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Clinicians, Consumers, Evidence
Centre for Clinical Effectiveness

Rapid Review

Clinical Registries: Informing a framework for hospital participation

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Executive Summary

This rapid review identified seven documents[1-7] which outlined benefits, costs and characteristics of clinical registries. As a rapid review, the internet only was searched, with no peer-reviewed databases included; it is important to note that searching these databases may have revealed further information about this issue.

Clinical registries in Australia

The literature suggests that Australia has few registries capable of benchmarking outcomes nationally. Registry development should target three areas: [2]

- Conditions or procedures associated with large variations in processes or outcomes of care, which have a significant impact on overall health care costs and patient morbidity
- Areas where transitions of care across health services influences optimal outcomes
- Medium-term to long-term safety of new clinical interventions.

Prioritising registry development in Australia by increasing the number of nationwide clinical registries will provide an enlarged inventory of valid, reliable and clinically credible measures of quality that can be compared among different institutions within Australia and internationally.[2]

Benefits of clinical registries

The benefits of well-established and maintained clinical registries can include: [3,4]

- Improvements in informed patient decision making
- Improvements in treatment
- Advances in healthcare research and governance
- Increasing healthcare value.

Larsson et al (2012) [3] proposes that disease registries can contribute to improving patient outcomes by engaging doctors and other clinical professionals in identifying, comparing, and adopting best practices that can both transform care and lower costs.

Benefits to the clinician have also been discussed. Contributing to and using registry data can[5].

- Foster improvement in their own practice
- Enhance epidemiological literacy
- Provide clinicians with an appreciation of strengths and limitations of information output from registries."

Challenges facing registries in Australia

In a study[5] that identified 28 Australian registries, only a few registries in their current state had the ability to collect data on quality of care and benchmark performance at a national level.

For benefits to be seen in Australia the following aspects of registries would need to improve:

- Coverage
- Length of operation and funding
- What data are collected, how they are collected, stored and registry output
- Governance structures within registries

- Quality of data within the registries according to recruitment, coding validation and reliability checks

Costs

The estimated costs of involvement in clinical registries – cost effectiveness

It is said to be extremely challenging to prove that funding a registry will reduce health care costs (at least per patient) however there are examples of indirect evidence[6]:

- Existing registries are currently used for economic analysis
- 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 10.4% to 7.9% respectively, with an associated annual cost saving of $44.6 million.
- Since its inception in 2001, the Victorian State Trauma Registry has demonstrated a 30% reduction in mortality among trauma victims

"There is emerging evidence of substantial cost savings resulting from clinical quality registries. For example it has been estimated that if a joint replacement registry had been established in the United States to monitor poorly performing hip prostheses, $2 billion of an expected $24 billion in total costs for this surgery could have been avoided."[1,3]

Other examples of improved outcomes from benchmarking are seen in[1]:

- Improved renal allograft survival
- Effective treatment of myocardial infarction
- Increased rate of complete malignant tumour removal

Funding clinical registries

The DLA Phillips Fox (2011) report defines the case for developing a sustainable model for funding the Australian Cardiac Procedures Registry (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.[6]

They provide an outline for funding of central registry functions:

Funding approach	Benefits	Risks
Health service pays	• registry becomes core function of health service • costs proportional to volume • reinforces responsibility of health providers for quality assurance	• setting appropriate price • complexity to model
Shared funding by hospitals, health insurers, government, device manufacturers	• engages all interested parties • establishes broad base for governance	• setting appropriate price • equitable division of funding among stakeholders • complex
Government funding	• simple to manage	• potentially disenfranchise some of the interested parties

In terms of 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."[6]

To be successful, registries must be supported. Larsson et al (2012) suggests the following sources of support:[3]

- Federal government
- Private sector players: insurance companies and the manufacturers of drugs and medical devices

The DLA Phillips Fox (2011) report states that the peripheral costs of registries should 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.[6]

Costs involved in setting up clinical registries

The Monash University Registry Science Handbook (2013) [1] outlines the costs involved in setting up a central clinical registry. These are listed below:

- Central registry costs may be up to $1 million per annum for a large national registry.
- Costs can typically be broken down into the following categories:
    - Developing and testing the minimum data-set;
    - Building and maintaining the web-based data acquisition and reporting system;
    - Development and support of the governance committees;
    - Establishing a liaison with clinicians and agreements with institutions;
    - Gaining ethics approval at each institution;
    - Data-collection and reporting costs;
    - Outcome determination via a call centre and/or data-linkage;
    - Statistical analysis costs;
    - Implementing quality control procedures.
- After the initial establishment phase there is usually ongoing work to increase the fraction of data retrieved from routinely collected clinical information systems.[1]
- For a major national registry with 50,000 cases reported annually the establishment of the IT systems will typically cost $250k and other set up costs are typically $500-800k. The cost of maintaining a major national registry may be in the order of $1-1.5 million per annum.[1]

Characteristics

The Framework for Australian clinical quality registries produced by the Australian Commission on Safety and Quality in Health Care [7] sets out the elements of a framework for Australian clinical quality registries. It provides details about the principles, guidelines and standards for clinical quality registries development and explains aspects of operating principles, technical guidelines, requirements specification, infrastructure and technical standards, logical architecture and design and security compliance guideline.

