



140 William Street
Melbourne Vic 3000
PO Box 4301
Melbourne Vic 3001
Australia
DX 147 Melbourne
Tel +61 3 9274 5000
Fax +61 3 9274 5111
www.dlaphillipsfox.com

**Funding for clinical quality registries - the Australian Cardiac Procedures
Registry**

Monash University Department of Epidemiology and Preventive Medicine

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Executive summary

The Australian Cardiac Procedures Registry (ACPR) was developed through a project sponsored by the Australian Commission for Safety and Quality in Health Care (ACSQHC) and undertaken by the Centre of Cardiovascular Research & Education in Therapeutics (CCRE) and the Australasian Society of Cardiothoracic Surgeons (ASCTS).

The ACPR is now designed and is operational, but like many clinical quality registries a sustainable funding source has not been identified.

There is an increasing and compelling body of evidence and opinion that supports the role of clinical quality registries as core elements of a properly-functioning health care system. There is strong support for the ACPR.

This report defines the case for developing a sustainable model for funding the ACPR and other clinical quality registries which achieve accepted standards of design, governance and operations and, therefore, have significant potential to impact on health care quality in clinical areas in which there is a high cost, high burden of disease, high risk or significant quality opportunity.

The report recommends the establishment of a national policy framework to define the types of registries in which there is a public interest in ensuring sustainable funding, and the conditions under which such funding should be provided.

It is clear that the ACPR has significant potential to impact positively on the quality of cardiac care in Australia. The prevalence and human and financial burden of cardiac disease in our society are compelling reasons to ensure sustainability of the ACPR. An adequate and reliable funding stream for the ACPR is a core condition of its sustainability.

For sustainability, funding arrangements need to meet a range of criteria including adequacy (covering infrastructure/core costs, data collection, analysis and reporting and growth and innovation); an acceptable cash flow which matches operational requirements; simplicity; an equitable distribution of the funding obligation amongst beneficiaries of the data and information produced by the registry; assured funding for a reasonable period; a funding approach that aligns with agreed performance objectives; and role clarity, with agreement on the extent to which different stakeholders can access data and information and engage in registry governance and operations.

A small number of Australian clinical quality registries have achieved sustainable funding streams from a variety of sources, including government and private sponsors. In addition, there are numerous clinical data collections being maintained in Australian hospitals which consume substantial resources but do not necessarily facilitate access to reliable and complete information that can be applied to understand and improve quality of care.

The report considers the elements of peripheral registry functions (data collection and patient follow up) which occur at a hospital level, and central registry functions (data management, quality control, reporting and governance). In addition, there are requirements for information technology and other infrastructure to support registry operations and governance. It concludes that the peripheral costs of registries should continue to be borne by the organisations that

deliver care, because participation brings potentially significant cost and clinical quality benefits to those organisations, their clinicians and patients. Because there is an identifiable public interest in complete participation by providers in registries which meet designated criteria for significance, the report argues that all health care provider organisations that provide relevant procedures should be obliged to participate in designated clinical quality registries and should absorb the costs of such participation within their usual care costs. Ultimately the costs of participation in the peripheral functions of the ACPR, which are extremely modest in comparison to the costs of both cardiac disease and cardiac procedures, will be passed on by provider organisations to governments and health care consumers, either directly or via health insurers.

Central registry functions should be undertaken by a small number of providers selected on the basis of their expertise and available infrastructure.

There is a high level of interest in the potential role of the ACPR and registries generally, and a willingness by a range of stakeholders including state governments, private health insurers and device manufacturers to explore an equitable approach to funding central registry functions, so long as there are appropriate assurances about registry design, operations and governance.

The report identifies a range of potential funders of central registry functions. The discussion proceeds on the basis that funding should relate primarily to the potential for the funder to realise cost and/or quality benefits related to the work of a registry. It also recognises the potential benefit of engaging stakeholder groups in registry funding where those stakeholder groups have capability to exert influence over clinical quality and their engagement in the funding process would enhance that influence.

Stakeholders reasonably require registry governance to be robust and transparent. Most stakeholders recognise that clinicians are the only group that can provide the specialist clinical advice necessary to design registries and interpret the data collected and, therefore, maintaining their engagement will be critical to the success of a registry strategy. It is widely recognised and accepted that safeguards need to be instituted to ensure clinician participation is not jeopardised by inappropriate expectations of use or disclosure of information. Stakeholder interest generally lies in ensuring there are robust and reliable mechanisms to identify and respond effectively to safety and quality risks and opportunities identified through registry data, rather than in direct access to those data.

Stakeholders also are concerned to ensure that funding arrangements are consistent with principles of fairness and equity within and between stakeholder groups. Responsibility for registry funding should not rest solely with one stakeholder group when others clearly will benefit.

A number of potential funding options are available. Under a 'business as usual' approach, central registry funding would also be the responsibility of service provider organisations, on the assumption that to properly manage high quality service provision they need to participate actively in registries. This system would have the benefit of engaging providers in registry-enabled quality improvement, but would be relatively complex to administer and would require administrative systems to ensure equitable contributions across a large number of stakeholders. Providers may also feel that it imposes an inequitable burden on them.

Distribution of central registry costs across a broader range of stakeholders including health insurers, governments and device/pharmaceutical manufacturers (where they derive a benefit related to their regulatory compliance obligations) has potential engagement benefits but would import additional complexity and require more sophisticated administrative arrangements.

Any arrangement which requires provider organisations and/or other stakeholders to contribute to central registry functions would require mechanisms to mandate equitable participation and, in relation to data submission, to ensure data quality. A range of mechanisms relating to funding, licensing and accreditation that would enable implementation of a registry funding scheme is potentially available across the public and private sectors. Options are identified at a high level in this report. Further analysis of the most appropriate mechanisms to ensure effective and equitable implementation of such funding arrangements should be undertaken if the principles in this report are accepted.

An alternative arrangement would be for central registry functions to be funded by government alone, either the Australian government or via equitable jurisdictional contributions. With the planned shift in funding responsibility for public acute health care from state and territory governments to the Australian Government over time, there is a strong argument that, consistent with policy and to promote simplicity, government contributions to clinical quality registry costs should be borne by the Australian government alone. Such a mechanism would be simple and would reflect government's role as the primary funder of Australian health care, but may result in less engagement of diverse stakeholders over time.

This report also identifies a range of central policy, standard-setting and governance roles which should be implemented to ensure the highest benefits of investment in national clinical quality registries are realised. An organisation such as the Australian Commission for Safety and Quality in Health Care would be appropriately placed to undertake such functions.

Recommendations

- 1 That a national policy incorporating the following elements is recommended for adoption by all jurisdictions:
 - Designation of a small number of registries for mandatory participation and national funding, if they meet agreed design principles, technical standards and governance standards, including specific standards for access to and use of registry data which appropriately balance clinician and other stakeholder needs.
 - Mandatory submission of data by health care provider organisations and individual clinicians to those registries.
 - Establishment of regulatory and/funding mechanisms to ensure participation is complete and effective.
 - A requirement for registries in which participation is mandated to meet criteria for relevance (e.g. high cost, high burden of disease, high risk or significant quality opportunity).
 - Endorsement of a small number of national centres of excellence which are positioned to develop the technological and human infrastructure necessary to support registries and undertake registry science.
 - Provision of adequate and reliable funding for the central registry functions of data management, quality control, reporting and governance, as well as for technical and other central infrastructure.
 - Application of a principle of equity of contribution to organisations which contribute to the funding of central registry functions.
 - Engagement in registry governance by participants that fund or submit data to a registry. Governance systems need to be designed, however, to eliminate the potential for influence over registry operations or reporting by individuals or entities whose interests may conflict with the interests of the public in robust registry operations and transparency of outcomes.
- 2 That a multijurisdictional body such as the Australian Commission on Safety and Quality in Health Care is authorised to endorse a small number of national clinical quality registries in accordance with robust criteria which address both clinical relevance and the effectiveness of governance and operations.
- 3 That provider participation in national clinical quality registries is mandated via regulation and reinforced via policy and purchasing mechanisms.
- 4 That an independent mechanism is established to ensure compliance by providers with data quality standards.
- 5 That provider organisations fund peripheral registry functions (data collection and patient follow up), as an element of their usual provision of care.

- 6 That central registry functions are funded via a fixed component (reflecting costs of fixed infrastructure) and a variable component (reflecting service volume).
- 7 That a broad range of stakeholders is consulted to determine the preferred mechanism of funding central registry functions, with the options being:
 - purchase of central registry functions by participating providers;
 - equitable funding of central registry functions by a range of stakeholders including hospitals, health insurers, governments and device/pharmaceutical manufacturers (where device/pharmaceutical manufacturers derive a benefit related to their regulatory compliance obligations); and
 - direct funding of central registry functions by government.
- 8 That if funding of central registry functions by private hospitals, private health insurers and/or device manufacturers/suppliers is confirmed as a viable funding mechanism, the regulatory frameworks of those subsectors are reviewed and the relevant industry bodies are engaged in a negotiation about how to achieve an equitable and simple funding mechanism.
- 9 That a multijurisdictional body such as the Australian Commission on Safety and Quality in Health Care is empowered to select registry centres of excellence.
- 10 That the following next steps are undertaken:
 - Further specific work is commissioned on the regulatory mechanisms available to mandate participation by public and private hospitals in peripheral registry functions.
 - Further consultation is undertaken with respect to the three potential options for funding central registry functions (provider organisations, health insurers, device manufacturers/suppliers and/or governments).
 - If private hospitals, private health insurers and/or device manufacturers/suppliers are confirmed as viable potential funders for central registry functions, further specific work is commissioned to determine the regulatory mechanisms available to embed contributions to national clinical quality registries within their usual responsibilities, and any legal barriers that may be relevant to such an approach.
 - A detailed assessment is undertaken of the public/private distribution of procedures in the ACPR, to enable consideration of potential distribution of funding responsibility.
 - A detailed funding formula is defined, to enable specific discussion of potential implications with the relevant industry sectors.
 - If there is stakeholder support, the ACSQHC and/or AHMAC are approached to discuss the policy framework and how funding for the ACPR may fit within it.

***“Science tells us what we can do;
Guidelines what we should do;
Registries what we are actually doing.”***

**Ralph Brindis, MP MPH, FACC
Immediate past CMO and chair, ACC National Cardiovascular Registry**

Background

Clinical quality registries

Clinical registers are databases that systematically collect health-related information on individuals who are:

- treated with a particular surgical procedure, device or drug, e.g. joint replacement;
- diagnosed with a particular illness, e.g. stroke; or
- managed via a specific healthcare resource, e.g. treated in an intensive care unit.

Clinical quality registers are a particular subset of clinical registers. Their purpose is to improve the safety or quality of health care provided to patients by collecting key clinical information from individual healthcare encounters which enable risk-adjusted outcomes to be used to drive quality improvement.

The system or organisation governing the register is known as the registry. Australian clinical quality registries are registries that are:

- (potentially) national in coverage; and
- primarily focussed on supporting improvement in clinical practice, particularly clinical safety and quality.

The Australian Cardiac Procedures Registry project

The Australian Cardiac Procedures Registry (ACPR) was developed through a project sponsored by the Australian Commission for Safety and Quality in Health Care (ACSQHC) and undertaken by the Centre of Cardiovascular Research & Education in Therapeutics (CCRE) and the Australasian Society of Cardiothoracic Surgeons (ASCTS).

