implanted (eg to assist in targeting other surveillance activities).

There may be some concern that any increase in TGA charges would be passed onto consumers by an increase in the cost of medical devices.

### *5.2.2 Medical device industry*

The reputation of the medical device industry will be enhanced in supporting timely action and communication with patients when a medical device is found to be defective. The enhanced ability to more rapidly and effectively implement alert arrangements will reflect well on the industry. However, the data collected will be of limited use to the medical device industry, as it does not record details of the surgery performed or patient outcomes.

There is no additional administrative burden (such as data collection or recording) on the medical device industry to establish a national contact register or build national capacity to contact patients.

#### *Option 2a*

Dependent on the funding model, the medical device industry would potentially bear the cost associated with a national contact register, either through a new levy or an increase in TGA annual charges. Using an NJRR type funding model, the additional levy on industry to raise \$2.5 million to fund option 2a initially is around \$253 per product (based on 9,883 products on the Prostheses List (Part A) but also noting that not all of the products on the Prostheses List would be considered to be high risk implantable medical devices).

In order to raise \$2.5 million through an increase to TGA charges for AIMDs, Class III and Class IIb medical devices, the TGA annual charge would need to increase by the following amounts (based on 7,087 products in these categories on the ARTG and noting that they are not all implantable devices).

<b>Category of Device</b>	<b>Number of devices*</b>	<b>Current Annual Charge</b>	<b>Increased Annual Charge</b>	<b>% increase</b>
AIMD	312	\$1,150	\$1562	35.8%
Class III	2254	\$1,150	\$1562	35.8%
Class IIb	4521	\$890	\$1209	35.8%

\* (included on ARTG as at 1 July 2012)

### *Option 2b*

Similarly, depending on a funding model, the medical device industry could bear the full cost of building national capacity to identify and contact patients following a hazard alert but this would be considerably less than the cost of a national contact register. In order to raise \$650,000 through an increase to TGA charges for AIMDs, Class III and Class IIb medical devices, the TGA annual charge would need to increase by the following amounts (based on 7,087 products in these categories on the ARTG and noting that they are not all implantable devices).

<b>Category of Device</b>	<b>Number of devices*</b>	<b>Current Annual Charge</b>	<b>Increased Annual Charge</b>	<b>% increase</b>
AIMD	312	\$1,150	\$1257	9.3%
Class III	2254	\$1,150	\$1257	9.3%
Class IIb	4521	\$890	\$973	9.3%

\* (included on ARTG as at 1 July 2012)

### *5.2.3 Health care professionals and medical craft groups*

Health care professionals already have a duty of care to contact their patients in the case of any potential risk to their health and safety, including risks associated with the performance of an implanted high risk medical device. Options 2a and 2b aim to facilitate the way in which health care professionals can fulfill their obligations, rather than imposing any new burden on them.

A nationally consistent means of quickly identifying recipients of high risk implantable medical devices will reduce the burden on hospitals to maintain individual systems and the challenges associated with maintaining the currency of contact details.

In considering the capacity of health care providers to contribute to a national patient contact register, private hospital operators expressed the view that health care providers already are required to absorb the cumulative costs associated with data entry and the dedicated investment required to respond to hazard alerts.

Health care services in the public or private sectors may incur some costs in implementing the extended data fields for high risk implantable devices in their relevant PAS. However, this cost is a one-off cost which is commensurate with the substantial period over which a patient may need to be contacted in case of performance issues with their implanted device.

As there are a limited number of commercial PAS vendors (iSoft, Cerner and IBA), there may be opportunities to negotiate data changes at the national or jurisdictional level. Some jurisdictions such as Queensland have also developed their own PAS. The ACSQHC estimates that the cost of developing detailed specifications for the national data elements would be less than \$30,000.

The data collected under option 2a or 2b would be of limited use in informing best clinical practice compared to option 1 (a national clinical quality register) as neither of these options provided for recording the details of the surgical procedure or patient outcomes.

#### *5.2.4 Government*

Options 2a and 2b will provide greater surety to Government that patients have received appropriate professional advice on any performance issues associated with high risk implantable medical devices which may place the safety of the patient at risk. Option 2b would be the less costly option for Government, if Government funding in part, or in full, is considered.

As PAS data is collected at the hospital level in each state/territory, the Government would need to negotiate with states/territories on additional nationally consistent data for high-risk medical devices implanted in patients and any associated costs.