Conclusion

“If registries are to advance from tools used principally as internal quality assurance assessment to tools used to monitor and benchmark performance and stimulate improvement in service delivery, then it is important that quality of the data be complete and accurate, provide for risk adjustment and be subjected to quality control checks. To get clinical ‘buy in’ it is important that the focus of the registry is on improving patient outcomes and not on emphasising the poor performance of particular caring services.”[5]

FULL REPORT

Objective

A rapid review of the grey literature was undertaken to determine the following:

- What are the benefits and costs involved with participating in a clinical registry?
- What are the characteristics of a high functioning clinical registry?

Methods

A search was conducted in Google and Google Scholar using the following search terms:

- (Clinical AND (register OR registries OR registry)) AND Australia

Results

This rapid review of the grey literature identified seven documents[1-7] which outlined benefits, costs and characteristics of clinical registries. Throughout the literature the term clinical registry can have different definitions, some of which are described below.

Definitions of clinical registries

In undertaking this rapid review we identified a number of different types of clinical registries described in the literature. These definitions have been provided below.

Clinical quality registries: The primary purpose of a clinical registry is to monitor outcomes and report on quality of care. Quality indicators collected by clinical registries assess whether care is safe and effective and delivered in a timely and appropriate manner and report this back to institutions and/or clinicians. Clinical registries may monitor quality of care within specific areas of the health service, such as in Intensive care or the Emergency Department or may be targeted at monitoring defined diseases or conditions.[1-2]

Condition/disease registries: The primary purpose of a condition/disease registry is to collect diagnostic details on patients with specific diseases or conditions. Examples of these registries include those monitoring the incidence of cancer, or those monitoring incidence, treatment and outcomes of patients with cystic fibrosis. If a condition/disease registry collects outcome data and reports quality indicators back to institutions and/or clinicians it would also be considered a clinical registry.[1, 3]

Drug/device/product registries: The primary purpose of drug/device/product registries is to monitor the medium to long-term safety of devices, drugs or products such as blood. Examples of these registries include those monitoring safety of implantable devices such as pacemakers or breast implants. As with condition/disease registries, drug/device/product registries may also be considered clinical registries if they collect and report quality indicators back to institutions and/or clinicians.[1]

Clinical registries in Australia

In 2011, Evans et al discussed the development of clinical-quality registries in the Australian setting. They note that Australia has few registries capable of benchmarking outcomes nationally…"Registry development should target three areas – conditions or procedures associated with large variations in processes or outcomes of care, which have a significant impact on overall health care costs and patient morbidity; areas where transitions of care across health services influences optimal outcomes; and medium-term to long-term safety of new clinical interventions. Clinical registries can play an increasingly important role as a stimulus for quality improvement by providing high quality data and analyses that are respected by clinicians."[2]

Prioritising registry development in Australia – increasing the number of nationwide clinical registries will provide an enlarged inventory of valid, reliable and clinically credible measures of quality that can be compared among different institutions within Australia and internationally.[2]

Benefits of clinical registries

In a paper which describes governance, management, analysis and application of high functioning clinical registries, Hickey et al (2013) suggest that "clinical registries can be used to improve the quality of patient care, underpin research, improve cost-effectiveness and provide information for regulatory purposes." The benefits of well-established and maintained clinical registries can include improvements in informed patient decision making, improvements in treatment, advances in healthcare research and governance and increasing healthcare value.[3,4]

Larsson et al (2012) proposes that disease registries can contribute to improving patient outcomes by engaging doctors and other clinical professionals in identifying, comparing, and adopting best practices that can both transform care and lower costs.[3]

"Clinicians have much to benefit from contributing to and using registry data. In addition to fostering improvement in their own practice, knowledge gained from using registries can enhance epidemiological literacy and provide clinicians with an appreciation of strengths and limitations of information output from registries."[5]

In a report conducted by DLA Phillips Fox (2011) that focused on funding for clinical registries, specifically the Australian Cardiac Procedures Registry, the authors provided the following table which outlines the benefits of a registry for each interested party:[6]

	Beneficiary									
Benefits	**Consumers**	**Clinicians**	**Professional groups**	**Aust Govt**	**State/Territory Govt/ Public Hospitals**	**Private Hospitals**	**Health insurers**	**Pharma manu-facturers**	**Device manu-facturers**	**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 service		✓	✓	✓	✓	✓	✓			✓
Assistance with post market surveillance				✓				✓	✓	
Reduced administrative burden of demonstrating accountability		✓	✓		✓	✓		✓	✓	
Improved accountability of the health care system	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Challenges facing registries in Australia

In a study that identified 28 Australian registries, commented that few registries in their current state had the ability to collect data on quality of care and benchmark performance at a national level. [5]