Building on the successful conduct of the Australasian Society of Cardiothoracic Surgeons (ASCTS) Victorian database project and the Melbourne Interventional Group (MIG) percutaneous cardiac intervention (PCI) registry and utilising the framework established from the existing cardiac surgical and PCI registries and the development work from implantable devices, the project has two aims:

- 11 Enhance and develop the merger of two existing clinical registries in cardiac surgery and percutaneous cardiac intervention into a scalable national cardiac procedures registry (the Australian Cardiac Procedures Registry) that will improve the reliability of information acquisition across all contributing locations.
- 12 Develop an additional module that will extend the registry information collection to include implantable devices such as pacemakers and implanted defibrillators. The development of such modules will enhance the cardiac registry functionality to provide a common platform to enhance its national utility.

The ACPR collects a standard set of information from all patients undergoing specific cardiac procedures within participating hospitals. The data are gathered from contributing sites using predetermined procedures and definitions and include identifying information, clinical details and outcome measures. Feedback is provided to participating hospitals and clinicians to enable them to benchmark their results (after risk adjustment) to other Australian units. Features of the registry include:

- Data are derived from individuals undergoing coronary artery bypass grafting and valve surgery, PCI, implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) device insertion.
- Collection is restricted to a minimum data-set of essential epidemiologically sound data elements.
- Co-morbidity data are collected to allow risk adjustment.
- Outcome data are sought routinely by:
 - telephone based questionnaire;
 - record review (if re-hospitalised); and
 - record linkage.
- Ethics approval has been received for 'opt-out' approach to recruitment.
- Data management occurs in a strong research environment (at Monash University) independent of clinical providers.
- Rigorous quality control procedures are in place to allow high levels of data-accuracy.
- Governance and registry management terms of reference have been established.

The ACPR will have an annual accrual of 85-90,000 records comprising approximately 30,000 coronary bypass procedures, 35,000 PCI procedures and 20,000 pacemaker, ICD and CRT device implantations.

The investigators in the ACPR project have concluded that identifying an adequate and reliable funding base is critical to the sustainability and effectiveness of the ACPR. CCRE therefore commissioned DLA Phillips Fox to consider and advise on a funding model for the ACPR, with a view to developing a broadly-applicable model for funding clinical quality registries.

In developing this report, DLA Phillips Fox has undertaken a high level review of the 'grey' literature relevant to sustainability and funding of clinical registries and conducted one-on-one and small group consultation with relevant stakeholders. A list of stakeholders consulted is at **Attachment 1**.

The role of clinical quality registries

Clinical quality registry capability and functions

Registries are uniquely capable of providing clinically credible data to allow benchmarking of outcomes, measurement of compliance with accepted treatments, identification and reduction of variation and a reduction of adverse events.

Registries have at least 10 important functions:¹

- 1 Registry data reveal a cross-sectional view of multiple clinical and demographic aspects of a particular disease that can then be studied in greater detail in prospective, community-wide studies or by means of national health statistics.
- 2 Registries reveal whether clinicians are managing a particular disease in accordance with the principles of evidence based medicine.
- 3 Registries are able to collect data on large numbers of patients rapidly and efficiently, thereby producing a picture of a disease and its management at a particular moment in time. Repeated registry samples provide a dynamic estimate of changing patterns of disease demographics and therapy.
- 4 Registry data enable individual clinicians to compare their own patient population and therapeutic strategies with that of other practitioners, enabling these physicians to modify their practice patterns.
- 5 Registries provide insights for clinical investigators that assist them in designing clinical trials. Indeed, registries are often the source of questions that lead to clinical trials.
- 6 Registries provide a quick estimate of the morbidity, mortality, and resource utilization associated with a particular disease.

¹ Alpert J in

http://eurheartj.oxfordjournals.org/content/21/17/1399.full.pdf+html?ijkey=1005a41921d2d3642c572c6313ca3782cec80233&keytype2=tf_ipsecsha

- 7 Collection of registry data by clinicians often focuses their attention on specific aspects of a particular illness that might otherwise be overlooked - for example, what are the exact criteria for making a particular diagnosis?
- 8 International registries enable clinicians and health care administrators to compare disease-specific management and outcomes in their country with those of other nations.
- 9 The media, general public, and politicians are often interested in various aspects of registry data. For example, are there gender, race, or ethnic differences in disease demographics and/or outcomes within a country?
- 10 Registry data can serve as a focus for educational discussions with residents and students.

Registries are an intrinsic element of the architecture of most modern health care systems, for example:

- In America the National Cardiovascular Disease Registries commenced in 1998 with the development of a PCI registry which, by February 2009, incorporated 1,100 participant organisations, 8.2 million patient records and 2.91 million PCI records. The registry is used to assess professional educational needs, support research and publications, enable participant compliance with requirements for preferred provider programs and performance tracking tools by health plans, post market surveillance, quality improvement, performance measurement reporting and utilisation review.
- In the United Kingdom, a pilot national adult cardiac procedures database project was established in 1994. Since then there have been six database reports - the most recent, 'Demonstrating Quality' was published in July 2009. All National Health Service hospitals and number of private providers contribute to the database. Results of mortality outcomes for all hospitals are available on the care quality commission website.
- In Sweden, there are more than 70 national quality registries which are supported financially through the Executive Committee for National Quality Registries. There are several cardiac registries, including in the following areas:
 - Heart failure
 - Coronary angiography and angioplasty
 - Heart surgery
 - Cardiac intensive care
 - Out-of-hospital cardiac arrest
 - Congenital heart disease
 - Adult congenital heart disease

- Secondary prevention in cardiac intensive care
- Catheter ablation
- Atrial fibrillation and anticoagulation.

Clinical registries will only ever be necessary in a limited number of circumstances – mainly in high cost, ‘high significance’ procedures where there is evidence of variation in approach or in outcomes. Procedures and specific conditions or interventions within a disease category (e.g. cardiac disease) can be grouped together into a single registry, resulting in a small number of national registries in key areas that meet agreed criteria for cost and significance.

The known quality benefit of providing credible feedback to clinicians creates a strong rationale for embedding registries for relevant conditions in the architecture of Australia’s health care system. The greater the degree of deviation from best practice of the target group at baseline, the greater the improvement.² More complex interventions generally yield greater results.

National clinical registries have struggled to gain momentum, however, principally because of difficulty establishing sustainable funding streams.

Operating principles and technical standards for clinical quality registries

There are numerous collections of data held within the Australian health care system at a unit, organisational, professional or network level. While many of these collections are designed and managed to very high standards, the value of others has been limited by suboptimal design and/or management.

Funders, patients and the community must experience high levels of confidence in the design and operations of clinical registries if those registries are to attract the policy and financial support they need to fulfil their potential to improve the quality of Australian health care.

With this in mind, the ACSQHC, CREPS and the National E-Health Transition Authority (NEHTA) have collaborated to develop 42 operating principles for Australian Clinical Quality Registries, with accompanying technical standards (the Principles and Technical Standards) (see **Attachment 2**). The purpose of the principles and technical standards is to:

- provide a means of improving existing clinical registries and enhancing the value of the information they provide;
- provide guidance for the establishment and maintenance of new clinical registries aiming to measure quality of care; and
- suggest a best practice model to which both new and existing clinical registries should adhere.

The Principles and Technical Standards establish a useful foundation for assessing and assuring the quality of registry design and operations.

² Jamtvedt G, Young JM, Kristoffersen DT, et al. Audit and feedback: effects on professional practice and health care outcomes. The Cochrane Library, Issue 3, 2003. Chichester, UK: John Wiley and Sons, Ltd.

Impact of clinical quality registries on cost and quality of health care

Until a clinical quality registry achieves sustainable operation, its direct impact on the cost or quality of health care cannot be evaluated.

It is now broadly accepted, however, that properly funded and operated national clinical quality registries that collect data on appropriately-selected disease groups or interventions can make measurable differences to both the cost and safety and quality of health care. A number of pertinent examples are described below.

The Australia and New Zealand Dialysis and Transplant Registry (commonly referred to as the ANZDATA registry) for example, was the source of data for the seminal publication: *The economic impact of end-stage kidney disease in Australia*. The ANZDATA registry and the Australian Diabetes, Obesity and Lifestyle (*AusDiab*) study also were the sources of data for the publication: *The cost-effectiveness of early detection and intervention to prevent the progression of chronic kidney disease in Australia*.

Other clinical quality registries have demonstrated a direct impact on clinical practice and the cost of clinical care, for example:

- Findings of the Australian Orthopaedic Association National Joint Replacement Registry show a decline in the rate of hip and knee revision surgery over a 4-year period from 14.8% to 11.1% and from 10.4% to 7.9%, respectively, with an associated annual cost saving of \$44.6 million. These findings have been accepted by the Australian Government which sponsors the registry and states that:

“The National Joint Replacement Registry (NJRR) provides the best available evidence about the effectiveness of joint replacement operations in the Australian clinical setting.

Surgeons will be able to make better clinical choices for joint replacements using data from the NJRR. This improves the quality of care and reduces the risk of people being readmitted into hospital in order to have their joint replacement surgery redone.”³

The registry is now assured of ongoing government funding supported by a government-imposed levy on device manufacturers.⁴ In his second reading speech introducing the relevant legislation, Senator Stephen Conroy noted the rationale for the levy was that the registry provides “*invaluable post-market surveillance of joint replacement prostheses, providing considerable benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices*”. Senator Conroy noted that the registry enables any devices showing high failure rates to be identified quickly and promptly removed from the market. It was suggested that the data produced by the registry also assist the industry by informing the development of new prostheses, allowing manufacturers to draw on reliable performance information for existing products and designs.

³ <http://www.health.gov.au/internet/budget/publishing.nsf/Content/budget2007-hfact48.htm>

⁴ The rationale for the levy which supports the Australian Government’s funding of the NJRR is that the registry makes a key contribution to post-market surveillance. A description of the post-market surveillance system in Australia is included at **Attachment 2**.

While the medical device industry has strongly advised that it considers it unfair to impose the entire operating costs of the registry on one stakeholder sector, it is clear that the registry's role in contributing to safety and quality and reduced cost of health care is now broadly accepted.

- Since its inception in 2001, the Victorian State Trauma Registry has demonstrated a 30% reduction in mortality among trauma victims.” The registry is widely recognised as providing an invaluable tool to monitor the impact of a substantial change in policy and systems design in the Victorian health care system and has enabled policy makers to rapidly identify and respond to changes in system-wide performance.

Existing funding models for clinical quality registries

Introduction

Many registries have been initiated by interested clinicians who access resources and funding from a variety of local sources - many ultimately become unsustainable because there is no reliable funding source.

A relatively small number of registries have achieved sustainable funding from government and/or private organisations. There are 28 clinical quality registries in Australia⁵ but there is no standard approach to their funding. Descriptions of existing funding arrangements for some of the major Australian registries are detailed below.

Private operation, mixed public/private funding

The ANZDATA registry records the incidence, prevalence and outcome of dialysis and transplant treatment for patients with end stage renal failure. ANZDATA is located at The Queen Elizabeth Hospital in Adelaide, South Australia. It collates and disseminates reports on the management of renal failure. Its functions include:

- 1 Provision of reports of individual hospital activity and outcome of treatment.
- 2 A database for collaboration with research studies.
- 3 Data to support health care planning.