### **5.3 Option 3: Establish specific clinical quality registers (as per option 1) and build enhanced national capability to identify and contact patients with data retained at hospital level (option 2b).**

As this option essentially combines options 1 and 2b, the main difference in impact is the cost. The expected cost of 2 national clinical quality registers (up to \$1.7 million per register) and building enhanced national capability to identify and contact patients with particular implanted high risk medical devices, when necessary (up to \$650,000), is \$4.05 million.

Option 1 (establishing specific national clinical quality registers) will not necessarily result in all patients being readily identified and contacted following TGA issuing a hazard alert for an implanted high-risk medical device enhance (for the reasons outlined on pages 20). For that reason option 3 includes developing national capability in this area, in parallel to establishing specific national clinical quality registers.

#### *5.3.1 Consumers*

Option 3 would benefit consumers by promoting national consistency in the current arrangements for hospitals to contact patients where TGA issues a hazard alert for an implanted medical device. These arrangements are further strengthened through access to Medicare data to ensure that every effort is made to contact patients as the need arises. Consumers would further benefit through TGA having access to good quality data to assess the performance of high risk implanted medical devices in order to determine its clinical effectiveness and safety.

#### *5.3.2 Medical device industry*

In order to raise up to \$4.05 million through an increase to TGA charges for AIMDs, Class III and Class IIb medical devices, the TGA annual charge would need to increase by the following amounts (based on 7,087 products in these categories on the ARTG and noting that they are not all implantable devices).

Category of Device	Number of devices*	Current Annual Charge	Increased Annual Charge	% increase
AIMD	312	\$1,150	\$1818	58%
Class III	2254	\$1,150	\$1818	58%
Class IIb	4521	\$890	\$1407	58%

\* (included on ARTG as at 1 July 2012)

Alternatively, a new levy could be established for the medical devices industry, noting that this would require legislative underpinning.

### 5.3.3 Health care professionals and medical craft groups

The impact of establishing specific national clinical quality registers on health care professionals and medical craft groups is described in Section 5.1.2.

A nationally consistent means of quickly identifying recipients of high risk implantable medical devices will reduce the burden on hospitals to maintain individual systems and address the challenges associated with patient contact details being out of date.

### 5.3.4 Government

Option 3 would benefit the Government by:

- improving the current disparate arrangements in the short term through national leadership in co-ordinating and promoting a best practice approach to patient identification and contact; and
- strengthening the post-market monitoring of high risk medical devices implanted in patient through expanded and timely performance information.

## 6. Consultation

In October 2012, the Department engaged ACSQHC to consult with relevant stakeholders in order to provide advice on technical, governance and funding options regarding the implementation of clinical quality registers with patient contact capability for specific high risk implantable medical devices and a single patient contact register for all other high-risk implantable devices. This followed the Government Response to the Senate Standing Committee on Community Affairs inquiry into *The Regulatory Standards for the Approval of Medical Devices in Australia*, which expressed support for clinical registers for high risk implantable medical devices and said that ‘the Government will continue to work with industry and medical groups to identify the most effective ways to track the use and performance of high risk implantable medical devices balancing benefits and costs to patients, providers and the wider community’<sup>46</sup>.

<sup>46</sup> Inquiries relating to high risk medical devices and associated submissions from industry, the medical profession and consumers are outlined in the preliminary RIS. The submissions strongly supported post-market surveillance. While there were some opposing views, there was widespread support for clinical registers as an approach. Department of Health and Ageing, *Regulation Impact Statement, Clinical Registers for High Risk Implantable Medical Devices*, October 2012, pp21-24.

Overall there was strong support from a wide range of stakeholders for the development by government of patient identification and contact capability in the event that a serious safety issue associated with a high risk implantable medical device.

However, there were variances within the stakeholder groups as to acceptable funding models, accessibility and governance. Consumer representatives were supportive of both a patient contact and recall register as well as clinical quality registers, however did not see that the patient had a role in funding registers (such as the breast implant register).

The Medical device industry representatives were also generally supportive, however did not agree that they should be the sole funders of registries and saw a role for government to establish infrastructure around set-up and governance. Similarly, the private health insurers were concerned that the cost be spread over a number of stakeholders. However, they acknowledged the value of clinical registers in improving medical practice and reducing costs.

Clinical craft groups such as the Cardiac Society of Australia and New Zealand were more supportive of the clinical quality models rather than a patient contact model, as they see more value in a clinical quality register.

