Australian Government

Department of Health and Ageing

Regulation Impact Statement

CLINICAL REGISTERS FOR HIGH RISK IMPLANTABLE MEDICAL DEVICES

Table of contents

EXECUTIVE SUMMARY

This Regulatory Impact Statement (RIS) is designed to support an in-principle agreement to the value of registers[1], and a commitment by Government to work further with industry, clinicians and consumers to refine advice on the types of registers that might be supported, and the manner in which they might be supported.

Medical devices are regulated by the Therapeutic Goods Administration (TGA), which also monitors the performance of devices once they are registered and available on the market. Sponsors[2] are required to report any problems that arise (adverse events) and doctors and consumers can (but are not obliged to) also report adverse events to the TGA.

Recent events, including those concerning Poly Implant Prothese (PIP) breast implants, have shown that locating patients with a high risk implantable device that may represent a health risk, can be difficult to identify and notify. Registers can be designed to provide data that will either (a) record clinical data about identified individuals to help to identify potential and unforeseen problems with a specific type of device, and provide a means to identify patients who have received those devices (clinical quality registers), or (b) provide just the latter function ('contact' registers) for a range of different device types. The National Joint Replacement Registry (NJRR) is an example of (a) above which demonstrates the potential of clinical quality registers to contribute to post market surveillance.

This Regulatory Impact Statement considers three options for dealing with this problem:

- The status quo;
- One or more clinical quality registers and/or a national contact register; and
- Registers managed by individual hospitals.

Option 2 is preferred as, on the evidence available to date, it provides the most effective and least costly potential to reduce risks to patients' safety, and costs to patients, industry, health service providers, government and other funders, due to poorly performing high risk

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[1] A register is defined as 'A written record containing (official) entries of items, names, transactions etc'. (Longman English Dictionary). A registry may be understood as a place of registration or an organisation that manages a register. However, for simplicity the term 'register' is used throughout this document except where it forms part of an official title or of a direct quotation.

[2] Under the *Therapeutic Goods Act 1989*, a 'Sponsor' is someone who:

- imports therapeutic goods,
- manufactures therapeutic goods,
- has therapeutic goods imported or manufactured on their behalf, or
- exports therapeutic goods from Australia.

The sponsor of a medicine is the person or company responsible for applying to the TGA to have their medicine included in the Australian Register of Therapeutic Goods.

implantable devices. A period of investigation is proposed to enable further consultation on the models, scope, governance arrangements and funding mechanisms for registers of high risk medical devices.

Consumers, professional medical groups, industry associations and others have expressed their views about the value of registers over a number of years now, in particular through submissions and evidence provided to three reviews and inquiries: the Review of Health Technology Assessment in Australia (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).

An implementation RIS and, if appropriate, a Cost Recovery Implementation Statement (CRIS) would be prepared should the Government choose to affirm its support for a particular register model or models.

PROBLEM

Implantable medical devices are regulated by the Therapeutic Goods Administration (TGA), which assesses these devices prior to supply in Australia and also has a role in post-market monitoring. In general, medical devices must be included on the Australian Register of Therapeutic Goods (ARTG) before they may be supplied in or exported from Australia.[3]

Several recent events have highlighted that important clinical information on adverse health outcomes associated with the use of high risk implantable medical devices is not available for post market evaluation, or for the efficient notification of potentially affected patients in the event of a problem with an implanted medical device.

In April 2010, Poly Implant Prothese (PIP) silicone breast implants were recalled, and then cancelled from the ARTG, after the French regulator expressed concerns that there may have been an increased incidence of ruptures of this product associated with the use of an unauthorised silicone gel. Following the expression of further concerns in relation to PIP breast implants by the French Government in December 2011, including a recommendation that women with these implants should consider having them surgically removed as a non-urgent precautionary measure, the TGA took extensive steps to test the devices, to consult with clinical experts, and to urge clinicians to communicate with their patients. A register of such devices would have enabled these patients and their clinicians to be contacted more quickly, sensitively and directly.

This Regulatory Impact Statement (RIS) is designed to support an in-principle agreement to the value of registers, and a commitment by Government to work further with industry, clinicians and consumers to identify the most effective ways to track the use and performance of high risk medical devices (including the number, nature and priority of possible registers), balancing benefits and costs to patients, providers and the wider community. As part of this process the Government is also considering funding options for the establishment of registers. A more detailed implementation RIS, based on this work and including information and options on patient participation and consent and data collection and management, will be developed prior to any Government decisions being made on the nature and operation of any register.

What are high risk implantable medical devices?

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

[3]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 www.tga.au/industry/artg-searching.htm. The ARTG is different in nature and purpose to a clinical register. Clinical registers are explained on p7.

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 were placed on the market. For this reason, post-market monitoring is particularly critical for the effective regulation of high risk implantable medical devices.