The ANZDATA registry is funded by The Australian Government Department of Health and Ageing, the New Zealand Government and Kidney Health Australia and is supported by private industry including pharmaceutical and device manufacturers.

The National Breast Cancer Audit, conducted by the Royal Australasian College of Surgeons, has collected information on over 70,000 breast cancer episodes from 270 surgeons in Australia and New Zealand since its commencement in 1998. Funding has been provided through a variety of sources, including the National Breast and Ovarian Cancer Centre, The National Breast Cancer Foundation and the Commonwealth Department of Health and Ageing.

⁵ McNeil J, Evans S, Johnson N and Cameron P. Clinical-quality registries: their role in quality improvement. *Med J Aust* 2010; 192; 244-245.

Private operation, Australian Government funding with cost recovery from device manufacturers

In 1998 the Commonwealth Department of Health and Ageing agreed to fund the establishment of the Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR). The Registry began data collection in South Australia on 1st September 1999 following which it was implemented in a staged manner in each of the Australian states and territories, becoming fully national during 2002.

Initially focussing on hip and knee arthroplasty, in 2007 the NJRR expanded its data collection to include shoulder, elbow, wrist, ankle and spinal disc replacement.

The Department of Health and Ageing continues to provide the entire funding to maintain the Registry. *The Private Health Insurance (National Joint Replacement Levy) Act 2009* enables the imposition of a levy on each sponsor for joint replacement prostheses in order to fund the National Joint Replacement Registry.

The arrangement is consistent with the recommendation of the Review of Prostheses Listing Arrangements (October 2007) which noted that:

“As such registries are effectively a form of post-market surveillance I believe the costs should be recovered from industry, as are the costs of the existing post-market surveillance activities conducted by the TGA. A number of parties argued that registries are a public safety mechanism and hence should be funded by the government, or confer a benefit on insurers and state governments and should be funded by them. However, as sponsors will pass costs on to those who purchase their products, it is purchasers who will ultimately fund registries. While there are multiple parties with interests in this area, a single body needs to take responsibility for gathering funds and disbursing them to registries. Given that the existing public regulatory functions of the TGA are funded by industry, I believe the TGA should take on this role.”⁶

Australian Government operation and funding

The Australian Government funds the National Diabetes Registry, a database managed by the Australian Institute of Health and Welfare that collects information about people who use insulin as part of their diabetes management.

Private operation, state government funding

The Australian and New Zealand Intensive Care Society (ANZICS) runs the Paediatric Intensive Care Registry (ANZPIC), funding for which is provided by Australian State and Territory health authorities and the New Zealand Ministry of Health.

Private operation and funding

Cystic Fibrosis Australia runs the Australian Cystic Fibrosis Data Registry, which received funding through industry sponsorship until the introduction of an internal fundraiser in 2002. The ‘Great Escape Car Rally’ was an initiative of the Chief Executive and has become an annual event raising \$350,000.

6

[http://www.health.gov.au/internet/main/publishing.nsf/Content/A397E63789AE5E5DCA25736B001D59C2/\\$File/Prostheses%20review%202007.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/A397E63789AE5E5DCA25736B001D59C2/$File/Prostheses%20review%202007.pdf). Page 25

The case for sustainable funding of the ACPR

The burden of cardiovascular disease

Cardiovascular disease is the largest cause of premature death in Australia. Although death rates are declining, cardiovascular disease continues to be one of the biggest health problems requiring attention in Australia and the health and economic burden it causes exceeds that of any other disease.

According to the Australian Institute of Health and Welfare:

“Based on the 2001 National Health Survey, 3.7 million Australians are estimated to have cardiovascular problems. In 2003, cardiovascular diseases accounted for 48,835 deaths in Australia. Coronary heart disease (also known as ischaemic heart disease: heart attack and related disorders) and cerebrovascular disease (stroke) were the two leading specific causes of death in both sexes and accounted for approximately 28% of all deaths in 2003. Heart failure and peripheral vascular disease accounted for 2% of deaths each.

Cardiovascular disease was the principal diagnosis for 445,349 hospital separations (6% of all separations) in 2002-03. Of these, 36% were due to coronary heart disease, 9% to heart failure, 9% to stroke and 6% to peripheral vascular disease. Males were more likely to be hospitalised for cardiovascular disease than females. Hospitalisation for cardiovascular disease increases rapidly with age, with those aged 55 and above accounting for 77% of separations.

Cardiovascular diseases and conditions are also one of the most common problems treated by general practitioners, accounting for 12% of all problems seen in general practice in 2003-04.”⁷

Improved treatment and management of risk factors for cardiovascular disease may cause the burden of death and disability to shift to older age groups. This age-associated shift in disease focus, in combination with growing number of older Australians, is likely to add considerably to health care costs over the next several decades. In addition to the continued emphasis on avoiding premature mortality, a stronger focus on the prevention of disability and enhancement of the quality of life in the ageing population will be required.

Quality improvement potential of the ACPR

The ACPR provides an excellent example of a registry with considerable potential to improve aspects of cardiovascular care in Australia. Procedures for the management of cardiovascular disease are some of the highest cost, highest volume and relatively higher risk components of health care. The number of cardiac procedures is increasing rapidly without rigorous monitoring of their safety, quality and outcomes. There is clear evidence of variation in approach and outcomes in Australia.^{8,9}

It is self evident that, to ensure good governance of the health care system, the indications for, conduct of and outcomes of these procedures need to be monitored and responded to. The

⁷ Australian Institute of Health and Welfare. Why is cardiovascular health a National Health Priority Area? <http://www.aihw.gov.au/nhpa/cardiovascularhealth/index.cfm>

⁸ Darren L Walters, Constantine N Aroney, Derek P Chew, Linden Bungey, Steven G Coverdale, Roger Allan and David Brieger. Variations in the application of cardiac care in Australia *Med J Aust* 2008; 188 (4): 218-223.

⁹ Sexton PT, Sexton T-L H. Excess coronary mortality among Australian men and women living outside the capital city statistical divisions. *Med J Aust* 2000; 172: 370-374.

only efficient and reliable way to achieve this is via a registry which enables the systematic collection and analysis of core data from which critical quality indicators of appropriateness, safety, effectiveness, efficiency and access can be extracted and analysed in a timely manner.

It is known that audit and feedback can improve professional practice, with the greatest relative effectiveness occurring when baseline adherence to professional practice is relatively low and when feedback is delivered more intensively.¹⁰

The standardised collection and routine risk-adjusted reporting of cardiac procedural activity will provide the following outcomes:

- 1 Benchmarking of outcome data with feedback to clinicians and hospitals which provides an ongoing stimulus to performance improvement. Similar feedback provided over many years by the ANZDATA registry is credited with helping achieve the high levels of performance in dialysis and transplant medicine in Australia, exceeding international benchmarks, especially for renal transplantation.
- 2 Improved outcomes from cardiac procedures leading to improved salvage of myocardium and a reduction in subsequent cardiovascular morbidity with fewer admissions for complications such as cardiac failure, arrhythmias and angina.
- 3 Early identification of outlier performance to ensure the maintenance of standards within the provision of cardiac services.
- 4 Trends analysis of cardiac procedural activities, providing valuable information for tracking changes in clinical practice and to explain why such trends are occurring. The data are also of value in exploring and explaining variability of practice, often identifying areas where further research is required.
- 5 Compliance analysis, assisting in assessing compliance with guidelines, which is an increasingly-used measure of quality of care. Compliance with guidelines may be relevant to assessing appropriateness of use of certain high cost procedures or devices.

Potential economic benefit of the ACPR

The magnitude of potential savings associated with the ACPR may be estimated from the following data:

- 1 Expenses related to cardiovascular disease consumed approximately 11% of health expenditure or 5.94 billion dollars in 2004-05. About 2 billion in costs were associated from coronary heart disease and 50% of this figure results from hospital admissions. With aging of the population these figures are expected to rise rapidly in the future.
- 2 US data suggest that about 14% 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

¹⁰ Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD000259. DOI: 10.1002/14651858.CD000259.pub2

patients undergoing CABG the additional expenditure would amount to approximately \$30 million. Reduction by 20% would save \$6 million.

- 3 Approximately 50,000 Australians were admitted to hospital with cardiac failure in 2001-2. If more effective treatment of acute ischaemia reduced this rate by 2 percent (i.e. 1,000 less admissions) the savings would equate to 7,500 bed days or approximately \$8 million.
- 4 Approximately 35,000 Australian patients undergo PCI annually and about 3 percent 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 percent to 1.5 percent through improved monitoring and benchmarking the savings would equate to 2100 bed days or approximately \$2.3 million dollars.
- 5 Cost savings associated with improved recognition of substandard devices have been reported from National Joint Replacement registries in both Australia and Canada. Early recognition of defective joint prostheses has been estimated to have saved over \$35 million dollars per annum in reduced need for surgical revision. This may be a guide to the potential savings to be expected from improved monitoring of cardiac devices which are used in similar volumes.

Stakeholder support for clinical registries

The following organisations and individuals have expressed support, directly or indirectly, for the establishment of registries generally and/or a national cardiac procedures registry specifically:

- **The Heart Foundation.** On 27 October 2007, Chief Executive Officer Dr Lyn Roberts announced the Heart Foundation's support for a national cardiac procedures register to be set up along similar lines to the existing national joint registry (funded by the government and run by the medical profession). She noted that with more than 300,000 cardiovascular diagnostic and treatment procedures performed in public hospitals and 250,000 in private hospitals each year, the need for a register is clear.¹¹
- **The Australian Health Insurance Association.** On 10 October 2007, Chief Executive Officer Dr Michael Armytage said announced publicly that there was widespread support for a Cardiac Register, based on the successful NJRR, and noted that "*We already have an excellent model on which to base a Cardiac Register and it should be established and funded as a matter of urgency*".¹²
- **The Review of Private Health Insurance Prostheses Listing Arrangements** recommended that the Government should consider establishing new registries for groups of prostheses beginning in the cardiac specialty and noted that

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<http://www.heartfoundation.org.au/SiteCollectionDocuments/HF%20Cardiac%20Procedures%20%20Register.pdf>

¹² <http://www.ahia.org.au/media%20releases/AHIA%20Media%20Release%20-%20National%20Cardiac%20Register%20Would%20Improve%20Health%20Outcomes%2010Oct07.pdf>

most groups believed it would be helpful if the concept of the NJRR could be extended and suggested that in the first instance a registry should be established to cover defibrillators, pacemakers, stents and other cardiac devices.¹³

- **The Australian Government Department of Health and Ageing** Review of Health Technology Assessment in Australia recommended:
 - That registers for high-risk implantable medical devices and/or procedures be established, with:
 - a. key stakeholders such as clinicians, health consumers and industry to participate in governance of and contribution to registries;
 - b. establishment of mechanisms to apply data from the register to future health technology assessments;
 - c. the feasibility, benefits and methodologies for data linkage to be explored in a pilot project in regard to a particular device identified by the high-risk implantable devices register;
 - d. consideration of how developments in e-health and data linkage could improve the efficiency of the post-market surveillance of medical technology more generally; and
 - e. the development of criteria, the identification of opportunities and the consideration of strategies for improvements in public investment in medical devices.¹⁴
- **The Australian Institute of Health and Welfare** has noted that “Australia does not have a national heart disease register, so it is a complex task to estimate the incidence and prevalence of coronary heart disease and the number of people receiving cardiac procedures”.¹⁵
- **Research Australia** has stated that “*clinical quality registries are an important part of improving the standard of health care in Australia and that the current inconsistency in data and information standards is a concern...*”.¹⁶
- **Researchers in the United States** called for more support for a cardiac devices registry in response to conflicting data about the failure rate of a widely used device, with some experts saying that debate would not be occurring if federal officials,