## 6.1 Consultation Process

The ACSQHC undertook a number of activities as part of the consultation process. A consultation paper was developed covering key issues including:

- clinical quality registers and contact registers as mechanisms to improve post-market surveillance of high risk implantable medical devices;
- best practice models for development, operation and governance including data governance and opt-in and opt-out consent models;
- priorities for the establishment of registers;
- relevant funding models including cost recovery funding models;
- potential for utilisation of standardised datasets;
- possible interoperability of register with existing healthcare clinical and administrative information systems;
- overview of potential registry establishment and operating costs and benefits;
- summary of outcomes of recent inquiries

The consultation paper was distributed to stakeholder organisations including health professional, industry and consumer groups and Commonwealth and State Government health and human service agencies (a list of these organisations is at **Appendix B** ). Submissions were invited and nine were received (listed at **Appendix C**).

An Expert Workshop was held on 7 November 2012 attended by people with expertise in the manufacture, distribution, purchasing, regulation, funding, use and follow-up of medical devices as well as the implementation of registers (a list of attendees is at **Appendix D**).



A number of stakeholders also participated in structured interviews conducted by the ACSQHC and face to face consultations were held with members of key committees (**Appendix E**).

## **6.2 Consultation Findings<sup>47</sup>**

### *6.2.1 Need for contact capability*

Overall there was strong support for development by governments of patient identification and contact capability in the event that a serious safety issue associated with a high risk implantable medical device is identified. All Participants including consumer representatives emphasised the strong expectation of patients and the community that governments would ensure this capacity. As submitted by one participant:

*'...contact databases, post market surveillance and clinical quality registers should form part of the Government's arsenal of tools for managing risk and improving patient's care'*

### *6.2.2 Mechanisms for post-market surveillance and patient contact*

There was a strong view that existing data collections should be utilised where possible to capture the data necessary to support patient identification and contact.

#### *Type of register*

Many participants supported utilisation of existing clinical quality registers subject to agreement with register owners on standards of governance, operations and data access. Participants noted the benefits which arise from investment in those registers which make a sustained and comprehensive contribution to improving the safety and quality of clinical care. Some argued that for this reason clinical quality registers provide a better return on investment than a more limited contact register and that they could be reliable sources of patient identification and contact data. However, it was agreed that there were potential barriers to utilising clinical quality registers for patient contact including reliable and timely access to relevant data and existing governance and legal protections.

There was also support for a contact register, as other participants noted that clinical quality registers are probably only useful and achievable in a limited number of disciplines and other methods of patient identification and contact (such as a contact register) would be necessary for devices not included in those few clinical quality registers.

#### *Use of admitted patient datasets*

There was support for routine capture in admitted patient datasets of data sufficient to enable patient identification and contact for all high risk implanted medical devices (subject to defined exceptions)<sup>48</sup>. The data would be retained in hospital or jurisdictional collections

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<sup>47</sup> Information in this section is drawn from unpublished ACSQHC consultations November 2012.

<sup>48</sup> It was suggested that it would be unnecessary to record implantation of high volume devices in which safety is well-established such as anastamotic staples.

or routinely uploaded into a central patient contact register. It was noted that some procedures occur outside admitted patient settings and that other mechanisms would be required to capture information on these procedures.

### *Efficiency issues*

Representatives of the NJRR did not support creation of a patient contact register and put the view that a clinical quality register provides better value for money. Some health insurers also strongly supported investment in clinical quality registers suggesting that the low number of recall events did not warrant a national patient contact register.

### *6.2.3 Operational considerations*

#### *Clinical quality registers*

Participants emphasised the need for stakeholder confidence in the governance and operations of clinical quality registers as a prerequisite to reliance on them for patient contact purposes. Particular emphasis was given to a skills-based governing body, transparency of operations, accountability to governments and the community and full engagement of clinicians in all clinical decision-making processes. There was strong support for adoption of robust standards of governance and operations for all clinical registers.

#### *National contact register*

There was strong support for a national patient contact register for high risk implantable medical devices to be operated directly by government. Many participants specifically did not support operation by a non-government entity such as a university. There was support for DHS being the operating department based on its experience with registers and management of health data systems. There was general support for DoHA to be the business owner and governance entity for a national patient contact register.

#### *Development of protocols*

Participants supported development of robust arrangements for timely access to data in accordance with agreed protocols. The consultation highlighted concerns that there is appropriate clinical engagement in the design and implementation of hazard alerts relating to implanted medical devices.

Consumers strongly advocated for the right to directly access the information that is held about them in clinical registers including patient contact registers.

#### *Unique identifiers*

It was noted that unique patient identifiers, unique provider identifiers and unique product identifiers will support implementation of a patient identification and contact capability and uniform adoption will be important to accurate information capture.