In the context of the Australian Commission on Safety and Quality in Health Care's (ACSQHC's) investigation of the case for a register of high-risk implantable medical devices in 2008-09, the TGA's Medical Devices Evaluation Committee (MDEC) sub-committee, the Implantable Medical Device Tracking Sub-Committee (IMTDSC), considered the types of candidate implantable devices and recommended that the following five categories of implantable medical devices be tracked:

1. *Medical devices that are life sustaining/supporting* – These devices are self-evident in that non-function or malfunction will result in either death or a life-threatening situation – eg. Active cardiovascular implants, prosthetic heart valves, implantable drug delivery devices.
2. *Medical devices with potential for significant morbidity from device "failure"* – These devices whose failure and/or replacement are likely to have a significant impact on patient morbidity. 'Failure' is interpreted in the broadest sense to include non-function, malfunction and device-related adverse events – eg. Hip implants, cochlear implants, vascular grafts.
3. *Medical devices that should be subject to strategic surveillance* – These are devices that should be tracked for strategic reasons, either because of problems that become evident following marketing or because of problems with devices of similar technology in the past – eg. silicone breast implants.
4. *Medical devices involving emerging technology* – These are devices where the long-term prognosis would be unknown or difficult to predict, including those

devices used on a trial or individual basis under the Special Access Scheme – eg. drug-coated coronary artery stents.

5. *Devices of biological origin* – These are devices that include banked, cultured and manipulated tissues or cells, that should be tracked because of potential risk for transmission of as yet unidentified infectious disease, or the potential for immunological sequelae[4].[5]

A list of devices that meet the above principles is at Attachment 1.

What are clinical registers?

Clinical registers are essentially databases of identifiable persons containing clearly defined sets of health and demographic information. They can range widely in scope and function.

Two types of registers are relevant in this context:

- ***Clinical quality registers*** 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, ***and*** enable patients to be contacted directly if necessary.

- ***Contact registers***, 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.

Effective device registers must contain complete and accurate information. Two factors affecting this are: registers' governance arrangements to achieve the full co-operation of clinicians and hospitals; and patients' choices about contributing data to encourage maximum participation.

Australia's most prominent implantable device register, the National Joint Replacement Registry (NJRR) was established by the Australian Orthopaedic Association (AOA) in 1998 with the support of Australian Government funding. Since 2009-10, the NJRR has been funded through a legislated levy on the devices industry. The design of the NJRR is simple. Data on all hip and knee replacement procedures are entered into a stand alone data base.

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[4] Sequelae is the plural form of sequela which is a pathological condition resulting from a disease, injury or other trauma.

[5] Australian Commission on Safety and Quality in Health Care, *A national register for high-risk implantable medical devices*, February 2009, pp.7-8.

The data are collected from hospitals on paper forms and submitted to a central facility where they are manually entered by Registry staff. Data are available to surgeons, hospitals, sponsors, government and the general public, to help inform decisions about the effectiveness of procedures and associated devices.[6]

Significance and magnitude of problem

At 4 August 2011, the numbers of Australian Therapeutic Goods Register (ARTG) entries for Class IIb, Class III or Active Implantable Medical Devices (AIMD) classifications (noting that non-implantable devices will also be included within these classification groupings) were: Class IIb 4895, Class III 2694 and AIMD 284.

In 2009, the ACSQHC estimated that approximately 350,000 high risk devices would be supplied in that year.[7] These included cardiac devices and valves, breast implants, stents, joint prostheses and implanted neurological stimulators.

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….'.[8]

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.[9]

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

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[6] Australian Orthopaedic Association, National Joint Replacement Registry, *Hip and Knee Arthroplasty, Annual Report 2011*, pp.5-8.

[7] Australian Commission on Safety and Quality in Health Care, p.9.

[8] 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.

[9] Australian Commission on Safety and Quality in Health Care, p.2.

significantly increased.[10] The financial implications of increased or early revision surgery are explored in discussion of impact analyses below.

Current Regulation

Despite rigorous pre-market assessment of Class III high risk medical devices, some risks only become apparent with widespread use of the device.[11] The nature of some safety issues is such that they only become apparent when a device is used in greater numbers and over a longer period than can be achieved in pre-market trials. The Australian regulatory framework for medical devices provides for post-market monitoring by the TGA, including: checking evidence of conformity; conducting periodic inspections of manufacturers' quality management systems and technical documentation; and imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices. The TGA carries out post-market monitoring to ensure the continuing regulatory compliance and safety of medical devices included on the ARTG for supply to the Australian market.

Reporting of adverse events

In support of the TGA's post-market monitoring activities, the sponsor of a medical device has ongoing responsibilities once a device has been included in the ARTG. These statutory responsibilities include that the sponsor must report to the TGA adverse incidents; overseas regulatory actions; and the results of investigations undertaken by the manufacturer. The sponsor must also maintain records of the customers (such as hospitals and surgeons) to whom the device has been distributed (but not the details of the patients in whom these devices were ultimately implanted).

Sponsors are required to report certain individual adverse incidents involving their medical devices to the TGA within statutory timeframes that depend on the seriousness of the incident.

The manufacturer is required periodically to review performance, safety and the benefit-risk assessment for its device through a clinical evaluation, and update the clinical evidence accordingly. These reviews by the manufacturer are expected to be assessed by notified bodies or those undertaking re-certification processes.