For the benefits to be seen in the Australian setting Evans et al (2011) suggests that the general aspects of registries would need to improve including coverage, length of operation and funding; what data are collected, how they are collected, stored and registry output; governance structures within registries; and quality of data within the registries according to recruitment, coding validation and reliability checks. [5]

The authors go on to report that "Registries are potentially useful and credible tools in measuring improvements in healthcare. At present we do not have a systematic approach to the way we use and interpret registry data. A central repository of registries including essential characteristics would enable clinicians, administrators and policy-makers to better utilize the value of this important resource nationally." [5]

Costs

The estimated costs of involvement in clinical registries – cost effectiveness

It is said to be extremely challenging to prove that funding a registry will reduce health care costs (at least per patient) however there are examples of indirect evidence:[6]

- Existing registries are currently used for economic analysis
- 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 10.4% to 7.9% respectively, with an associated annual cost saving of $44.6 million.
- Since its inception in 2001, the Victorian State Trauma Registry has demonstrated a 30% reduction in mortality among trauma victims

The Monash University Registry Science Handbook (2013) states that "if the data burden required of hospitals and clinicians is kept to a minimum the cost of participation in clinical quality registries should usually be seen as part of the cost of business for the reporting institutions."[1]

"There is emerging evidence of substantial cost savings resulting from clinical quality registries. For example it has been estimated that if a joint replacement registry had been established in the United States to monitor poorly performing hip prostheses, $2 billion of an expected $24 billion in total costs for this surgery could have been avoided."[1,3]

Other examples where the improved outcomes from benchmarking *might be expected* to reduce healthcare costs include:[1]

- Improved renal allograft survival reducing the financial burden associated with long-term dialysis;
- More effective treatment of myocardial infarction, reducing costs of managing subsequent cardiac failure; and
- An increased rate of complete malignant tumour removal reducing the cost associated with adjuvant treatment.

Funding clinical registries

The DLA Phillips Fox (2011) report defines the case for developing a sustainable model for funding the Australian Cardiac Procedures Registry (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.[6]

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In terms of 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."[6]

A study that examined the use of 13 disease registries in 5 countries (Australia included) demonstrated evidence of improved health outcomes associated with registries, documentation of how registries may have helped achieve these outcomes, and estimates of costs avoided as a result of registry-associated improvements.[3] In order to achieve these results registries must be supported. Larsson et al (2012) suggests the following sources of support:[3]

- Federal government: can support registries by creating a legislative and regulatory framework that facilitates their establishment and by providing seed funding to get them up and running.
- Private sector players: insurance companies and the manufacturers of drugs and medical devices should support disease registries because the high quality data that registries produce would help them focus on genuine innovations to improve clinical outcomes and bend the health care cost curve.

The DLA Phillips Fox (2011) report states that the peripheral costs of registries should 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…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."[6]

Costs involved in setting up clinical registries

The Monash University Registry Science Handbook (2013) outlines the costs involved in setting up a central clinical registry. These are listed below: [1]

- Central registry costs may be up to $1 million per annum for a large national registry. These costs may be provided by a variety of sources including government, industry and charities. Some of these costs are fixed i.e. building the registry, while others are variable depending on the number of sites, patients and clinicians contributing to the registry. [1]
- Costs can typically be broken down into the following categories: [1]
    - developing and testing the minimum data-set;
    - building and maintaining the web-based data acquisition and reporting system;
    - development and support of the governance committees;
    - establishing a liaison with clinicians and agreements with institutions;
    - gaining ethics approval at each institution;
    - data-collection and reporting costs;
    - outcome determination via a call centre and/or data-linkage;
    - statistical analysis costs;
    - implementing quality control procedures.
- After the initial establishment phase there is usually ongoing work to increase the fraction of data retrieved from routinely collected clinical information systems. [1]
- For a major national registry with 50,000 cases reported annually the establishment of the IT systems will typically cost $250k and other set up costs are typically $500-800k. The cost of maintaining a major national registry may be in the order of $1-1.5 million per annum. [1]

Conclusion: Implications for Monash Health

With few Australian registries capable of benchmarking outcomes nationally, registries should target only conditions or procedures associated with large variations in processes or outcomes which have a significant impact on overall health care costs and patient morbidity, transitions of care across health services and medium-term to long-term safety of new clinical interventions.

The benefits of clinical registries are relevant to the health service, clinician and consumer including improvements in informed patient decision making; improvements in treatment; advances in healthcare research and governance; increasing healthcare value; fostering improvement in clinicians own practice; enhancing epidemiological literacy; and providing clinicians with an appreciation of strengths and limitations of information output from registries.

While there is evidence to suggest that clinical registries can contribute to and demonstrate healthcare cost savings there is also a body of literature that discusses the importance of secure funding frameworks, not only for set up but also maintenance and sustainability.

"If registries are to advance from tools used principally as internal quality assurance assessment to tools used to monitor and benchmark performance and stimulate improvement in service delivery, then it is important that quality of the data be complete and accurate, provide for risk adjustment and be subjected to quality control checks. To get clinical 'buy in' it is important that the focus of the registry is on improving patient outcomes and not on emphasising the poor performance of particular caring services."[5]

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