#### *6.2.4 Responsibility for data collection and submission*

The majority of Participants supported specific allocation of responsibility for data collection to the organisations in which the procedures are performed. While clinician-led registers (such as the NJRR) have worked very well in specific clinical disciplines, Participants concluded that it would be unsound to rely on clinicians as the primary source of data for all high risk medical devices.

While it was noted that data at a patient level are held by suppliers, Participants did not support a proposal that suppliers be responsible for maintaining individual patient records. They concluded that it would be difficult to ensure data integrity across a distributed system for a range of reasons including commercial confidentiality and privacy.

The prevailing view was that it is reasonable to expect health services to collect and hold or submit data about high risk implantable medical devices for patient contact purposes because this enables them to fulfill their duty of care to the patient. In this context, Participants identified a number of incentive and accountability mechanisms including regulatory powers and payment of benefits. However, some Participants, particularly those from the private hospital sector, raised concerns about the cumulative costs involved.

#### *6.2.5 Patient consent processes*

Most Participants noted that requirements for explicit patient consent processes ('opt-in' consent processes) have been highly unsatisfactory in the context of clinical quality registers, resulting in very low levels of consumer participation. Opt-out consent processes are strongly endorsed by consumer organisations. Participants noted the difficulty of negotiating such arrangements with ethics committees and the associated cost burden. Some Participants questioned the need for specific consent processes and suggested a systematic review of privacy legislation. The consensus view was that requirements for consent should then be reviewed but if specific consent processes are required 'opt-out' processes are manageable.

#### *6.2.6 Funding Issues*

##### *Clinical quality registers*

Participants emphasised the need for clinical quality registers to be sustainable. Although there was no clear consensus about how to fund them, there was strong support for their costs to be distributed equally amongst stakeholders who derive benefit from them including device manufacturers/suppliers, health insurers, government and other funders. There was no support from any Participants for a funding strategy that imposes a direct cost on consumers.

##### *Patient contact register*

Participants suggested funding for a patient contact register should rest with either government or device sponsors.

It was suggested that cost recovery from device suppliers based on a flat fee for all devices would be inequitable as it would not reflect the cost of each prosthesis nor the volume of prostheses sold. While some participants proposed that a formula for cost recovery should reflect these parameters, others noted that sales volumes may be commercially confidential.

#### 6.2.5 Summary of views of stakeholder groups\* – aspects of options

<b>Participants – Key Points</b>	<b>Comment/Relationship to Options**</b>
All support capability to enable patient contact.	All 3 options would address this issue. Option 1 provides limited patient contact capability as not all devices would be covered.
Strong support for utilisation of existing data sources and systems to capture patient contact data where possible; specifically: - existing clinical quality registers; - routine data capture in admitted patient data sets.	All Options build on existing systems: Option 1 provides limited patient contact capacity due to extent of coverage; Option 3 incorporates both existing clinical registers and nationally consistent patient data. Option 2 also establishes a new stand-alone register;
Considered that in terms of patient safety and quality of clinical care, clinical quality registers provided greater benefits than a patient contact register.	Options 1 and 3 incorporate support for clinical quality registers. However, Option 1 provides limited patient contact capacity.
Support national contact register for devices not covered by clinical quality registers.	Option 2 establishes a contact register. Option 3 incorporates future consideration of a contact register.
Strong support for adoption of robust standards of governance and operations of all clinical registers.	Incorporated in Options 1 and 3
Strong support for a national contact register to be operated directly by government.	Incorporated in Option 2
Support for development of protocols for timely access to data and appropriate clinical engagement in hazard alerts.	Specifically incorporated in Options 2 and 3
Support for systematised unique patient, provider and product identifiers.	Specifically incorporated in Options 2 and 3
Considered that health services should collect and hold or submit patient contact data.	All Options require patient data collection by health services: Option 1 may also involve reliance on clinicians for some data capture. Clinical

<b>Participants – Key Points</b>	<b>Comment/Relationship to Options**</b>
	registers would hold and submit data. Under Option 2 data would be submitted by health services and held in a national register. Under Option 3 data would be held and submitted by health services with future consideration of a national contact register to hold data.
Considered that ‘opt in’ consent processes are highly unsatisfactory and that ‘opt-out’ processes are preferred and manageable.	‘Opt-out’ processes could be incorporated in Options 1 and 3 through standards for clinical registers.
Strong support for costs for clinical quality registers to be distributed equally amongst stakeholders who benefit but not consumers.	Funding options do not include direct costs to consumers (i.e. a fee for service option).
Suggested that funding for a patient contact register should rest with either government or sponsors. Formula for sponsors should be equitable.	Funding Options consider Government or cost recovery from industry. Cost recovery elements of all Options would be subject to a CRIS process to derive an equitable formula.

