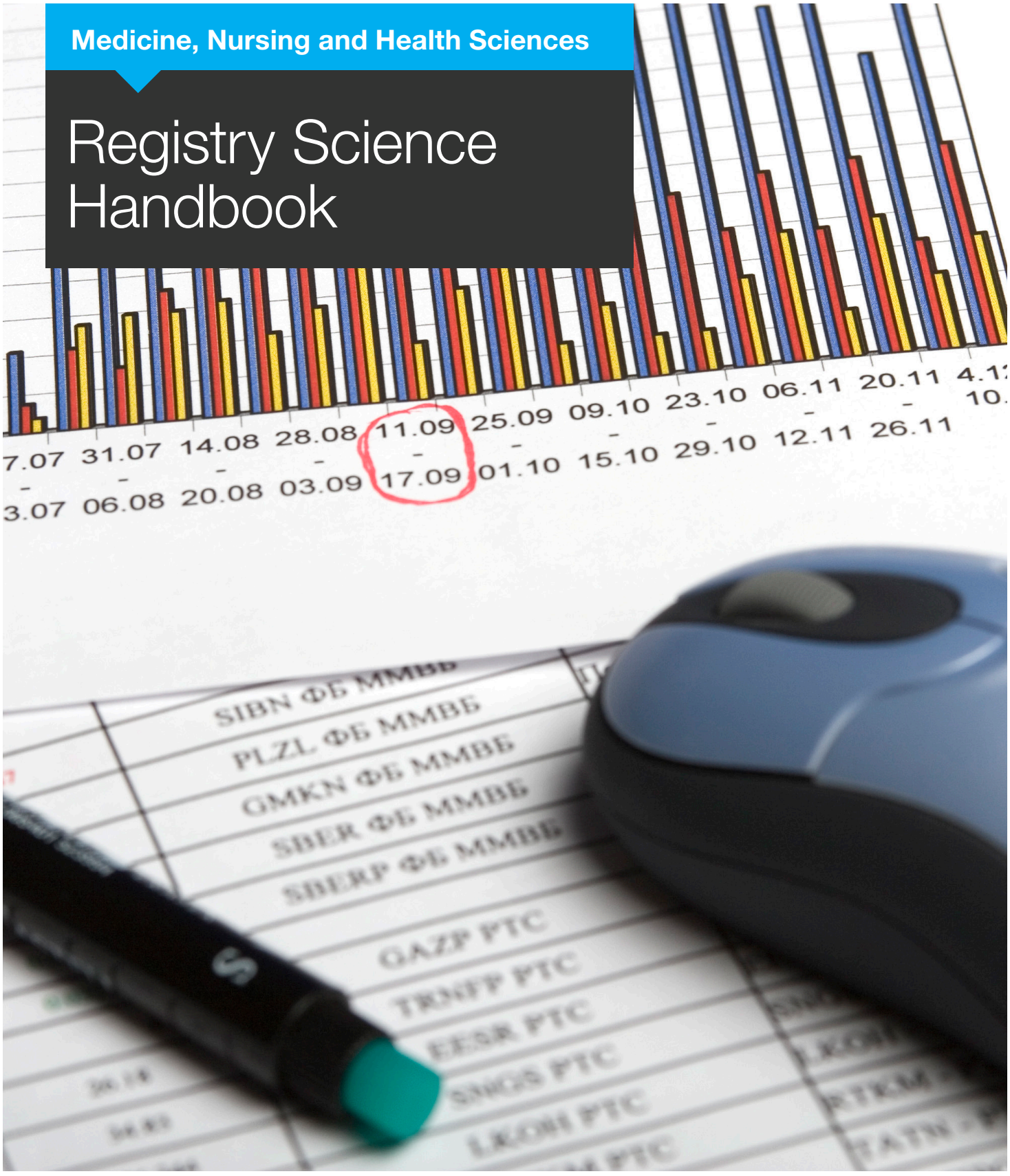
MONASH University

M8 Alliance

Medicine, Nursing and Health Sciences

Registry Science Handbook



Creating Knowledge for Improved Health

Australia ▪ China ▪ India ▪ Italy ▪ Malaysia ▪ South Africa

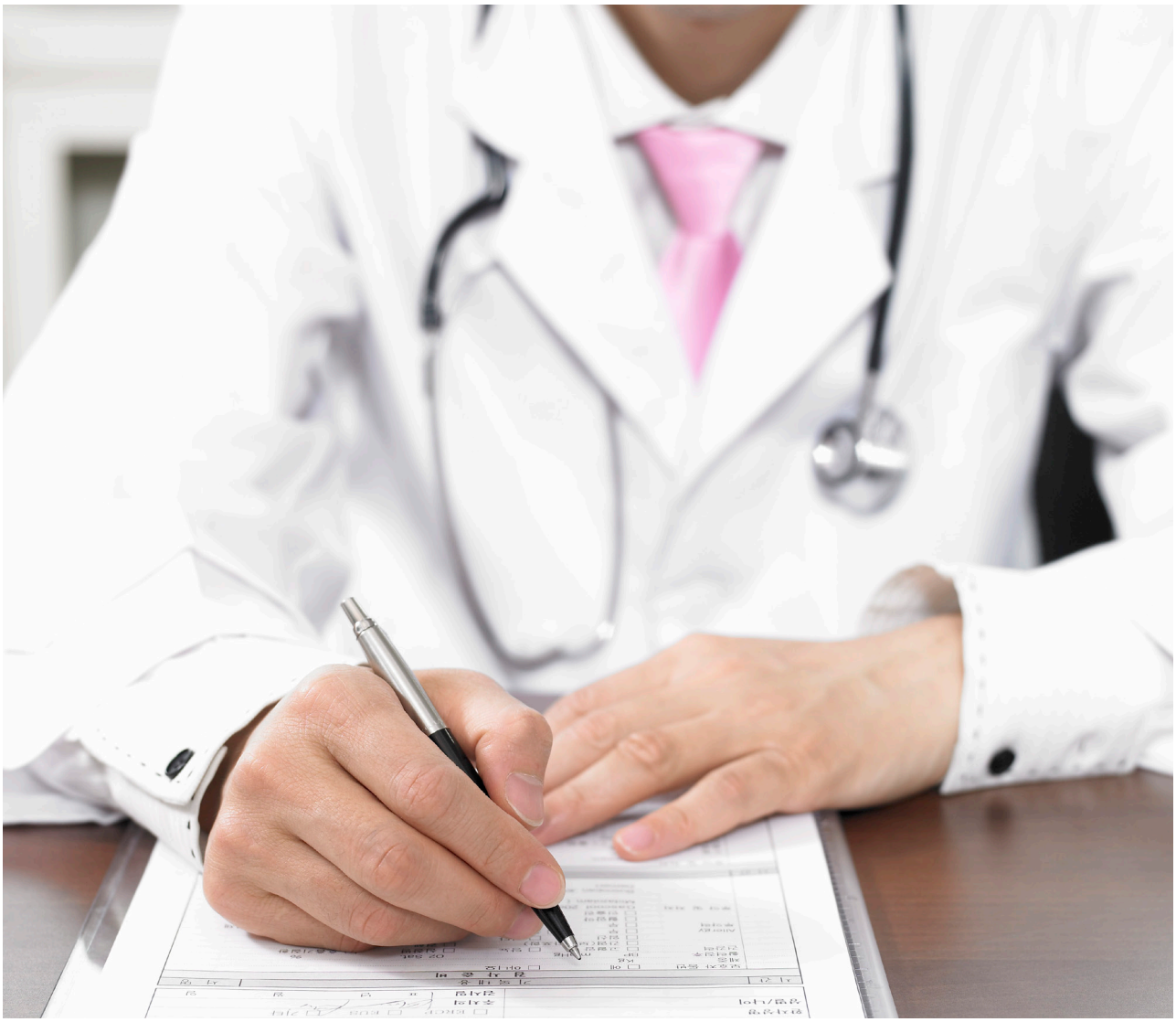
www.med.monash.edu

Contents

Foreword

- Clinical quality registries provide a cost effective strategy for measuring and benchmarking outcomes of treatment.
- This approach is applicable to many of the most expensive and complex treatments delivered in hospitals. It provides hospitals and clinicians with feedback about their performance in a way that is not provided by most other strategies. Initiatives such as ‘pay for performance’ are likely to increase the need for benchmarked outcome data.
- The data provided by registries leads to improved patient outcomes, fewer adverse events and diminished costs. Registries will increasingly underpin high quality clinical and health services research. Opportunities will exist to scale up existing registries to provide benchmarking services nationally and internationally.
- Despite value, several improvements are required before registries reach their optimum potential. More efficient methods of collecting registry data from routinely collected clinical records need to be established. There also needs to be a consensus on what is a ‘high quality’ clinical outcome, and outcome ascertainment and risk adjustment also need to be improved.