The TGA's powers in relation to the keeping of records and reporting of adverse events and other safety matters are those set out in the *Therapeutic Goods Act 1989* and are limited to

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[10] 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,

[11] Prior to I July 2012, hip, knee and shoulder joint replacements were classified as Class IIb and may not have undergone pre-market assessment.

sponsors and manufacturers. Sponsors and manufacturers must report life-threatening or serious public health related adverse events. There is non-mandatory reporting for non-urgent or less serious health related other events.

The TGA's powers do not include the regulation of clinical practice, including surgical practice, or matters relating to doctor-patient consultations. The Medical Board of Australia is responsible for all matters relating to the regulation of medical practitioners in Australia.

Reporting of adverse events by users (medical practitioners and their patients) is voluntary. The relevant TGA guidelines make it clear that users are encouraged to report events associated with the use of a medical device to either the sponsor or to the TGA. The TGA supports reporting by health professionals, patients and the public by making available a Users' Medical Device Incident Report on the TGA website, and by providing information directly to health professionals through a range of mechanisms about how and when to report medical device adverse events.

Recalls of medical devices

Following a TGA risk assessment and further investigation if required, subsequent action may include product recovery (recalls); issuing of hazard and safety alerts; product modification/ improvement by a manufacturer; and/or surveillance audits of manufacturing sites.

The TGA can take regulatory action[12] to suspend or cancel a device from the ARTG where, for example, the outcomes of the TGA's investigations indicate that there is a potential risk of death, serious illness or serious injury if the device continued to be included in the Register and can cancel a device from the ARTG if satisfied, for instance, that the safety or performance of the device is "unacceptable".

The TGA coordinates approximately 500 recalls of medical devices each year. The vast majority of recalls are undertaken voluntarily by the sponsor in cooperation with the TGA.

In voluntary recalls, the TGA expects that sponsors will act in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG).[13] In mandatory recalls (that is, where the powers under the *Therapeutic Goods Act 1989* are used), the TGA will usually require sponsors to comply with particular parts of the URPTG.

In practice the TGA decides on a case by case basis whether to allow a sponsor to recall medical devices voluntarily or whether the TGA should exercise its statutory recall powers. As noted above, the vast majority of recalls are voluntary. This is for both practical and legal reasons. The TGA cannot exercise its statutory recall powers unless certain criteria are met, for instance that a TGA delegate formally determines that the quality, safety or performance

[12] Under the *Therapeutic Goods Act 1989* powers to take regulatory action are conferred on the Secretary of the Department of Health and Ageing. Those powers are exercised by officers of the TGA occupying positions to which relevant regulatory powers have been delegated by the Secretary.

[13] http://www.tga.gov.au/industry/recalls-urptg.htm.

of the device is "unacceptable".[14] Moreover, any decision to mandate a recall would be subject to internal and Administrative Appeals Tribunal review if the sponsor chose to challenge the basis for the recall.

Whether the recall is voluntary, or the result of the TGA exercising its statutory powers, the sponsor cannot as a matter of law be required (for obvious reasons) to recall any devices that have actually been implanted in patients - the obligations of the sponsor are limited to recalling devices that have been supplied to hospitals and surgeons and other customers to whom they have been distributed (but not the patients into whom the device has been implanted).

Only in circumstances where the TGA could order a statutory recall of a device can it direct the sponsor of the device to inform the public or particular persons about those circumstances (for instance that the safety of the device is unacceptable or that it has been cancelled from the Register). Even so, because the sponsor will not normally deal directly with patients or have access to patient contact information, this power could not be used to require the sponsor to contact those patients with implanted devices directly.

Where there is no stock to be recalled and all affected devices have been implanted the sponsor can issue a hazard alert which is sent to all those to whom the device has been supplied including surgeons (where this is known). The TGA can also request that it be sent to relevant colleges and associations. The hazard alert can contain information and advice to surgeons to contact patients for review and or to take specific action. The TGA can also request that the sponsor sent similar information to surgeons in the form of a product notification as part of a recall. [15]

Limits of current post market surveillance regulation

The capacity of the sponsor and/or manufacturer to provide comprehensive information to the TGA about adverse events and for the TGA to collect such information depends, to some extent, on relevant information being provided by those who have direct experience of those events, that is, patients and health professionals.

As a result, the adverse events reported to the TGA by healthcare professionals and consumers are limited to those that are reported voluntarily. The TGA has taken steps to raise awareness about the importance of adverse event reporting and to make it easier to report but voluntary reporting cannot be expected to deliver complete information. This severely restricts the TGA's capacity to systematically obtain and evaluate all data that could potentially be available.

In the event of a recall, while there is capacity to work with professional associations and to provide public information, there is no clear process to ensure that the people affected by the

[14] This would be grounds for cancelling the device from the ARTG.

[15] http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-100406.htm.

recall can be directly contacted. The absence of such a process poses a potential risk to public health and safety.

OBJECTIVE

The objective of government action is to enable:

a) early identification of unforeseen hazards in relation to the performance of high risk implantable medical devices; and

b) effective contact with patients where there is evidence that a high risk implantable device may pose an unforeseen risk to their health.

OPTIONS

Three main options have been identified to address the issues outlined above.