<b>Consumers - Key Points</b>	<b>Comment/Relationship to Options**</b>
Advocated for the right to directly access their information in clinical registers, including patient contact registers.  Strongly support opt-out consent processes.	Sound data governance is central to Principle 8 for Clinical Quality Registers.  Could be incorporated in Options 1 and 3 through standards for clinical registers.

<b>NJRR Representatives - Key Points</b>	<b>Comment/Relationship to Options**</b>
Did not support a central patient contact register.  Suggested that device sponsors should be required to maintain patient contact details for high risk implantable devices, where this information was not otherwise available.	Option 1 does not incorporate a patient contact register but provides limited contact capacity.  Consensus view was that this proposal was not practical or appropriate for reasons of data integrity, limited transparency and privacy.

<b>Health Insurers - Key Points</b>	<b>Comment/Relationship to Options**</b>
Supported investment in clinical quality	Options 1 and 3 involve investment in clinical

<b>Health Insurers - Key Points</b>	<b>Comment/Relationship to Options**</b>
registers.  Queried whether a national contact register would be cost-effective given the relatively low number of Hazard Alerts.	quality registers.  Options 1 and 3 involve investment in clinical quality registers. Option 3 requires further assessment of the cost-effectiveness of a national contact register.

<b>Private Hospital Sector – Key Points</b>	<b>Comment/Relationship to Options**</b>
Concerned about the costs involved in data collection.	All Options require patient data collection by health services. Prevailing view was that this enables health services to fulfil their duty of care.

\* Stakeholder groups identified in this table were specified in relation to particular views expressed in the consultations.

\*\* Option 1- National clinical quality registers

Option 2 - National patient contact register or building national capability to contact patients

Option 3 - Option 1 plus building national capability to contact patients

## **7. Conclusion**

The RIS identifies concerns around the safety and performance of high risk implantable medical devices requiring a more effective process for contacting affected patients where performance issues are identified, and increased capacity for post-market surveillance. The concerns have been consistently identified as priority issues in the HTA Review report and two Senate Inquiries.

The merits of the following options have been considered:

1. Establish specific national clinical quality registers
2. Establish a single national patient contact register or build national capability to contact patients
3. Establish specific clinical quality registers and build national capability to contact patients with data retained at hospital level

In addition, the impact of these options on consumers, the medical device industry, health care professionals, private health insurance and Government have been analysed, along with the costs and benefits. Stakeholders have been consulted on implementation options through an expert workshop and targeted interviews conducted by the Australian Commission on Safety and Quality in Health Care in 2012.

Option 1 will only partially address the Government’s objectives, as it will not necessarily result in any increased capability to identify and contact patients who have been implanted with a particular type/model/serial number of a high risk medical device when the need arises. This requirement is considered to be critical in light of recent events concerning

devices such as hip implants and breast implants and the risk of either unnecessarily alarming the community or not providing appropriate advice to affected patients. In considering options to establish specific national clinical quality registers it will be more cost-effective to build on existing pilots or state-based registers than to develop new national registers.

Similarly option 2 alone will only partially address the Government's objectives; it will not provide information to the TGA, the medical device industry or health care professionals to assist in monitoring the performance of a high risk implantable medical device, or to inform best clinical practice. While a national patient contact register (option 2a) will provide increased capability to identify and contact patients who have been implanted with a high risk medical device it is a much more costly option to Government than building national capacity with the data remaining at the hospital level (option 2b). Given the relatively small number of TGA hazard alerts each year, it would be difficult to justify the expense of a centralised contact register with the data held nationally. Further the feasibility of option 2a would be subject to state/territory agreement to identified patient data being transferred to a national level.

Option 3 combines the proposal to establish national clinical quality registers (option 1) while in parallel also building national capacity to identify and contact patients (option 2b). This option strengthens TGA post-market monitoring, benefits the medical device industry in having access to data about the actual use of high risk medical devices, provides valuable data for analysis on surgical techniques and outcomes to medical craft groups and supports health care professionals to provide appropriate advice to patients in addressing any health risks associated with their specific implanted high risk medical device.

After these considerations, option 3 is recommended as the most appropriate way in which to implement the Government's commitment. The need to build national capacity to facilitate patient identification and contact in the immediate future is seen as the highest priority.