- We anticipate that it may be of interest to people involved with registries, either as steering committee members or recipients of registry data. We are always grateful for comments that may improve our registry strategy.
- Finally, I would like to thank my colleagues Sue Evans, Angela Brennan and Chris Reid for their valuable contributions to the document.

John J McNeil AM, MBBS, MSc, PhD, FRACP, FAFPHM
Professor & Head
Department of Epidemiology and Preventive Medicine
School of Public Health & Preventive Medicine
Monash Faculty of Medicine Nursing & Health Sciences



Introduction

A clinical registry has been defined as "*an organised system that uses observational study methods to collect uniform data to evaluate specific outcomes for a population defined by a specific disease, condition or exposure that serves one or more predefined scientific, clinical or policy purpose*"(1).

- Registries of various forms have been in existence for many years. For example, cancer registries have been established in many countries, principally to monitor the incidence of various types of malignancy. Other registries have been established as research projects, to provide information about the clinical course of diseases, to facilitate product recalls or to monitor the safety of new drugs and devices.
- Recently, interest in registries has increased because of their potential contribution to advancing the "safety and quality" agenda in medicine. This is because registries produce a credible method for benchmarking care between different providers nationally and overseas. Benchmarking is one of the most effective strategies for quality improvement.
- In addition to benchmarking, registries have the potential to provide a wealth of additional information of value to clinicians, researchers and health administrators. Registries designed specifically to benchmark outcomes and improve quality of care are commonly referred to as 'clinical quality registries'.
- Clinical quality registries complement other approaches including sentinel event reporting, limited adverse occurrence screening, incident reporting, morbidity and mortality review, accreditation, credentialing and patient satisfaction surveys.

Clinical quality registries

Clinical quality registries are being established with increasing frequency in many advanced countries. Their development has been facilitated by:

- Improving access to IT infrastructure including web-based data entry and data capture;
- A more accepting ethics environment;
- Greater acceptance by clinicians (in some cases supported by a requirement for membership for some clinical colleges);
- Increasing agreement on governance and funding models;
- Growing acceptance that registries may reduce inappropriate treatments and reduce healthcare costs;
- Recognition that investment in administrative data to monitor clinical outcomes has not achieved the desired results;
- Growing recognition of the importance of collecting patient-reported outcomes.