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[http://www.health.gov.au/internet/main/publishing.nsf/Content/A397E63789AE5E5DCA25736B001D59C2/\\$File/Prostheses%20review%202007.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/A397E63789AE5E5DCA25736B001D59C2/$File/Prostheses%20review%202007.pdf)

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[http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/\\$File/hta-review-report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-review-report.pdf)

¹⁵ <http://www.aihw.gov.au/publications/cvd/echdta/echdta-c02.pdf>

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[http://www.health.gov.au/internet/safety/publishing.nsf/Content/0C3D19DE3FE702EFCA2575AB00838448/\\$File/16008.PDF](http://www.health.gov.au/internet/safety/publishing.nsf/Content/0C3D19DE3FE702EFCA2575AB00838448/$File/16008.PDF)

medical device makers and more doctors had thrown their weight more fully behind efforts to develop a national database of patients who get heart devices.¹⁷

- **The Australian Medical Association** has noted, in relation to assessing new technologies, that *“as no pre-market assessment process is 100% conclusive, it is important that post-market monitoring and evaluation is in place to ascertain the clinical effectiveness of a new device or technology over time. Clinical registries allow clinicians to identify problems early, respond appropriately and support clinical decisions about which devices are likely to deliver the best patient outcomes ... The collection of clinical outcome data through clinical registries, coupled with interim funding of the medical service and device or technology while clinical outcome data is being collected, would ensure timely patient access to new medical treatments.”*¹⁸
- **Health consumers** support the use of registries and the gains in safety and quality that can be made from them. At the December 2007 Consumer Health Forum Consumer Representatives Workshop on New Health Technologies and Medical Devices, consumers called for more monitoring activities and mechanisms, including the creation of more registries similar to that of the National Joint Replacement Registry.¹⁹
- **The National Health and Hospitals Reform Commission** identified the need for investment in the delivery of new tools and capabilities that leverage e-health information to deliver provider efficiencies (e.g. new electronic clinical registries) and enhanced health monitoring (such as bio-surveillance capabilities).²⁰

Direct consultation during this project confirmed the following stakeholder views:

- Stakeholders generally recognise that:
 - registries are ‘a good thing’ which can produce useful information about health care provider performance;
 - cardiac procedures are both high cost and high risk; and
 - a cardiac procedures registry has the potential to generate a considerable quality and economic dividend.
- There are mixed views about the conditions under which stakeholders would be prepared to contribute to funding of the ACPR. Discussion related to the following:
 - Accessibility of registry information, with varying views as to whether information about individual clinicians, individual institutions and sector-wide performance should be transparent to various stakeholders, including funders and the broader community.

¹⁷ http://www.nytimes.com/2009/02/27/business/27device.html?_r=1

¹⁸ [http://www.health.gov.au/internet/main/publishing.nsf/Content/htareview-068/\\$FILE/068_Australian%20Medical%20Association.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/htareview-068/$FILE/068_Australian%20Medical%20Association.pdf)

¹⁹ <http://www.chf.org.au/pdfs/sub/sub-478-draft-operating-standards-technical-design.pdf>

²⁰ <http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report>

- Registry governance, with varying views about who should participate in governance, whether a level of independence of governance is essential to ensure stakeholder confidence in the registry and whether funders should be entitled to participate in governance.
- Accountability of the registry, in particular whose responsibility it should be to respond promptly and effectively to identified performance problems and/or opportunities.

These issues are explored further in the following sections of this paper. On balance, however, there appears to be relatively strong and broadly-based support amongst government and private sector stakeholders for well designed and operated clinical quality registries which provide reliable information for the improvement of safety and quality in health care. Cardiac procedures are recognised as an area of medicine which would benefit from the availability of well constructed registry data.

The costs of the ACPR

In comparison to both the costs of procedures and the potential safety and quality benefits that can be derived from clinical quality registries, registry costs are modest.

Fixed and variable costs for the ACPR are estimated to be less than \$1.5 million annually. In the context of the high prevalence of cardiac disease and the vast volumes of procedures undertaken (e.g. Approximately 35,000 Australian patients undergo PCI annually) these costs are extremely affordable. Registry costs generally of less than \$50 per patient are anticipated.

Parameters for sustainable funding

Introduction

Many clinical quality registries in Australia have been initiated by interested clinicians without the benefit of dedicated financial support. Some clinical groups have developed registries and then sought to access external sources of funding but have encountered obstacles, actual or perceived. Only a small number have managed to establish funding streams sufficient to ensure adequate registry coverage, sound operations and good governance.

Clinicians who seek public funding streams for their registries may be unwilling to accept conditions relating to access to and use of data by government and other third parties, which they may perceive as onerous and/or inappropriate. Some who have sought private funding via device or pharmaceutical suppliers have been concerned at the potential for the independence of their registry to be, or be seen to be, compromised.

Registries that operate nationally but seek state and territory government funding need to negotiate with 8 jurisdictions to achieve an equitable and adequate contribution - this is a major structural barrier to achieving sustainable funding.

As a consequence, funding for many registries is inadequate, fragmented and uncertain, reducing their capacity to meet benchmark standards of data collection and analysis and impairing their ability to develop and make their potentially high contribution to improving health care quality.

Dimensions of sustainability

Sustainability is the capacity of a project to continue to deliver its intended benefits over a long period of time.²¹ Financial sustainability is a critical (but not the only) element of overall sustainability.

The key dimensions of financial sustainability are:

- **Adequate funding:**
 - to cover infrastructure/core costs;
 - to cover core costs of data collection, analysis and reporting;
 - to enable registries to accommodate growth and demonstrate innovation.
- **An acceptable cash flow** that matches operational requirements.
- **Simplicity.** Complex funding arrangements will introduce inefficiency and uncertainty.
- **An equitable distribution of the funding obligation** amongst beneficiaries of the data and information produced by the registry. Stakeholders advise that if they perceive inequity within or between funding groups, they will be reluctant to provide or continue funding.
- **Assured funding for a reasonable period**, of sufficient duration to avoid uncertainty which may hinder development and/or require unnecessary investment of time and resources in recurrent funding applications. To achieve an appropriate balance between stability on the one hand and management/governance accountability on the other, we consider that funding should be assured for at least a 5 year period, with a notice period of at least 1 year before funding is either renewed or withdrawn.
- **A funding approach that aligns with agreed performance objectives**, supporting efficient and effective registry operations and avoids the creation of perverse incentives that may impact on registry design, operations or governance.
- **Role clarity**, including agreement on the extent to which funding bodies and other stakeholders can access data and information and their role in registry governance and operations.

²¹ Bamberger, M. & Cheema, S. (1990). *Case studies of project sustainability: Implications for policy and operations from Asian experience*. Washington, DC: The World Bank quoted in http://www2.ed.gov/admins/lead/safety/training/sustaining/prevention_pg4.html#defined

Financial sustainability alone is insufficient to ensure the ongoing effectiveness and, therefore, sustainability of a clinical quality registry. The following conditions are also necessary for overall registry sustainability:

- An adequate level of recruitment of eligible patients, sufficient to avoid introduction of bias into the registry. This requires high levels of clinician/organisational engagement, which in turn may depend on:
 - their confidence in registry operations and broad recognition of the value of registries; and/or
 - a mechanism to mandate participation to a high level of quality.
- Effective operational management and governance in accordance with accepted principles and technical standards, which will assist to maintain confidence by clinicians, organisations and funders in the registry.
- Appropriate returns on investment (i.e. in the form of useful data/information for the investing entity or individual).

Funding for peripheral functions

Peripheral functions include:

- data collection
- patient follow-up.

Data collection and patient follow-up usually is undertaken in the hospital setting by clinicians and data managers. Much of this work is contributed by clinical staff within their usual roles although some hospitals complement this clinical resource with data managers. Depending on the jurisdiction and/or institution, the costs of these data management positions may be:

- supported by the hospital from within overall operational budgets;
- sponsored directly by the relevant health department; or
- supported by private sources (e.g. private practice funds, device and/or pharmaceutical sponsors).

Attention needs to be given to the sustainability of both clinical and specialist data management input into registries. Clinical input usually is not directly funded, is necessary for local leadership of registries and is vulnerable to the usual pressures of clinical service delivery. Data collection positions tend to be vulnerable to changes in organisational financial position, grant conditions or government policy.

There is a strong argument that the peripheral costs of registries should continue to be borne by the organisations that deliver care, because participation brings potentially significant cost and clinical quality benefits to those organisations, their clinicians and patients. For a complete registry data set to be achieved, however, each participating organisation needs to value those benefits highly and prioritise scarce resources towards data collection. This may be difficult for

some organisations in the context of multiple competing demands for resources. If some organisations decline to participate because they lack the willingness or means to invest in local infrastructure, however, the validity of the entire registry may be jeopardised.

The validity of the results of registries relies on complete or near-complete inclusion of all eligible patients.²² To gain benefit from national clinical quality registries, therefore, complete or near-complete participation by organisations and clinicians providing the relevant services is necessary. Different approaches to encouraging or requiring organisations and clinicians to participate, ranging from the provision of incentives to mandating participation, are considered later in this report.

Funding for central functions

Central functions include:

- data management;
- quality control;
- reporting; and
- governance.

In addition, information technology and other infrastructure are required to support registry operations and governance.

Data management, quality control and reporting for clinical quality registries usually are undertaken by a central body. These functions also need to be supported by sound and adaptive information technology platforms, with associated costs. While some of these services have been provided by individuals and professional groups on a predominantly volunteer basis, expert third parties (often university departments) are developing increasing expertise in these areas and also offer the benefit of independence from clinicians and organisations who contribute the data.

Current funding sources for central registry functions include governments (commonwealth and state) and the private sector (e.g. device manufacturers, pharmaceutical companies and not-for-profit disease-based advocacy and research organisations).

It is likely that there will be substantial efficiencies achieved through the concentration of these functions in a small number of centres nationally, allowing them to develop the technological and human infrastructure and expertise necessary to support and advance registries. In this context, the Swedish model is interesting - three 'competence centres' for the National Quality Registries have developed, with more planned in different areas. In a competence centre, several registries share the costs for staff and systems. Competence centres aim to promote the development of new registries, create synergy effects by collaboration among registries (e.g. in technical operations, analytical work and use of registry data to support clinical quality improvement) and help to optimise the utility of registry data. Each registry continues to be managed independently.

²² McNeil J, Evans S, Johnson N and Cameron P. Clinical-quality registries: their role in quality improvement. *Med J Aust* 2010; 192; 244-245.