This option would streamline the current arrangements for identifying and contacting patients in the case of a Hazard Alert and increase the post-market regulatory rigour of certain high risk implantable medical devices. The additional regulatory scrutiny also aims to reduce the potential for high rates of revision procedures related to product failure in the future.

The proposed changes strengthen public health and safety where an implanted device fails and provides another important source of information to enable the TGA to meet the challenges associated with increasingly sophisticated implantable medical devices which are either life-saving or add substantially to quality of life.

The recovery of costs from the medical device industry to support a national approach to contacting affected patients is consistent with the Commonwealth's guidelines, as the activities of the medical device industry drive the need to alert patients to substandard devices. While the medical device industry derives a financial benefit from clinical registers, given the broader benefits of national clinical quality registers to the public health system, a

shared funding arrangement between the Government and the medical device industry may be appropriate.

While recovery of costs (either in part or in full) may mean that TGA annual charges for the medical device industry will be increased or a new levy imposed on the industry, these changes reflect the level of scrutiny expected by the community, in particular given the nature of these products.

Options for partial or full cost-recovery which would provide an equitable basis for recovery of costs from relevant sectors of the medical device industry through for example an increase in TGA charges or a new levy should be explored further in 2013, including consultation with stakeholders.

## **8. Implementation and review**

### Building National Capability to Contact Patients - National Patient Identification and Notification Protocol

The Government will need to seek the agreement of state/territories to develop and promulgate the proposed national protocol, noting that for many facilities this may mean collecting additional Patient Administration System data.

### National Clinical Quality Registers

It is proposed that the Department of Health and Ageing take responsibility for administering funding to support the sustainability of national Clinical Quality Registers, including providing advice to Government on priority procedures associated with those high risk implantable medical devices which have most commonly been subject to Hazard Alerts in recent years. Dependent on the specific nature of the funding process, funding guidelines or criteria will need to be developed. A process for identifying the registers to be funded will need to be agreed and funding agreements developed and monitored. The Department will require additional resources to undertake these activities.

### Review

A review is to be carried out in 2016-17 to assess the effectiveness of the arrangements in meeting Government's objectives.



### Strategic Principles for a National Approach to Australian Clinical Quality Registries

**Principle 1:** Consumers, clinicians, management and governments receive regular reports from Clinical Quality Registries on appropriateness of care (process and compliance with guidelines), and effectiveness of care (patient outcomes) to support ongoing improvement of health care in Australia.

**Principle 2:** Clinical Quality Registries, operating in close coordination with expert national clinical groups, provide an effective mechanism for:

- design of indicators of quality of care
- comprehensive data collection and analysis, and
- outlier management within a sound clinical governance framework.

**Principle 3:** National data governance arrangements and best practice infrastructure provide support for comprehensive reporting, monitoring and management of clinical practice variance.

**Principle 4:** Where existing data flows do not support analyses of quality of care, Australian Clinical Quality Registries are efficient and effective in providing consumers, clinicians, management and government with information for managing and improving delivery of health services.

**Principle 5:** Dedicated investment in Australian Clinical Quality Registries supports infrastructure, data cleansing, reporting and analysis of quality of care, based on succinct datasets captured routinely by clinicians at the point of care.

**Principle 6:** Australian Clinical Quality Registries have sound governance arrangements with strong clinical leadership and a demonstrated framework for quality improvement.

**Principle 7:** Prioritisation of Australian Clinical Quality Registry support is premised on gaps in existing data flows, the significance of the national burden of disease and the cost of interventions, the existence of variation in practice and outcomes, the ability to improve quality of care including reduction in practice variation, availability of national clinical leadership and consideration of existing data, and cost/benefit options.

**Principle 8:** Data governance for the collection, holding and analysis of patient-level, Australian Clinical Quality Registry information is managed as part of the national health information agenda, in a framework that protects patient privacy and complies with regulation. National data governance arrangements are essential to making the data collection, ethics approvals and reporting activities of Australian Clinical Quality Registries more efficient.

**Principle 9:** A secure, future-proof and scalable Australian Clinical Quality Registry design and infrastructure should support and host multiple Registries. Efficiency and best practice are best achieved through the operation of a small number of Australian Clinical Quality Registry systems or centres.