Option 1: Status quo

Under this option no substantive changes would be made to the current framework which includes initiatives underway to facilitate the recognition and reporting of adverse events. With the exception of devices monitored with the assistance of the National Joint Replacement Register (NJRR), post market monitoring would continue to rely on current arrangements including adverse event reporting by device sponsors (mandated) and by health professionals, patients and the public (non-mandated).

Option 2: Establishment of national registers

This option involves three potential approaches:

a) specific clinical quality registers[16] of patients who have had particular procedures (such as cardiac or cosmetic surgical procedures) involving the implantation of high risk medical devices; or

[16] The Australian Commission on Safety and Quality in Health Care provides a set of criteria for prioritising support for registers. They 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

b) a national contact register of all patients in receipt of high risk implantable medical devices (without clinical data other than the date of implantation, and identifiers for the patient, the device, the health care provider and the health care facility) to ensure that such patients can be directly contacted if necessary using Medicare enrolment data; or

c) a combination of the two.

Option 3: Establishment of individual registers by hospitals

Under this option, individual hospitals would be encouraged to establish registers of high risk implantable medical devices provided to their patients, to enable subsequent contact with them in the event of a recall. Participation in registers could be encouraged through accreditation and licensing processes.

Participation in Registers - Privacy and patient consent

Consent can be obtained through either an 'opt-out' or an 'opt-in' system. The former involves formal informed consent by the patient as part of their standard provision of consent to undergo a procedure. There is an option not to participate, but it requires an active decision of the patient. An opt-out model proposed by the Australian Foundation for Plastic Surgery for a breast device register involves patients being provided with an explanatory statement that outlines all the details relevant to their data and the purposes of the register. The information provides a toll-free number to call over a two week period if they choose to 'opt out'.[17]

It has been demonstrated that requiring specific permission in advance (opt-in) leads to the collection of a relatively small fraction of eligible cases and the resulting data analysis has limited credibility for quality improvement and does not provide complete information to enable contact with individuals. For example, the current Australian Breast Implant Register which has an 'opt-in' system, captured less than 4% of the PIP implants sold in Australia.[18] A recent US report on consent models for electronic exchange of health information noted that 'In order to achieve quality improvement, one must have access to measurable

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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.

[17] Australian Foundation for Plastic Surgery, Monash University (DEPM), *Breast Device Registry An International Perspective,* Global Summit, Munich May 2012.

[18] Australian Society of Plastic Surgeons, Submission to Senate Standing Committees 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, p.2.

information captured from thousands of transactions. In that respect an *opt-out* model may be preferable to its *opt-in* counterpart, as it likely will include clinical information for a larger percentage of the patient population.'[19]

A report by the ACSQHC on Australian Clinical Quality Registers recommends that opt-out consent be a standard approach taken upon the establishment of new registers.[20] The ACSQHC Operating Principles for Australian Clinical Quality Registries, endorsed by Health Ministers in November 2010, cover issues of data collection, security and custodianship, and ethics 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, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity.[21]

Further investigation of options to support registers will be guided by these principles.

IMPACT ANALYSES

Affected parties

- Consumers
- Medical technology industry
- Health care providers

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[19] Goldstein MM, Rein AL, *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis*, March 2010, p.55.

[20] Australian Commission on Safety and Quality in Health Care, Operating Principles and Technical Standards for Australian Clinical Quality Registries, November 2008, p.54.

[21] Australian Commission on Safety and Quality in Health Care, Australian Clinical Quality Registries, Operating Principles, 2010, p.56.

- Governments

Option 1: Status quo

Costs

Costs associated with the current systems of post market monitoring include medical costs (to Medicare, private health insurance, Pharmaceutical Benefits Scheme, public hospitals and out of pocket costs) of avoidable revision surgery, and of increased patient morbidity arising from the effects of poorly performing devices and further avoidable procedures.

The NJRR provides the most concrete evidence of the actual and potential costs of *not* investing in clinical registers. Its 2011 annual report found:

> Although it is a relatively short time since full national implementation of the Registry, it has already influenced joint replacement in a beneficial manner. The proportion of revision hip replacement has declined from 13.0% in 2003 to 11.2% in 2010. This equates to 630 less hip revisions in 2010 and 2,883 less since 2003.
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> Similarly, the proportion of revision knee procedures has declined from a peak of 8.8% in 2004 to 8.1% in 2010, equating to 299 less knee revisions in 2010 and 1,548 less since 2004. The reduction in revision surgery has been brought about as a result of increased use of the type and class of prostheses shown to have better outcomes and a decline in use when less satisfactory outcomes are identified.[22]

The average cost of a revision is in the order of $25,000. Therefore, the reductions in procedures described above equate to about $110 million over 6 to 7 years. This represents just one element of the costs of avoidable revision surgery, and does not include, for example, the costs of pre- and post-operative medical care, including pharmaceuticals and diagnostic imaging.

The department estimates that hip and knee prostheses represent approximately 60 per cent of the utilisation of most high risk implantable devices.

Benefits

There are no additional benefits to the status quo. Health care providers, consumers and the medical technology industry would not have access to comprehensive data on which to evaluate the relative performance of different medical devices in order to inform treatment choices and product development.