This model could be applied in Australia to provide the necessary support and expertise for clinical registries. It would not be sensible to reproduce the information technology infrastructure and personnel necessary to support clinical quality registries in multiple sites across Australia. A monopoly provider would be equally problematic because it would result in little if any competitive pressure to engage in the innovation and development, or 'registry science', necessary to maintain excellence. The availability of two or perhaps three 'registry centres of excellence' which are accountable independently for their performance and could offer their expertise to different registry groups, however, would provide a sustainable infrastructure for a network of national clinical quality registries.

Later in this report, we consider how such centres could be funded, the standards which would guide their operation and to whom they would be accountable.

Potential funders of the ACPR

Consideration of how sustainable funding can be achieved for the ACPR needs to start with consideration of who is likely to benefit from its effective operation. Below, we analyse the potential beneficiaries of clinical registries generally, and the ACPR specifically.

Payers (i.e. individual consumers; Australian, state and territory governments; and private health insurers) will benefit from information derived from the registry in terms of:

- reduced funds wasted by better targeting procedures based on unbiased evidence of effectiveness in the Australian healthcare setting;
- reduced outlays for 'complications' and reduced expenses for treatment of unnecessary morbidity;
- the promotion of a more systematic and evidence based approach to patient management with less idiosyncratic behaviour of the part of certain payers; and
- better information to predict and explain changes in financial outlays.

It should be noted, however, that ultimately there are only three categories of payers in the Australian health care system:

- state and territory governments;
- the Australian government; and
- individual consumers.

Private health insurers are intermediaries who derive their funds from individuals, who in turn receive rebates from the Australian Government. The ultimate payers are individuals and the Australian Government.

Providers (i.e. public hospitals (usually owned by state and territory governments); private hospitals; device manufacturers; pharmaceutical manufacturers; clinicians) will benefit from information derived from the registry in terms of:

- easy access to unbiased evidence of effectiveness in the Australian healthcare setting on which to base recommendations for procedures and device choices;
- more systematic and reliable information with which to plan future resource requirements for patients;
- better information with which to target improvements; and
- system improvements, as optimal outcomes in acute care commonly require high-level performance of a system of care. Components of this system may include pre-hospital care, emergency room care, procedural efficiency and skill, and postoperative care. Poor performance may result from deficiencies in any one of these links. Registry data (with adequate refinement) is capable of measuring performance across a system of care and identifying high or low performance in specific components.

It should be noted that there is a direct cost to providers of maintaining existing data collections, the cost-benefit of which may not be defined or understood. Many health services and clinicians are contributing to localised data collections which may not comply with appropriate technical standards of design and operation and which may not provide useful or reliable information. This cost is hidden in the usual operating costs of health services but is likely to be significant. Redirecting these resources into collection of data to contribute to well-designed, quality-controlled registries may represent a much more effective use of scarce health care resources.

Policy makers and **regulators** (i.e. Australian, state and territory governments) will benefit from information derived from the registry in terms of:

- registry data provides information about utilisation in different geographical areas. This may be useful in establishing whether disparities are occurring in access to new treatments, and/or explaining geographical variation in outcomes; and
- monitoring device safety, as the use of cardiac devices is increasing exponentially with major variation in indications and minimal surveillance for medium to long term safety. Cardiac devices have a history of failures, particularly affecting electrical leads. The registry will provide a basis for safety surveillance.

Consumers will benefit from information derived from the registry in terms of:

- improved health outcomes with access to the most effective and appropriate procedures and devices based on unbiased evidence of effectiveness in the Australian healthcare setting;
- reduction in adverse outcomes by the early identification of procedures with higher levels of risk; and

- rapid identification of individuals who have received specific devices that may require observation/intervention.

Medical and other health care professionals will benefit from information derived from the registry in terms of training and credentialing. Registries provide objective information about procedure volumes and outcomes at an institution or provider level. This assists specialist colleges to identify appropriate training programs and assists in the assessment of competence amongst trainees. At present there is a considerable qualitative aspect of these assessments.

Organisations responsible for training and credentialing will benefit from access to more systematic and objective data that is better able to withstand challenge.

In the context of the ACPR, we identified the following stakeholders/potential funding partners:

- | | |
|---|---|
| <ul style="list-style-type: none"> • Consumers • Clinicians • Professional groups such as the Cardiac Society of Australia and New Zealand and the Australian Society for Cardiac and Thoracic Surgeons. • Australian Government • State and territory governments | <ul style="list-style-type: none"> • Public hospitals (funded by state and territory governments) • Private hospitals • Health insurers • Pharmaceutical manufacturers/suppliers • Device manufacturers/suppliers (prosthetic and non-prosthetic) • Advocacy/research groups such as the National Heart Foundation. |
|---|---|

On the following page, we identify the potential benefits for each group.

Table 1: Registry beneficiaries

Benefit	Beneficiary									
	Consumers	Clinicians	Professional groups	Australian Government	State/territory governments/public hospitals	Private hospitals	Health insurers	Pharma manufacturers	Device manufacturers	Advocacy/research groups
Improved capacity to monitor and reduce cost of usual care	✓	✓		✓	✓	✓	✓			
Improved capacity to monitor and improve quality of care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Reduced hardship associated with adverse events	✓	✓								
Reduced cost associated with adverse events (including potential liability)	✓			✓	✓	✓	✓	✓	✓	
Improved ability to plan services		✓	✓	✓	✓	✓	✓			✓
Assistance with post-market surveillance				✓				✓	✓	
Reduced administrative burden of demonstrating accountability		✓	✓		✓	✓		✓	✓	
Improved accountability of the health care system	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Stakeholder expectations

Introduction

Discussion with stakeholders confirms a high level of interest in and support for the concept of clinical registries, but a corresponding expectation that any funding commitment will generate a reasonable benefit for funding partners.

Funders are uniformly disinterested in sponsoring registries which are not well designed or operated. There is strong support for the imposition of an agreed set of operational standards. Most stakeholders consulted during this review were not familiar with the principles and technical standards developed by the ACSQHC, but strongly supported their conceptual basis.

Funders have differing views, however, about other conditions of involvement. These are discussed below.

Equity of participation

Many stakeholders referred to a desire for equitable participation, so that the funding burden does not fall unfairly on one stakeholder group. This is perceived as a significant problem with the levy which has been applied to prosthetic manufactures for the purposes of funding the national joint replacement registry. In that context, the strong message from the medical devices industry is “we don’t mind contributing, but the burden should not fall on us alone”.

We believe there is merit in establishing a principle of equitable contribution amongst potential beneficiaries.

Similarly, if it is accepted that registries offer a major quality and safety benefit, there is a strong argument for mandating participation by health care providers (clinicians and organisations) so that all consumers enjoy that safety and quality benefit, not just those whose providers have elected to participate. This raises questions as to how that could be achieved.

Appropriate standards of operation

There is strong stakeholder support for the proposition that, to ensure that it is directed and applied appropriately, funding should only be provided for selected registries that meet:

- criteria for relevance (e.g. high cost, high burden of disease, high risk or significant quality opportunity); and
- the operating principles and technical standards (established by the ACSQHC or similar).

Transparency and accessibility of information

There is a strong commitment to transparency of registry processes and demonstrable accountability of clinicians and providers for the quality of services they provide. There is a corresponding acceptance that many clinicians will not engage in processes which, in their view, require an unreasonable level of disclosure of information, particularly at a level which identifies individual clinicians, and that registries will fail if registry sponsors insist on this level of disclosure.

Most but not all stakeholders who may be interested in funding clinical registries are likely to be willing to compromise on disclosure requirements in order to ensure continuing clinician engagement, so long as there is a robust governance system in place which ensures registry data are acted on when real safety concerns emerge and to improve clinical quality generally.

While some stakeholders believe that only participating clinicians should have access to performance information generated by registries, the more common view is that both clinicians and provider organisations should have access to sufficient information to enable benchmarking and improvement of performance at the individual and team/organisational level.

Most stakeholders also believe that aggregate, non-identifiable (at either an organisational or individual level) performance data should be disclosed to the general public. A small minority of stakeholders suggested that identifiable performance data (to the level of the organisation and/or individual clinician) should be disclosed to the general public, to enable individuals to make personal health care decisions and to ensure a high level of accountability of health care providers.

Many stakeholders believe that if outlier under-performance becomes apparent which cannot be or is not addressed by internal mechanisms including feedback of benchmarked data and counselling of providers where warranted, those data should be disclosed via a prescribed internal process to defined individuals or groups to enable action to address apparent underperformance. Generally, stakeholders do not consider that, as funding partners, they would require access to data that identify individual clinicians in these circumstances. Almost all accept that the initial access to individually-identifying data and response to apparent under-performance should be confined to the personnel who are charged with managing the registry – generally this will be clinicians from the relevant clinical specialty, and support staff.

Some but not all stakeholders hold the further view that if internal processes fail to address apparent under-performance, registry governance processes should then require identifiable data to be disclosed externally to regulators, funders and purchasers of services (e.g. to state health departments, hospitals, health insurers and regulators such as the TGA and professional regulatory boards) to enable appropriate regulatory or purchasing action to be taken.

Engagement in governance

Most stakeholders also consider that if they contribute to registry funding, they should have a right to participate in the governance of the registry. Through engagement in governance, they seek to achieve the following:

- ensuring there is a balanced stakeholder contribution to the identification and prioritisation of development and research opportunities (i.e. research science) and generally ensuring registry managers are aware of the range of views held by various registry stakeholders;
- assisting to develop policy;
- allowing a degree of independent scrutiny of operations and ensuring performance of the registry complies with accepted operational principles;
- advocating for resources;

- contributing to the establishment of a positive culture to guide the work of the registry; and
- overseeing the implementation of effective risk management processes.

These are all legitimate governance functions and we believe there would be considerable benefit in registries having an independent governance group, involving relevant stakeholders, who are responsible for leadership, advocacy, performance monitoring (of the registry, not individual clinicians), compliance and risk management. These functions are separate and distinct from the operational management of the registry.

Registry governance committees (however named) should operate in accordance with generally accepted principles of good governance which require participating individuals to act in the interests of the organisation as a whole (rather than their nominating group) and to remove themselves from any situation in which a conflict of interest may arise. Development of terms of reference and role statements for registry governance groups would be critical to ensuring governance is not jeopardised by role confusion or conflict of interest.

A link to regulation

A minority of stakeholders suggested that they would be disinterested in funding clinical quality registries unless there was a clear and unambiguous commitment by regulatory bodies to act decisively against providers, hospitals or device manufacturers/suppliers as appropriate where apparent poor performance is disclosed and is not transparently addressed within an agreed period.

On balance, it appears that most stakeholders would support a governance system which enables staged release of information in defined circumstances, with the major emphasis on establishing robust internal registry governance systems to identify and respond to apparent underperformance, and stakeholder participation in governance.

A framework for sustainable funding of the ACPR

Elements of a national policy framework

We consider that there is a considerable public interest in clinician and organisational engagement in well-designed and managed clinical quality registries.

Health care providers, device manufacturers/suppliers, health insurers and/or governments, all of whom have the capacity to influence safety and quality of care based on registry data, could be engaged in submitting registry data, funding selected registries, governing selected registries and/or receiving and responding to data from selected registries.