**Principle 10:** Australian Clinical Quality Registries must meet the requirements of national operating principles.

### Consultation paper distribution list

The Consultation Paper was distributed to the following key stakeholder organisations:

ACT Department of Health  
Australasian College of Cosmetic Surgery  
Australian Institute for Health and Welfare  
Australian Orthopaedic Association National Joint Replacement Registry  
Australian Private Hospitals Association  
Australian Society of Plastic Surgeons  
Cardiac Society of Australia and New Zealand  
Catholic Health Australia  
Clinical Excellence Commission (NSW)  
Commonwealth Department of Health and Ageing  
Commonwealth Department of Human Services  
Consumers Health Forum of Australia  
GS1 Australia  
National E-Health Transition Authority  
National Heart Foundation of Australia  
Northern Territory Department of Health  
NSW Agency for Clinical Innovation  
NSW Ministry of Health  
Medical Technology Association of Australia  
Monash University Department of Epidemiology and Preventive Medicine  
Office of the NSW Chief Health Officer  
Private Healthcare Australia  
Queensland Department of Health  
Royal Australian College of Surgeons  
Royal Australian and New Zealand College of Obstetricians and Gynaecologists  
Royal Australian and New Zealand College of Radiologists  
South Australian Department of Health  
Tasmanian Department of Health and Human Services  
Therapeutic Goods Administration  
Victorian Department of Health  
Western Australian Department of Health

### Submissions received

The Commission received submissions on the Consultation Paper from the following organisations and individuals:

Australasian College of Cosmetic Surgery

Australian Society of Plastic Surgeons

GS1 Australia

Medical Technology Association of Australia

National E-Health Transition Authority

National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand (joint submission)

Professor Emily Banks, National Centre for Epidemiology and Population Health Australian National University

Royal Australian and New Zealand College of Radiologists - MRI Reference Group

Western Australian Department of Health

In addition, comment was received from the TGA Advisory Committee on the Safety of Medical Devices.

### Attendees at the expert workshop

The following individuals attended the expert consultation workshop at the Commission offices on Wednesday 7 November 2012:

Mr Bruce Battye NSW Ministry of Health  
Mr Neville Board Australian Commission on Safety and Quality in Health Care  
Mr David Braddock Australian Institute for Health and Welfare  
Dr Jane Cook Therapeutic Goods Administration  
Mr Adrian Cosenza Australian Orthopaedic Association National Joint Replacement Registry  
Prof Richard de Steiger Australian Orthopaedic Association National Joint Replacement Registry  
Ms Melissa Doyle Royal Australian and New Zealand College of Radiologists  
Mr Greg Eliovson Australian Society of Plastic Surgeons  
Dr Sue Evans Monash University Department of Epidemiology and Preventive Medicine  
Mr David Evenden Commonwealth Department of Human Services  
Dr Jan Fizzell Office of the NSW Chief Health Officer  
Mr Andrew Goodchild National E-Health Transition Authority  
Dr Paul Gould Cardiac Society of Australia and New Zealand  
Ms Anna Greenwood Consumers Health Forum of Australia  
Dr Mukesh Haikerwal National E-Health Transition Authority  
Ms Jenny Hargreaves Australian Institute for Health and Welfare  
Mr Martin Johnston Hospitals Contribution Fund of Australia  
Mr Alan Jones Australasian College of Cosmetic Surgery  
Ms Fee Koch Medical Technology Association of Australia  
Mr Greg Kovacs Private Healthcare Australia  
Ms Winnie Liu Australian Society of Plastic Surgeons  
Dr Nigel Lyons NSW Agency for Clinical Innovation  
Ms Michele McKinnon South Australian Department of Health  
Prof John McNeil AM Monash University Department of Epidemiology and Preventive Medicine  
Ms Julie-Anne Mitchell National Heart Foundation of Australia  
Ms Michele Nelson Commonwealth Department of Human Services  
Dr Grant Phelps Tasmanian Department of Health and Human Services  
Mr David Ross Medical Technology Association of Australia  
Mr Graeme Schippers Commonwealth Department of Human Services  
Mr Marcel Sieira GS1 Australia  
Ms Sharon Swain ACT Department of Health  
Ms Jenny Vallance Australasian College of Cosmetic Surgery  
Ms Victoria van Straaten Queensland Department of Health  
Dr Heather Wellington DLA Piper  
Mr Nick Wilcox Australian Commission on Safety and Quality in Health Care  
Ms Catherine Winter Commonwealth Department of Health and Ageing  
Mr Peter Woodley Commonwealth Department of Health and Ageing

### Interviewees

The following key stakeholder organisations participated in structured interviews conducted by the Commission:

Australasian College of Cosmetic Surgery  
Australian Institute for Health and Welfare  
Australian Orthopaedic Association National Joint Replacement Registry  
Australian Society of Plastic Surgeons  
Cardiac Society of Australia and New Zealand  
Commonwealth Department of Human Services  
Consumers Health Forum of Australia  
GS1 Australia  
National E-Health Transition Authority  
National Heart Foundation of Australia  
Medical Technology Association of Australia  
Monash University Department of Epidemiology and Preventive Medicine  
Private Healthcare Australia  
Queensland Department of Health  
Royal Australian College of Surgeons  
Royal Australian and New Zealand College of Obstetricians and Gynaecologists  
Royal Australian and New Zealand College of Radiologists  
Western Australian Department of Health

In addition, face-to-face consultations were conducted with members of the Commission's Inter-Jurisdictional Committee and Private Hospitals Sector Committee.