Summary

As there are no additional benefits to the status quo, the net result is a continuing burden of costs to all affected parties.

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[22] Australian Orthopaedic Association, National Joint Replacement Registry, *Hip and Knee Arthroplasty, Annual Report 2011*, p.6.

- Consumers bear the out of pocket costs of avoidable surgery and associated medical services, as well as morbidity associated with poorly performing devices.
- Industry bears the cost of reduced consumer confidence and lack of early intelligence on the performance of the products.
- Health care providers bear the cost of reduced consumer confidence in their services involving poorly performing devices, and the costs of investigating which patients have received poorly performing devices, in the event of a recall, by interrogating clinical case notes.
- Governments (and insurers) bear the avoidable cost of reimbursing devices, revision surgery and other associated medical services.

Option 2: Establishment of national registers

This option consists of the establishment of one or more clinical quality registers, and /or a national 'contact' register. The following discussion covers the costs and benefits of national registers in broad terms. The specific costs and benefits of sub-options 2(a), 2(b) and/or 2(c) would need to be explored in a more detailed RIS following consultation and refinement of options with key stakeholders.

Costs

Clinical quality registers

The establishment and ongoing costs of national clinical registers will vary according to a range of factors including the type of register (a simple contact register, or a series of clinical quality registers); the number of registers to be established; administrative arrangements including the possibility for co-hosting a number of registers under the auspices of a single organisation, which would affect establishment and ongoing costs; and data requirements and infrastructure.

Preliminary departmental estimates of establishment and ongoing costs per register range from $1 million to $2 million per annum.[23] The NJRR is the most relevant clinical quality register in Australia. The cost of running the NJRR was approximately $1.7 million in 2011-12.

Key procedures which could be covered by individual clinical registers include cardiac surgery, vascular surgery, breast implant surgery and neurosurgery. The approximate total cost of these four registers would be between $4 million and $8 million per annum.

The unit cost (NJRR) is estimated to be in the order of $20 per procedure based on the time taken to collect, record, transmit data and respond to requests for error checking. The usefulness of extrapolating from this unit amount to estimate the cost of register coverage for

[23] Based on the experience of the NJRR and other registers.

all high risk implantable devices is limited as fixed costs will depend on the number of registers supported.

The cost to health service providers for both types of registers is expected to be low.

The health service providers likely to be most directly affected are the hospitals or other facilities where surgery is undertaken and data would be gathered. In 2009-10, there were 1326 hospitals of which approximately 711 public acute hospitals and 573 private hospitals provide the relevant surgical services.

The data required, or similar to that required, are generally already held by clinicians and hospitals as part of routine record keeping required under conditions of accreditation and professional registration. For example, hospitals currently collect an admitted patient care national minimum data set (APC NMDS). The data is supplied on a regular basis to state or territory health authorities and include demographic, administrative and length of stay data as well as information on the diagnoses of patients, the procedures they underwent in hospital and external causes of injury and poisoning. In addition, data in respect of more than 99 per cent of procedures involving hip and knee prostheses are already provided to the NJRR.

The design of the mechanism for extraction of data such as this for use by the register will be an important component in minimising the impost on providers and health care facilities. As an example, the cost to health service providers of participating in the NJRR is minimal due to the simplicity of the form, which takes about 1 minute to complete, using stick-on labels with patient, device and procedure data.

It is recognised that the involvement and support of surgeons and related medical professionals is critical to ensuring the success of registers through an ongoing commitment to provision of reliable data. Clinicians' support for the governance and administrative arrangements for registers will be an important factor influencing advice on register options. The NJRR serves as a helpful model in this regard.

Contact register

A national contact register would cover a greater number of procedures but would require fewer data items, involve less analysis and reporting, and could leverage existing Government investments in Medicare infrastructure operated by the Department of Human Services. Data for the national contact register may be able to be extracted from routine administrative records with minimal impost on clinical staff. Subject to registry design, preliminary estimates of establishment costs range from approximately $2.5 million to $3.5 million and ongoing costs have been estimated at between $1.5 million and $2.5 million.

Funding sources

Funding to establish and maintain clinical registers has been provided to date from a number of sources including cost recovery from industry, funds provided by professional associations, fees levied on patients and Government funding. Further work on the parameters of optimal arrangements for national registers is required to enable firm costing of options. This work will include further consultation with stakeholders (see section 5) and development of a cost recovery impact statement if appropriate.

Benefits

The benefits of registers equate to the costs of avoidable surgeries and other medical services, and patient morbidity averted as a result of earlier identification of poorly performing devices and earlier notification of affected patients and health service providers. These are described above as costs associated with the 'status quo' option.

In addition, an assessment of the potential economic benefit of the Australian Cardiac Procedures Registry through improvement of aspects of cardiovascular care in Australia provides the following estimates:

- 'US data suggest that about 14 per cent of patients experience at least one adverse event after coronary artery bypass grafting (CABG) and each affected patient stays, on average, 5.3 days longer in hospital. If similar rates applied to the 21,000 Australian patients undergoing CABG the additional expenditure would amount to approximately $30 million. Reduction by 20% would save $6 million.