Recommendation 1

That a national policy incorporating the following elements is recommended for adoption by all jurisdictions:

- Designation of a small number of registries for mandatory participation and national funding, if they meet agreed design principles, technical standards and governance standards, including specific standards for access to and use of registry data which appropriately balance clinician and other stakeholder needs.
- Mandatory submission of data by health care provider organisations and individual clinicians to those registries.
- Establishment of regulatory and/funding mechanisms to ensure participation is complete and effective.
- A requirement for registries in which participation is mandated to meet criteria for relevance (e.g. high cost, high burden of disease, high risk or significant quality opportunity).
- Endorsement of a small number of national centres of excellence which are positioned to develop the technological and human infrastructure necessary to support registries and undertake registry science.
- Provision of adequate and reliable funding for the central registry functions of data management, quality control, reporting and governance, as well as for technical and other central infrastructure.
- Application of a principle of equity of contribution to organisations which contribute to the funding of central registry functions.
- Engagement in registry governance by participants that fund or submit data to a registry. Governance systems need to be designed, however, to eliminate the potential for influence over registry operations or reporting by individuals or entities whose interests may conflict with the interests of the public in robust registry operations and transparency of outcomes.

Below, we explore some of these principles in more detail.

Selection of registries for mandatory participation and funding

As discussed earlier in this paper, only a small number of registries which meet agreed national criteria should be selected as national clinical quality registries for mandatory participation and funding in the first instance, on the basis of their potential impact on the safety and quality of health care and the strength of the design, operations and governance of the registry.

The ACPR should be one of these registries. Generally, however, there should be a transparent process for selecting national clinical quality registries. We suggest that the selection process should be the responsibility of a multi-jurisdictional body such as the ACSQHC, advised by experts including people with knowledge and experience of the clinical, medical device, public hospital, private hospital and private health insurance sectors.

Robust criteria will be required to guide the selection process. The principles and technical standards already developed will provide a firm foundation but may need to be tailored to each registry so that proposed arrangements for operations and governance are specified in detail and understood by all participating stakeholders. Issues about data management and the role and responsibilities of the governing body need to be worked through and agreed in the preliminary stage. Generally, we consider that the following data disclosure principles should apply:

- routine disclosure of individual data to individual clinicians to enable them to benchmark against their peers;
- routine disclosure of unit-based data to organisations to enable benchmarking against their peers;
- disclosure of identified outlier data that indicates persistent individual or organisational under-performance to individuals and groups internal to the registry, who have the specific responsibility of addressing apparent under-performance in accordance with registry policy;
- disclosure of identified outlier data indicating under-performance that is persisting following robust internal remediation efforts to agreed external parties including health authorities and regulatory agencies; and
- public reporting of non-identifiable data.

Recommendation 2

That a multijurisdictional body such as the Australian Commission on Safety and Quality in Health Care is authorised to endorse a small number of national clinical quality registries in accordance with robust criteria which address both clinical relevance and the effectiveness of governance and operations.

Overall funding options

There are a number of options for funding:

- A 'business as usual' approach (described in more detail below) would place both the peripheral and central funding obligation with provider organisations (public and

private hospitals). Those organisations would pass that burden to funders (either governments or consumers, directly or via health insurers).

A variation on this theme would be for government to fund specific data collection positions in public hospitals to ensure data collection is of adequate quality. A similar mechanism for directly funding positions is not clearly available in the private sector.

- An approach which places the peripheral funding obligation with provider organisations but distributes the obligating for funding central functions to other organisations which either derive direct benefit from the registry or have capacity to leverage their funding contribution to drive safety and quality by providers. This group includes device manufacturers/suppliers(who, arguably, will benefit from registries with a device component because it will assist them with their post-market surveillance), pharmaceutical manufacturers and health insurers (who have the ability to promote safety and quality systems and performance in private hospitals and are interested in doing so on behalf of their clients).
- An approach which places the peripheral funding obligation with provider organisations (which would pass them on to funders) and the central funding obligation directly with governments, recognising that the ultimate funders of health care are governments and individual consumers.

Funding peripheral registry functions

In all circumstances, we consider that the obligation for funding peripheral functions should rest with provider organisations. Eventually, this obligation will be passed on to their ultimate funders (governments and consumers, either directly or via health insurers).

While representation has been made to us that some provider organisations may fail to invest in properly qualified data collectors, we believe this should be addressed via mechanisms that mandate participation and create appropriate sanctions (e.g. loss of procedural funding) if participation does not meet expected standards. Fundamentally, an obligation for provider organisations to allocate resources to collect and submit data and follow up patients will create a level of engagement which we do not believe will be achieved if this function is funded as a line item by government. In addition, while it would be relatively simple for government to fund specific data collection positions in the public sector, the range of funders to private hospitals would make such a mechanism extremely complex.

Mechanisms to engage public and private hospitals in peripheral registry functions

Engagement of public and private hospitals in peripheral registry functions could be voluntary or mandatory. Our view is that voluntary engagement is likely to be incomplete, impairing the overall viability of the registry.

Possible mechanisms for mandating participation include:

- Governments and health insurers may elect not to pay for relevant procedures (e.g. cardiac procedures) unless providers participate appropriately in mandated registries.
- Providers could be required as a condition of government funding (for public hospitals) or licensing and/or receipt of health insurance benefits (for private hospitals) to participate in mandated registries.

- Participation in mandated registries could be a condition of third party accreditation, which in turn could be a condition of funding of provider organisations by governments and health insurers.

These mechanisms are not mutually exclusive and a combination of mechanisms (e.g. a regulatory requirement backed up by obligations contained in performance agreements with government and/or contracts with health insurers) is likely to be most effective

At present, public hospitals in Australia are almost universally owned, funded and operated by state and territory governments. Agreement by all jurisdictions to a national policy for participation in national clinical quality registries should be sought through a multi-jurisdictional body such as the Australian Health Ministers Advisory Council. Each jurisdiction then has numerous local policy and purchasing mechanisms available to mandate participation by public hospitals in peripheral functions necessary to support national clinical quality registries.

Regulation of private hospitals in Australia is effected at a state and territory government level, with objectives (where stated) usually related to service quality and/or the configuration/planning of the service sector. The regulatory approach has varied considerably between jurisdictions in both focus and intensity.

There are various mechanisms that could be considered to achieve full participation by private hospitals in selected national clinical quality registries, including:

- via state and territory licensing/regulatory arrangements;
- via private health insurer contracting arrangements with hospitals. Care would need to be taken that such arrangements did not breach competition law prohibitions, for example those relating to third line forcing;
- via Ministerial declarations of hospitals, provided for in the *Private Health Insurance Act 2007*; and/or
- via incorporation into accreditation requirements (a requirement of compliance with which could then be incorporated into Ministerial declarations or into private health insurer contracting conditions with private hospitals, both referred to above).

Private hospitals which were subject to such a requirement as a condition of funding would then need to fund local infrastructure and/or require clinicians who provide services in their facilities to cooperate in the provision of data sufficient to enable the organisation to comply with the requirement.

Further detailed analysis and legal advice on regulatory issues, including competition law issues, would need to be obtained to make a firm recommendation about the most appropriate mechanism, but an initial review suggests that a combination of regulatory and funding mechanisms is available which could enable full participation by both the public and private hospital sectors.

While a linkage with accreditation is a potential mechanism for ensuring full provider participation, it may be difficult to engage accreditation providers in a compliance mechanism such as this and a direct regulatory requirement may be simpler and more reliable. An

accreditation-related mechanism should continue to be considered, however, as national processes for strengthening accreditation are developed.

Any regulatory mechanisms mandating participation would need to provide for appropriate consequences if data submission was inadequate or incomplete. One mechanism would be to link payment by health insurers and governments for the relevant clinical services to a hospital's submission of data in accordance with agreed standards. This could be able to be effected through regulatory or contractual mechanisms.

An independent mechanism would also need to be established to develop standards for, audit compliance and investigate concerns about data provision by individual providers, particularly if those concerns could lead to funding consequences. The ACSQHC is likely to be an appropriate body to oversee such a process.

Recently-announced health financing reforms, with proposals to pool Commonwealth and state government funds in hospital funding pools, are likely to change funding relationships between governments and public hospitals compared with the current situation whereby funding flows from the Commonwealth via the states to hospitals in accordance with a variety of financing regimes which apply in different jurisdictions.

Recommendation 3

That provider participation in national clinical quality registries is mandated via regulation and reinforced via policy and purchasing mechanisms.

Recommendation 4

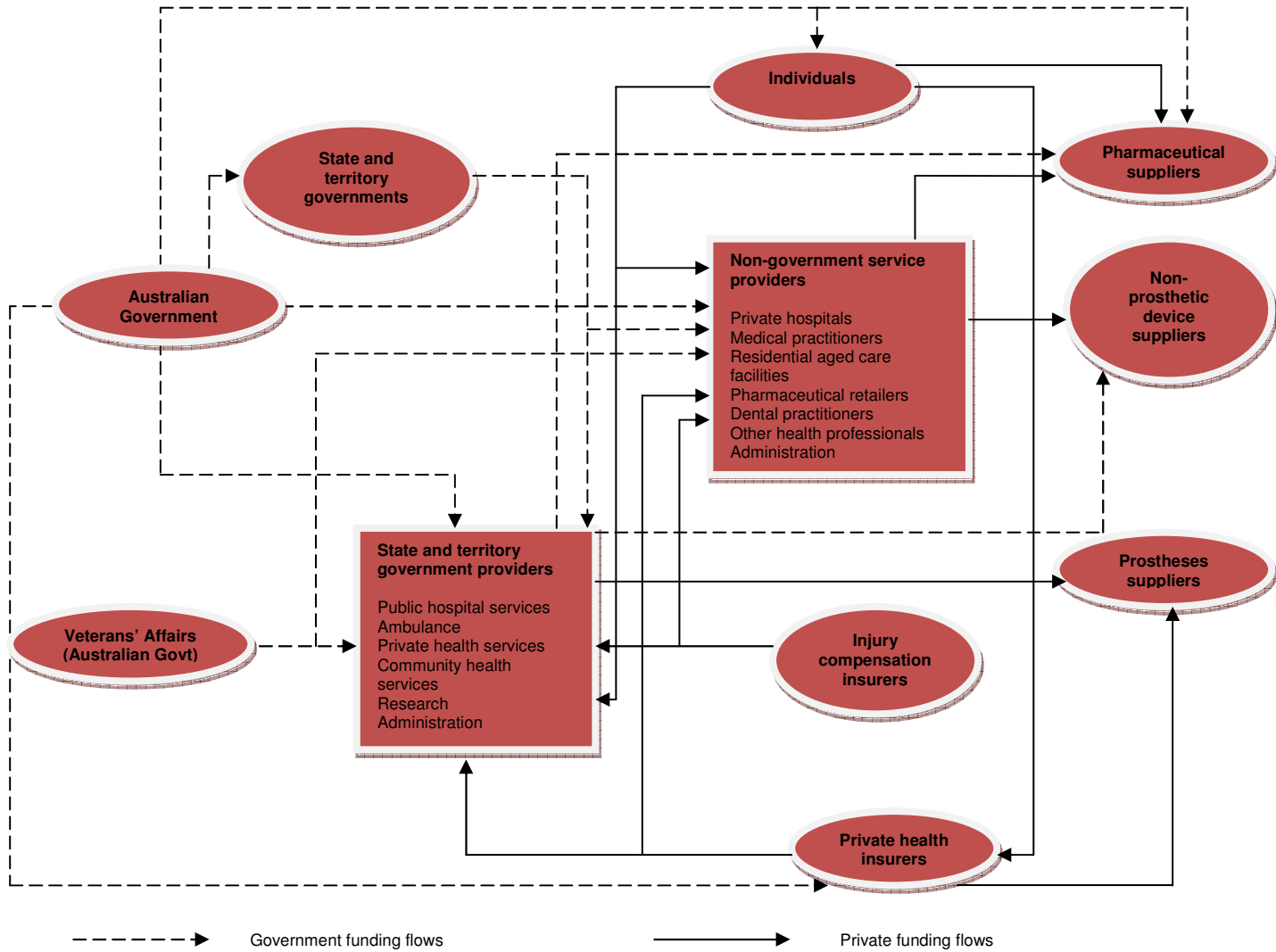
That an independent mechanism is established to ensure compliance by providers with data quality standards.