### Acronyms

ACIR	Australian Childhood Immunisation Register
ACSQHC	Australian Commission on Quality and Safety in Health Care
AIHW	Australian Institute of Health and Welfare
AOA	Australian Orthopaedic Association
AODR	Australian Organ Donor Register
ARTG	Australian Register of Therapeutic Goods
BCSR	Bowel Cancer Screening Register
DHS	Commonwealth Department of Human Services
DMAC	Data Management and Analysis Centre
DoHA	Commonwealth Department of Health and Ageing
HTA	Health Technology Assessment in Australia
IEC	Institutional Ethics Committee
MTAA	Medical Technology Association of Australia
NJRR	National Joint Replacement Register
NMDS	National Minimum Data Set
NITRS	National Implantable Device Tracking and Recall System
PAS	Patient Administration System
PIP	Poly Implant Prothèse
PKI	Public Key Infrastructure
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

### Glossary

Adverse event	An incident in which harm resulted to a person receiving health care. Such an incident may or may not lead to revision procedures.
Clinical quality register	A register of patients who have had particular procedures (such as cardiac or cosmetic surgical procedures) involving the implantation of high risk medical devices, to evaluate the effectiveness of those procedures including the post-market performance of the associated devices, and to ensure that the health outcomes of all patients in receipt of these devices can be clinically assessed. These registers can serve to improve clinical performance and contribute information that might lead to a decision to recall a device.
Contact register	A register containing data only on the date of implantation, and identifiers for the patient, the device, the health care provider and the health care facility, to ensure that all patients in receipt of high risk implantable medical devices can be directly contacted if necessary using Medicare enrolment data.
Cost Recovery Impact Statement (CRIS)	A statement documenting compliance with the cost recovery policy. Only agencies with significant cost recovery arrangements must prepare a CRIS.
Hazard alert	A recall action where precautionary information is issued about an implanted medical device where it has been proven that there is no stock to be recalled and all devices are already implanted. In the event that stock is implanted and available in the market, an Urgent Medical Device Recall is carried out in conjunction with the hazard alert.
HTA review	The review commissioned by the then Minister for Health and Ageing, the Hon Nicola Roxon MP, and the then Minister for Finance and Deregulation, the Hon Lindsay Tanner MP in 2009 to address the regulatory burden on business that results from HTA processes and to ensure that processes are efficient, measured and proportionate. The HTA review highlighted the need for enhanced capacity to monitor post-market performance of high risk implantable medical devices.
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related device (including any diagnostic product for in vitro use) that is intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of medical treatment.
Medical Device classifications	All therapeutic goods have risks, some of which are insignificant, and some serious. The TGA approves and regulates products based on an assessment of risks against benefits. The TGA applies scientific and clinical expertise to ensure that the benefits of a product outweigh any risks. In assessing the level of risk, factors such as potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.
National Joint Replacement Registry (NJRR)	The National Joint Replacement Registry is an initiative of the Australian Orthopaedic Association (AOA). The Registry was established in 1999 becoming fully national in mid 2002. The purpose of the Registry is to improve and maintain the quality of care for individuals receiving joint replacement surgery. Information on hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement is collected from all hospitals in Australia undertaking joint replacement surgery.
Patient Administration System	A system which records patient demographics and details all patient contact with a hospital both outpatient and inpatient .

## Glossary

Post market monitoring	A series of activities conducted by TGA to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market and take action where this does not occur
Revision procedures	The need to undergo further corrective surgery.
Sponsor	<p>Under Section 7 of the Therapeutic Goods Act 1989 a sponsor, in relation to therapeutic goods, means:</p> <ul style="list-style-type: none"><li>• A person who exports, or arranges the exportation of, the goods from Australia; or</li><li>• A person who imports, or arranges the importation of, the goods into Australia; or</li><li>• A person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who:</li><li>• Exports, imports or manufactures the goods; or</li><li>• Arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia.</li></ul>