- Approximately 50,000 Australians were admitted to hospital with cardiac failure in 2001-2. If more effective treatment of acute ischaemia (inadequate blood supply to a local area due to blockage of blood vessels leading to that area) reduced this rate by 2 per cent (i.e. 1,000 less admissions) the savings would equate to 7,500 bed days or approximately $8 million.

- Approximately 35,000 Australian patients undergo PCI[24] annually and about 3 per cent of these experience prolonged hospitalisation following the procedure due to complications. Average hospital stay is approximately 4 days and with complications this doubles. If the rate was reduced from 3 per cent to 1.5 per cent through improved monitoring and benchmarking the savings would equate to 2100 bed days or approximately $2.3 million dollars'.[25]

An international study of thirteen registers in five countries (Australia, Denmark, Sweden, the United Kingdom and the United States) also sought to quantify the economic benefit of registers. It found that if the United States had a register for hip replacement surgery it would avoid $2 billion of an expected $24 billion in total costs for these surgeries in 2015.[26]

The Victorian State Trauma Registry has demonstrated an increase in the quality of survival over time among trauma victims. The follow-up of major trauma patients who survive to hospital discharge is a unique attribute of the VSTR. The long-term outcomes information provides critical information about the quality of survival of major trauma patients in Victoria, and the capacity to monitor the burden of major trauma over time. The data provide

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[24] Percutaneous coronary intervention, or angioplasty – a common non-surgical procedure used to restore blood flow to blocked arteries, particularly coronary arteries that feed the heart.

[25] DLA Phillips Fox, *Funding for clinical quality registries – the Australian Cardiac Procedures Registry*, Monash University Department of Epidemiology and Preventive Medicine,pp16-17.

[26] Stefan Larsson, Peter Lawyer, Goran Garellick, Bertil Lindahl and Mats Lundstrom, *Use of 13 Disease Registries in 5 Countries Demonstrates the Potential to Use Outcome Data to Improve Health Care's Value*, Health Affairs, December 2011.

a reliable basis for monitoring of the system and informing changes to the system which have contributed to improved patient outcomes.[27]

The NJRR provides evidence that there will also be benefits for clinicians, and the medical devices industry. The Registry provides surgeons with access to their individual data through an online facility. A separate online facility is available for orthopaedic companies to monitor their own prostheses as well as regulatory bodies to monitor all prostheses used in Australia.[28]

Industry benefits from the improved availability of comprehensive data on device performance. This information would better equip the industry to proactively monitor medical devices over time and to adjust their pre-market testing and data collection where appropriate to respond to identified issues. The reputational and financial risks to industry would therefore be reduced.

Summary

The costs of establishment and operation of national clinical registers depend on a number of factors. A range of possible funding models could be applied to meet these costs.

Much of the data necessary for clinical quality registers and a national contact register are already held by medical professionals and hospitals and, if a simple collection tool is applied, data collection will represent a low cost to health care providers.

There appear to be significant benefits for all key stakeholder groups. This assumption is supported by the consultation undertaken to date (consultation section refers). If an effective cosmetic surgery register had been in place, the number of patients with PIP breast implants could have been known, the performance of the implants (including the rate of device rupture) could have been more accurately assessed, and patients with these implants could have been more readily contacted to ensure that they received appropriate clinical follow-up. Studies also point to the significant potential for savings in other areas of high morbidity such as cardiac and neurosurgery.

Net benefits accruing to each of the affected parties are summarised below.

Consumers would benefit from national registers through:

- improved health outcomes due to increasingly effective procedures and devices;
- reduction in adverse outcomes and avoidance of additional procedures through the early identification of higher risk procedures and devices; and
- rapid identification of individuals who have received devices that may need intervention or closer observation.

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[27] Department of Health, Victorian State Trauma Registry, 1 July 2009 to 30 June 2010 Summary Report, p.48.

[28] Australian Orthopaedic Association, National Joint Replacement Registry, *Hip and Knee Arthroplasty, Annual Report 2011*, p.6.

Industry would benefit in terms of:

- systematic and reliable information on effectiveness to inform product development, testing regimes and (where necessary) product recall; and
- increased consumer confidence and decreased risk of harm to industry reputation.

Health care providers would benefit through:

- unbiased evidence of effectiveness on which to identify problems, develop responses and support clinical decisions (including choice of procedure and device) to achieve the best patient outcomes.

Governments would benefit through:

- improved and more comprehensive information to monitor device performance, to allow systematic evaluation and to 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.

Given the diversity of the potential register models, as well as administrative, governance and financing options, it is proposed that an investigation be undertaken in consultation with key stakeholders to firm up appropriate options (including technical and governance options) and consider relevant funding mechanisms prior to any Government decision.

Option 3: Establishment of individual registers by hospitals

Costs

Because the scale of individual registers established by hospitals would be smaller than national registers, it may be expected that individual registers would not benefit from economies of scale or co-ordinated resourcing that would usually apply to national registers. It would therefore be expected that establishment and operating costs for a number of individual registers may not be an efficient use of available resources.

The administrative and governance models would be likely to vary significantly and equitable funding models would therefore be complex to derive.