Funding central registry functions

Stakeholders generally support the concept that registries should be viewed as core elements of a properly governed and operating health care system (see section on stakeholder views below) and should become a 'business as usual' feature of the clinical management of health care, in the same way as financial information systems are accepted as integral to the operations of the health care system. Some stakeholders consider a 'business as usual' funding mechanism to be a key sustainability criterion.

Figure 1 below demonstrates the complexity of funding in Australian health care.

Figure 1: Funding flows in the Australian health care system²³



²³ Adapted from 2004f, *Health expenditure Australia 2002-03*, Health and Welfare Expenditure Series no. 20, AIHW Cat. No. HWE 27, AIHW, Canberra

'Business as usual' in the context of the ACPR implies that organisations that provide cardiac procedures (i.e. public and private hospitals) would fund and undertake peripheral registry functions (i.e. data collection and patient follow up) and pay to subscribe to a centre of excellence that provides central registry functions. The rationale would be that participating in a registry is an essential element of the business of providing cardiac procedures and that becoming a registry subscriber, with associated costs, will generate interest in and commitment to acting on registry data.

Figure 1 demonstrates:

- the complexity and interconnectedness of funding flows in the Australian health care system;
- that funding is based on a combination of grants and fee-for-service payments;
- that each service provider is funded by multiple direct and indirect sources. The ultimate financing burden, however, rests with three stakeholder groups:
 - the Commonwealth Government (via a range of mechanisms including grants to the states and to health care providers, taxation rebates, personal benefits payments, rebates to individuals of private health insurance costs and rebates to individuals of medical and pharmaceutical costs);
 - the state and territory governments (via grants and fee-for-service payments to public and private hospitals and professionals); and
 - individuals (via private health insurance contributions and fee-for-service payments to providers).

A 'business as usual' funding mechanism poses the following risks:

- **Excessive complexity.** Health care funding currently involves a complex system of interconnected grant and fee-for-service flows from multiple parties to health care organisations (and via those organisations to third party suppliers of goods and services) and individual clinicians. Administrative complexity and cost is likely to be high if the same multiple parties are involved in funding clinical quality registries, particularly if that funding is based on a fee-for-service system.
- **Inequitable assumption of responsibility.** There are numerous direct and indirect stakeholders. For example, there are 8 state/territory jurisdictions, 37 private health insurers, more than 750 public hospitals and more than 550 private hospitals in Australia. It is unlikely that all relevant stakeholders, even within a specific subsector, will agree to participate voluntarily in the ACPR, which could prove to be a significant disincentive to those stakeholders within this group who are otherwise inclined to support registries. We believe that, to achieve the level of participation necessary to assure registry integrity, participation would need to be mandated through some regulatory means.
- **Inconsistency.** We believe that a registry funding frameworks should be able to be applied across different organisational and clinical settings. While it may be possible to impose certain requirements on a small number of hospitals which undertake

certain procedures (e.g. cardiac procedures) a similar arrangement may not be possible for a procedure or condition for which there is a more distributed system of care.

- **Uncertain funding flows.** Unless legally binding funding arrangements are established for an appropriate period (at least 5 years, with at least 1 year's notice if funding is to cease after 5 years), funding will continue to be unreliable and subject, year-by-year, to the financial performance and position of the various funders and provider organisations. We note that the future funding of the Australian health care system is the subject of significant public debate at present and funding flows may change substantially in the foreseeable future.

Costs of a cardiac procedures registry which are imposed on providers will be passed on to government or individuals. There is a strong argument that, for of simplicity (which is another of our criteria for sustainability) it would be preferable to look to those ultimate funders to support registries, rather than imposing costs on providers who will pass them on to the ultimate funders (either directly or via insurers) in any case.

The alternative argument is that there would be benefits from incorporating an obligation to fund registries into usual funding stream. Most significantly, a 'business as usual' approach would be highly likely to engage providers actively in registry functions. Payment for a service is likely to generate an interest in the quality and outcomes of that service. Payment by providers, with a regulatory mechanism to ensure their full participation, is a realistic possibility to support Australian clinical quality registries.

Below, we explore the risks and benefits of different approaches to funding central registry functions. All are premised on the expectation that peripheral functions will be funded by provider organisations.

Table 2: Options for funding central registry functions

Central funding approach	Benefits	Risks
Providers purchase central registry functions – a ‘business as usual’ approach	<p>Embeds registry as an element of usual service provision</p> <p>Each provider’s contribution could be related directly to service volume (e.g. via a funding formula which establishes a licensing fee and a fee-for-service payment, or is entirely fee-for-service based)</p> <p>Reinforces provider responsibility for monitoring performance and using data for safety and quality improvement</p>	<p>Price would need to be set by a reliable and accepted mechanism</p> <p>Complexity – would require a specific financial management system to ensure equitable distribution of responsibility</p>
Central registry functions are funded equitably by hospitals, health insurers, governments and device/pharma manufacturers (where they derive a benefit related to their regulatory compliance obligations)	<p>Engages organisations with apparent power to influence the way care is delivered (i.e. health insurers)</p> <p>Establishes the basis for a broad governance framework for clinical quality registries</p>	<p>Price would need to be set by a reliable and accepted mechanism</p> <p>May be difficult to establish an equitable basis for contributions amongst diverse providers</p> <p>Complexity – would require a specific management system to ensure equitable distribution of responsibility within and between subsectors</p>
Central registry functions are funded by government (either Commonwealth or equitably by jurisdictions)	<p>Simplicity. Funding could be managed via an inter-governmental agreement with contributions depending on population or volume of services in each jurisdiction. New national agreements may enable a single point of funding</p>	<p>May result in clinicians and provider organisations disengaging from the registry</p> <p>May lose opportunity for providers or health insurers to more directly influence safety and quality, unless alternative engagement mechanisms are established</p>

We favour a model of funding for central registry functions consisting of a fixed amount for registry infrastructure and fee-for-service allocations based on case volume, reflecting the actual distribution of fixed and variable costs. Various hybrid options could be considered including core funding of central registry infrastructure by government, with fee-for-service payments by other stakeholders proportionate to the activity they provide/fund.

Equity of contribution within and between subsectors, depending on the benefits different subsectors will derive from a registry, should be a core principle when relative funding

obligations are being established. Procedural volume (for providers and health insurers) as well as the substituted cost of fulfilling post-marketing surveillance obligations of device manufacturers/suppliers would be relevant considerations, if these parties are to contribute to funding of central registry functions. As an example, if the distribution of the relevant cardiac procedural services approximates 50% public and 50% private, an appropriate allocation of funding responsibility could be:

- Australian/jurisdictional governments 40%
- Private health insurers 40%
- Device manufactures/suppliers 20%.

Given the obvious practical difficulties of registries negotiating with the Australian Government and 8 state and territory governments, we consider that government funding streams (i.e. reflecting the relative contributions of the Australian Government and all state and territory governments for services provided in public hospitals) should be centralised. In the context of the relatively low cost of the central registry function and proposed new mechanisms to fund public health care services by the Australian Government and the states/territories, it should be possible to agree a simple, centralised government funding mechanism. The public sector contribution could be managed directly or via the ACSQHC, which could have an overriding monitoring and governance role.

A private health insurance contribution is likely to be supported by the industry as a whole and could be implemented by agreement. Six private health insurers collectively comprise almost 80% of the private health insurance market in Australia and it may be feasible to negotiate with these providers alone. This may result, however, in inequity between providers, and there may be problems with sustainability. Alternatively, there is a levy mechanism currently available within the private health insurance regulatory framework which supports various costs which are currently shared in the industry (e.g. costs associated with the Private Health Insurance Administration Council, the Private Health Insurance Ombudsman, risk equalisation and meeting liabilities of collapsed insurers). This regulatory mechanism has been invoked to impose the national joint replacement register levy on device manufacturers. The private health insurance regulatory framework could be reviewed to determine the feasibility of imposing a levy to support sector-wide quality activities with a public benefit, such as registries, and the mechanisms that may be available to support the management of monies collected through such a scheme. Imposition of such a levy clearly would require the support of the Australian Government but in the context of the expressed support by several private insurers, this may be achievable.

We suggest that, if further consultation confirms the merits of private health insurer engagement in funding central registry functions, a more detailed analysis of the private health insurance regulatory framework is undertaken and a detailed proposal is put to the private health industry via its industry body.

A contribution from device manufacturers/suppliers has been captured in relation to the National Joint Replacement Registry, although there are significant criticisms of the way the levy has been designed. As noted earlier in this paper, concerns relate to the imposition of the entire responsibility for funding the registry on the device manufacturing sector and an apparent lack of correlation between the amount of the levy incurred and the number of devices sold by

each manufacturer. As with private insurers, however, the device industry is open to the possibility of contributing to funding, providing principles such as equity and proportionality are adhered to. We suggest that, if the broad principles proposed in this paper are accepted, a more detailed proposal for funding of the ACPR, which addresses the device industry's concerns about equity and proportionality, is put to the industry via its industry body.

Recommendation 5

That provider organisations fund peripheral registry functions (data collection and patient follow up), as an element of their usual provision of care.

Recommendation 6

That central registry functions are funded via a fixed component (reflecting costs of fixed infrastructure) and a variable component (reflecting service volume).

Recommendation 7

That a broad range of stakeholders is consulted to determine the preferred mechanism of funding central registry functions, with the options being:

- purchase of central registry functions by participating providers;
- equitable funding of central registry functions by a range of stakeholders including hospitals, health insurers, governments and device/pharmaceutical manufacturers (where device/pharmaceutical manufacturers derive a benefit related to their regulatory compliance obligations); and
- direct funding of central registry functions by government.

Recommendation 8

That if funding of central registry functions by private hospitals, private health insurers and/or device manufacturers/suppliers is confirmed as a viable funding mechanism, the regulatory frameworks of those subsectors are reviewed and the relevant industry bodies are engaged in a negotiation about how to achieve an equitable and simple funding mechanism.

Designation of registry 'centres of excellence'

As noted above, we consider that designation of two to three national registry 'centres of excellence' will enable sufficient competitive tension between providers of those central services while allowing the quality and cost benefits of concentration of expertise to be realised.

The role of these registry 'centres of excellence' would be to service national clinical quality registries (which would choose which centre of excellence to affiliate with), promote the development of new registries, support collaboration among registries (e.g. in technical operations, analytical work and use of registry data to support clinical quality improvement) and help to optimise the utility of registry data. Each registry would continue to be managed independently.