Individual registers would differ in structure and processes resulting in separate data collections of varying quality and limited comparability across local areas and States and Territories. The continuity of the registers would also be vulnerable to changes in the administration or funding of the hospitals and in the event of hospital closures.

Where a patient had a procedure in one hospital, and then a related procedure (say revision surgery), then such registers would not associate these events. Likewise, were a surgeon to perform procedures in more than one hospital, then such registers would not comprehensively detect patterns in the outcomes of that surgeon's procedures.

Benefits

This option, compared to the status quo, would result in improved capacity to contact patients in the event of a device requiring follow up or removal, although effectiveness would be limited by patients moving following surgery and the lack of linkages between individual registers.

Some of the benefits outlined for option 2 may be expected in terms of feedback of clinical quality data to surgeons on the performance of devices. However, the capacity of option 3 to realise these benefits would be significantly compromised by the fragmented nature and variable quality of the data which would be generated under this option, and difficulties achieving comparative (benchmarking) data. The varied sources and models would affect the completeness and comparability of information for evaluation and detract from the potential to significantly improve health outcomes.

Summary

The costs of this option would be affected by inefficiencies arising from lack of co-ordination and likely duplication. It would be both more costly and less efficient than any version of Option 2.

While it would yield some benefits in improving the capacity for surgeons or hospitals to contact patients if there are risks to their health, option 3 does not provide the complete and systematic information necessary to evaluate and inform improvements in clinical practice and medical devices leading to better health outcomes nationally. There are also challenges for hospitals maintaining contact details for patients for prolonged periods after device implantation, and pragmatic issues relating to management of local registers in the event of changed hospital arrangements.

Consumers, industry and government would benefit in broadly the same terms as described under Option 2, though the total costs would be greater and the benefits compromised by lesser coordination and quality of data across an array of health service based registers.

Health services would bear a much higher burden of cost and regulation, being primarily responsible not only for proving, but also recording, storing and analysing data.

CONSULTATION

A number of inquiries relating to high risk medical devices have been undertaken which have sought submissions from industry, the medical profession and consumers. These are outlined below:

The Review of Health Technology Assessment in Australia (HTA Review) was released in February 2010. The review included three recommendations (13, 14 and 15) about improving post-market surveillance of medical devices. Recommendation 13 relates to increasing the rate of reporting by medical practitioners and consumers to the TGA of adverse events associated with the use of therapeutic goods, and recommendations 14 and 15 relate to better use of data from post-market surveillance of devices and the establishment of registers of high risk implantable devices. The Government deferred acceptance of recommendations 13, 14 and 15 pending further consideration of implementation options and costs.

The Senate Standing Committee on Community Affairs inquiry into *The Regulatory Standards for the Approval of Medical Devices in Australia*. The report from this inquiry, released in November 2011, recommended that the Government implement the outstanding recommendations in a timely manner, and that implementation of registers should be prioritised according to identified health need. The Government has not yet responded to these recommendations.

The Senate Standing Committee on Community Affairs inquiry into *The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants.* The report released in May 2012 recommended that the Department of Health and Ageing establish an opt-out Breast Implant Registry as a priority and that the design of such a register should be based on the National Joint Replacement Registry. The Government has not yet responded to these recommendations.

Submissions

Submissions to the inquiries have strongly supported post-market surveillance. This position has been voiced across stakeholder groups. For example:

> *Stryker supports a robust post-market surveillance process for all medical devices. This is an important component of the regulation of all devices to ensure that any problems not identified during pre-market assessment processes are addressed*… . (Stryker Australia)[29]

> *The reality of medical device regulation is that pre market scrutiny is always imperfect. The DePuy ASR hip – which is of particular interest to the enquiry was granted premarket approval by regulators in Europe and Australia. Such cases reinforce the importance of effective postmarket regulation – to detect such failures as early as possible so that prompt action can be taken to correct the deficiency and remove the affected devices from the marketplace.* (Brandwood Biomedical Pty Ltd)[30]

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[29] Stryker Australia, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, October 2011, p10

[30] Brandwood Biomedical Pty Ltd, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p5

CHF recommends that the Committee calls for the urgent implementation of the recommendations of the TGA Transparency Review, particularly those that relate to post-market surveillance and the management of adverse events.(Consumers Health Forum)[31]

As no pre-market assessment process is 100 per cent conclusive, it is important that post-market monitoring and evaluation is in place to ascertain the safety and clinical effectiveness of medical devices over time. (Australian Medical Association)[32]

There has also been widespread support for clinical registers as an approach.