Selection of these 'centres of excellence' could be by a multijurisdictional body such as the ACSQHC, with appropriate expert advice including from persons with knowledge of the medical device and public and private hospital sectors.

Recommendation 9

That a multijurisdictional body such as the Australian Commission on Safety and Quality in Health Care is empowered to select registry centres of excellence.

Conclusions and next steps

There are strong public interest arguments to support the designation of a small number of national clinical quality registries, including the ACPR, which meet agreed standards of design, operations and governance and which have the potential to make a substantial impact on the safety and quality of health care.

Sustainable funding is a key success factor for registries. Achieving sustainable funding streams for national clinical quality registries has been a challenge and the ACPR is no exception. This paper identifies the dimensions necessary for sustainable funding as a basis for evaluating potential funding mechanisms.

Some existing registries have achieved government funding (in one case supported by a levy on device manufacturers) while others are sponsored by a variety of private and public sources.

There is a strong argument that registry funding should be normalised to reflect the role of well-designed and operated registries in quality and safety in Australian health care.

A funding system which reflects the various registry stakeholders and interests is appropriate. For the ACPR, we consider this means that government, health insurers and device manufacturers/suppliers may be appropriate funders of central functions. Health insurers and device manufacturers/suppliers have expressed support in principle for the concept of participation in an equitable funding scheme.

With respect to the provision of central registry function, we suggest that a small number of organisations that meet agreed criteria should be designated for this function and that funding should flow to them from a combination of stakeholders which could include government, private health insurers and device manufacturers/suppliers. Public sector contributions should be channelled through a single entity, possibly the ACSQHC. A mechanism to enable equitable contributions by private health insurers and device manufacturers/suppliers, if thought appropriate, needs further consideration but we consider that regulatory mechanisms are potentially available which would achieve both equity and efficiency.

Public and private hospitals should be required to contribute to peripheral functions including data collection and patient follow up. We have briefly considered the various regulatory and other mechanisms that may be available to ensure this function is embedded as part of the usual business of public and private hospitals. Further analysis is required to ensure there are no regulatory barriers to the potential approaches that have been identified.

Recommendation 10

That the following next steps are undertaken:

- Further specific work is commissioned on the regulatory mechanisms available to mandate participation by public and private hospitals in peripheral registry functions.
- Further consultation is undertaken with respect to the three potential options for funding central registry functions (provider organisations, health insurers, device manufacturers/suppliers and/or governments).
- If private hospitals, private health insurers and/or device manufacturers/suppliers are confirmed as viable potential funders for central registry functions, further specific work is commissioned to determine the regulatory mechanisms available to embed contributions to national clinical quality registries within their usual responsibilities, and any legal barriers that may be relevant to such an approach.
- A detailed assessment is undertaken of the public/private distribution of procedures in the ACPR, to enable consideration of potential distribution of funding responsibility.
- A detailed funding formula is defined, to enable specific discussion of potential implications with the relevant industry sectors.
- If there is stakeholder support, the ACSQHC and/or AHMAC are approached to discuss the policy framework and how funding for the ACPR may fit within it.

Attachments

Attachment 1 - Persons consulted

Attachment 2 - Summary of operating principles, Australian clinical quality registries**Attributes of Australian clinical quality registries**

- 1 Australian Clinical Quality Registries should be developed with clear and precisely defined purposes.
- 2 For Australian Clinical Quality Registries to provide the maximum value to the health system they should focus their core data collection on the essential elements required to serve their main purposes.
- 3 Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible;
- 4 Methods used to collect data in Australian Clinical Quality Registries should be systematic, with identical approaches used at the different institutions contributing information.
- 5 Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.
- 6 In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up.
- 7 Australian Clinical Quality Registries must ensure that complete registry data are collected from the eligible population.

Data collection

- 8 The collection of data for an Australian Clinical Quality Registry must not impact on the provision of health care and should not be a burden or incur a cost to consumers.
- 9 Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors.
- 10 Data should be uniformly and easily accessible from the primary data source.
- 11 Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases (if approved by relevant ethics committees, etc.).
- 12 Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc.;
- 13 To avoid duplicating data capture, Australian Clinical Quality Registries use data from existing data sources, including administrative data, where they are of a satisfactory quality;

- 14 Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registers or other databases.

Data elements

- 15 Australian Clinical Quality Registries should collect individually identifiable patient or subject information.
- 16 Where patterns or processes of care have an established link to outcomes and process measures are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries.
- 17 Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools.

Risk adjustment

- 18 Australian Clinical Quality Registries should collect objective, reliable co-variables for risk adjustment to enable factors outside the control of clinicians to be taken into account by using appropriate statistical adjustments.

Data security

- 19 To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems.
- 20 The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines.
- 21 Institutional policy principles set out in Part B: Technical standards should be met.

Ensuring data quality

- 22 Australian Clinical Quality Registries should report as a quality measure the percentage of eligible patients recruited to the registry.
- 23 Australian Clinical Quality Registries should have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected.
- 24 Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible.
- 25 Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks.
- 26 Australian Clinical Quality Registry reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur.

Organisation and governance

- 27 Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry.
- 28 Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes a formal plan ratified by the Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately.

Data custodianship

- 29 Custodianship of clinical register data needs to be made explicit in Contracts and/or Funding Agreements.
- 30 Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data.
- 31 Third parties wishing to access data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data or contact with patients is sought.

Ethics and privacy

With the exception of instances where data collection has been mandated through legislation or enabled through regulation or legislation:

- 32 Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry.
- 33 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.
- 34 Participants or their next of kin should be made aware of the collection of register data. They should be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This should be at no cost to the registry participant.
- 35 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.

Information output

- 36 Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.
- 37 Australian Clinical Quality Registries must report without delay on risk-adjusted outcome analyses to institutions and clinicians.

- 38 Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings.
- 39 Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.
- 40 Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.
- 41 Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance.

Resources and funds

- 42 Australian Clinical Quality Registries should be appropriately funded to allow data collection, reporting and the institution of strong quality control procedures.

Attachment 3 - Regulation and post-market surveillance of medical devices

The Prostheses List, produced by the Department of Health and Ageing twice a year (June and December), includes all the prosthetic devices covered by private health insurance.

Pacemakers, defibrillators, cardiac stents, hip and knee replacements, intraocular lenses, and other devices that are surgically implanted during a stay in hospital are included. Prostheses also include human tissue that is surgically implanted, such as human heart valves, corneas, bones (part and whole) and muscle tissue. External devices, such as artificial legs, external breast prostheses, wigs or other similar products, are not included on the Prostheses List.

The legislation underpinning these arrangements is the National Health Amendment (Prostheses) Act 2005, the Private Health Insurance Act 2007 and the Private Health Insurance (Prostheses Application and Listing Fees) Act 2007, and their related Rules.

Insurers pay a benefit for a listed prosthesis when:

- the prosthesis is provided as part of an episode of hospital treatment or hospital-substitute treatment; and
- a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

The Prostheses List currently allows for two categories of prostheses:

- No-gap prostheses are listed with a single benefit which is covered in full by private health insurers for consumers with appropriate cover.
- Gap-permitted prostheses have both a minimum and a maximum benefit listed. For these prostheses, private health insurers are required to pay at least the minimum benefit.

Consumers with cover may incur an out-of-pocket expense for these prostheses, which, at a maximum, will be the difference between the minimum and the maximum benefit.

At least one no-gap prostheses must be available for each MBS item. The decision of which prosthesis to use is a clinical choice to be made between the doctor and the consumer. If a doctor considers a gap-permitted prosthesis the most clinically suitable for a consumer, the doctor is required to provide appropriate clinical and financial information to enable the consumer to give informed financial consent before the procedure begins.

1. The manufacturer's post-marketing surveillance system

The manufacturer's post-marketing surveillance system enables the manufacturer to gain and review experience about their medical devices supplied in Australia. The surveillance activities are part of the manufacturer's overall quality manufacturing system. They are also undertaken as one of the conditions of supplying the medical device in Australia, or simply as a result of ongoing research and development.

The post-market surveillance system requires manufacturers to:

- systematically review experiences gained after the device was supplied in Australia;

- implement corrective action, commensurate with the nature and risks involved with the medical device and;
- notify the sponsors of the medical device of adverse events and near events.

Information feeding into the surveillance system can come from many sources:

- expert user groups,
- customer surveys,
- customer complaints and warranty claims,
- service and repair information,
- literature reviews,
- user feedback other than complaints,
- device tracking and registration registers, and
- user reactions during training programs.

In most cases, the manufacturer's surveillance system already exists as part of the internal quality system. Even though a certified quality system is not required for manufacturers of Class I medical devices (non-sterile or non-measuring), the manufacturer is still required to have a post-marketing system.

2. Post market monitoring of market compliance by the TGA

Market monitoring by the TGA is a series of activities carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market and to take action when this does not occur.

Monitoring activities may include:

- audits of technical and clinical information to show compliance to the essential principles;
- inspections of manufacturer's or sponsor's records and documentation;
- on-site tests or taking samples for off-site testing;
- testing or auditing to confirm compliance with the essential principles;
- audits of distribution records;
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts; and
- audits of compliance with Good Manufacturing Practice (GMP) requirements for selected therapeutic goods.

If problems are found the TGA may cancel or suspend entries in the ARTG under Part 4-6 of the Act. Other parts of the Act could then be invoked leading to:

- recalls (outlined in the section, Recalls of Therapeutic Goods, on page 20),
- safety alerts (outlined in the section, Non-Recall Actions for Therapeutic Goods, on page 21), and
- product improvements undertaken by the manufacturer.

3. Vigilance Programs

Vigilance programs are a range of activities undertaken by the TGA and the manufacturer or sponsor after any party becomes aware of:

- adverse events,
- malfunctions,
- results of testing, or
- other information,

about medical devices supplied in Australia.

Under the new regulatory system, notification and evaluation of adverse events is known as the Medical Devices Vigilance System. The vigilance system improves the health and safety of patients, users and others by reducing the likelihood of an adverse event being repeated. This is achieved by:

- evaluating reported adverse events;
- disseminating information, where appropriate, that could be used to prevent such repetitions, or to alleviate the consequences of such incidents; and
- modifying, where appropriate, the medical device or removing it from the market.

All adverse events, regardless of whether they have to be reported under the vigilance system, should be included in the manufacturer's post-market system.

Australian sponsors' post-market responsibilities

The sponsor is responsible for ensuring that the manufacturer of the medical devices has procedures in-place for the introduction and maintenance of the post-marketing surveillance system. They should also have procedures to:

- collect information from users about incidents and the performance of devices and send this information to the manufacturer (section 41FN of the Act);
- report details of certain incidents and performance issues to the TGA (section 41FN of the Act);

- report any overseas regulatory actions to the TGA if the product involved from the same batch or production run was supplied in Australia (section 41FN of the Act);
- report results of investigations undertaken by the manufacturer to the TGA (section 41FN of the Act);
- assist the TGA and the manufacturer in the investigations (section 41FN of the Act);
- follow-up action taken under the Vigilance System (section 41KA of the Act); and
- maintain distribution records for product supplied in or exported from Australia (section 41FO of the Act).

In addition, the sponsor is required to have access to:

- the technical documentation that demonstrates the conformity of the products to the essential principles (section 41FN of the Act), and
- evidence that appropriate conformity assessment procedures have been applied (section 41FN of the Act).