Registries are an important source of information in assisting companies in the monitoring of the performance of a procedure or product. (Johnson and Johnson Medical Pty Ltd)[33]

Australia needs a National Cardiac Procedures Register to help save lives and improve outcomes for patients with heart disease…With more than 300,000 cardiovascular procedures performed in public hospitals and 250,000 in private hospitals each year, the need for a register is clear. The register would work in a similar way to the national joints register by gathering data on outcomes of various cardiac procedures including angioplasty with stent implantation and coronary artery bypass grafts. (National Heart Foundation Australia)[34]

The AMA considers there is a critical need for device registries to be established in Australia…Sufficient evidence exists demonstrating that patient safety is best managed with the use of clinical registries. (Australian Medical Association)[35]

Due to the success of the AOA NJRR, AOA would advocate for the establishment of additional registries for things such as Anterior Cruciate Ligament (ACL) reconstructions, hip fractures, cardiac/cardio/thoracic devices and trauma registries. (Australian Orthopaedic Association)[36]

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[31] Consumers Health Forum of Australia, Submission to Senate Standing Committees 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, p6

[32] Australian Medical Association, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p2

[33] Johnson & Johnson Medical Pty Ltd, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p31

[34] National Heart Foundation Australia, Submission to Senate Standing Committees 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, p2

[35] Australian Medical Association, , Submission to Senate Standing Committees 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, p1

[36] Australian Orthopaedic Association, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p4

> *Many consumers consulted by CHF have expressed support for more registries being established to collect data, for example following the model of the National Joint Replacement Registry (NJRR), which collects data after each joint replacement procedure. These registries should be set up for those technologies for which post-market surveillance is most needed.* (Consumer Health Forum)[37]

There were few opposing views although the Department of Innovation, Industry, Science, Research and Tertiary Education (DIISRTE) noted that:

> *DIISRTE is concerned that overreacting to the particular details of this case may result in unnecessarily increasing the health technology assessment regulatory burden for all Australian medical technology companies without sufficient evidence of the need to do so.*[38]

Johnson & Johnson Medical Pty Ltd also noted that registers have limitations that should be recognised.[39]

Questions relating to the source of funding for registers are unresolved. Existing registers are funded through a number of different arrangements. The Medical Technology Association of Australia (MTAA) commented that the cost of registers should be shared amongst stakeholders who would benefit.[40] Further consultation would be required to identify efficient, effective and equitable funding mechanisms.

CONCLUSION AND RECOMMENDED OPTION

The status quo (Option 1) does not enable the Government to take steps to ensure that unforeseen hazards in relation to high risk implantable medical devices are identified or to ensure that patients are able to be promptly contacted where there is evidence that a device poses an unforeseen risk to their health. This poses a threat to public health and safety, and a net burden to consumers, industry, health service providers, government and other funders.

Option 2 is preferred as it provides significant potential to achieve the Government's objective. Clinical registers have been strongly supported by consultation undertaken to date

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[37] Consumers Health Forum of Australia, , Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p5

[38] Department of Industry, Innovation, Science, Research and Tertiary Education, , Submission to Senate Standing Committees 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, p1

[39] Johnson & Johnson Medical Pty Ltd, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p36

[40] Medical Technology Association of Australia, Submission to the Senate Standing Committees on Community Affairs Inquiry into *the Regulatory Standards for the Approval of Medical Devices*, July 2011, p8

on post-market surveillance of high risk implantable medical devices. A national contact register offers an alternative or complementary option to contact affected patients and health service providers quickly and efficiently. A period of investigation period is proposed to enable further consultation on the models, scope, governance arrangements and funding mechanisms for registers of high risk implantable devices.

Option 3 is not supported as it would not deliver the same scale of benefits as Option 2. It is likely to be a higher cost option, with compromised benefits, and therefore a much less efficient use of resources.

IMPLEMENTATION AND REVIEW

Implementation would involve a period of research and consultation prior to development of a preferred option for Government consideration. An implementation RIS and, if appropriate, a Cost Recovery Implementation Statement (CRIS) would be prepared as part of this work.

It is proposed that the investigation be undertaken in three main phases as follows:

- Scoping and definition (July 2012)
- Research and consultation (August to November 2012)
- Proposal development including RIS and CRIS (if needed) (December 2012 – January 2013)

A plan for review and evaluation of the preferred option will be included in the proposal for Government decision.

ATTACHMENTS

Attachment 1

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

A NATIONAL REGISTER FOR HIGH-RISK IMPLANTABLE DEVICES

Implantable devices identified as high risk

- Active implantable cardiac devices, such as pacemakers, defibrillators and cardiac re-synchronisation devices (fit within category 1 and category 2)
- Permanently implanted leads and electrodes associated with active implanted cardiac devices – pacing/defibrillation leads and electrodes (fit within category 1and category 2)
- Prosthetic heart valves, both mechanical and tissue derived valves (fit within category 1 and category 2)
- Devices of incorporating, viable biological origin, for example porcine derives pancreatic eyelet cells (fit within category 5)
- Silicon gel-filled breast implants (fit within category 3)
- Aortic aneurysm stents (fit within category 2 and category 3)
- Medicine-coated or drug-eluting coronary artery stents (fit within category 2 and category 4)
- Hip, knee, ankle and shoulder prostheses (fit within category 2)
- Temporo-mandibular joint (TMJ) prostheses (fit within category 3 and category 4)
- Implanted neurological stimulators, such as cerebral cortex and vagal nerve stimulators (fit within category 2 and category 4)
- Implanted diaphragmatic/phrenic nerve stimulators (fit within category 1)
- Implanted infusion pumps (fit within category 1 and category 2)
- Ventricular assist pumps, both left ventricular assist (LVAD) and bi-ventricular assist (BiVAD) ‘artificial hearts’ (category 1 and category 4).