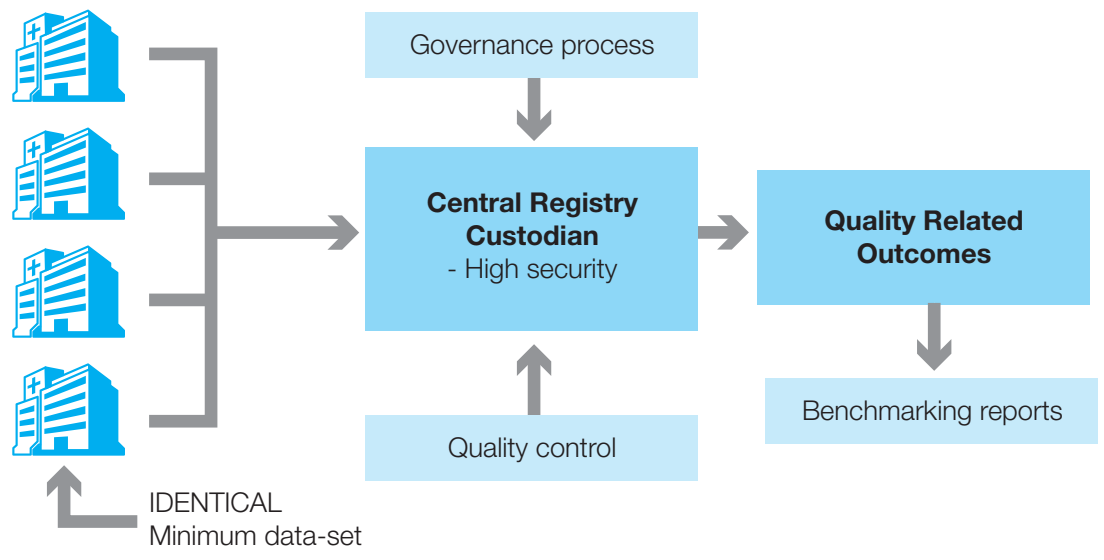
Basic Registry Structure

The essential features of a clinical quality registry include:

- Collection of an identical set of 'epidemiologically sound' data from 100% of patients treated in both the public and private sectors.
- Data elements includes both 'process' and 'outcome' measures.
- Outcome measures to be collected from all subjects at a defined time.
- Risk adjustment to be undertaken to allow for important differences in patient mix.
- Ethics approval to be sought from each participating institution to allow for 'opt-out' consent.

The basic registry structure is illustrated diagrammatically in Figure 1 below.

Figure 1: Basic architecture of a clinical quality registry



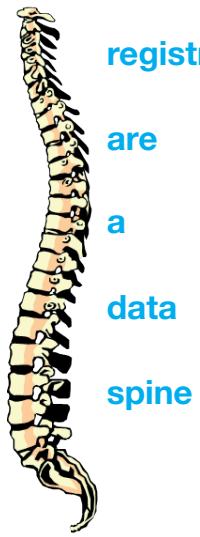
Registry fundamentals

- Some aspects of registry design may vary according to the purpose for which the registry was established. However, a typical clinical quality registry established to benchmark clinical care requires:
  - Systematic measurement of defined outcomes at predefined intervals;
  - Rapid reporting back of information to participating clinical units.
- A clinical quality registry shares many features of an observational cohort study. In common with other cohort studies, registries generally lack “external controls” and are therefore of limited use for identifying the efficacy of an intervention, unless the effect is particularly pronounced. The major comparisons that can be drawn from their data are “internal” i.e. by comparing sub-groups within the registry. These may be defined (for example) by different hospitals, providers, treatments, or devices. As with all such studies, this type of comparison might be influenced by bias or confounding and may require statistical adjustment.
- The purpose of clinical quality registries is fundamentally to improve quality and safety of care. This is achieved by feeding back information to stakeholders concerning:
  - Variation in process and outcomes of care;
  - Benchmarking of process and outcome measures amongst providers of care;
  - Appropriateness of treatment and/or compliance with treatment guidelines;
  - Access to care;
  - Safety and effectiveness of care.
- The technical challenges of establishing and maintaining registries are substantial. They should be established in a strong research environment with extensive access to the appropriate skills including:
  - Clinical medicine;
  - Clinical epidemiology;
  - Biostatistics;
  - Clinical data management;
  - Bioethics, privacy law & research governance;
  - Clinical quality improvement.
- The key activities involved in the establishment of a registry can be summarised as:
  - Establishing collaboration with clinicians and other interest groups (see below);
  - Development of a governance model;
  - Data collection and data-management;
  - Bio-statistical analysis;
  - Clinical interpretation of results;
  - Quality improvement.
- Registry development involves collaboration with a series of partners. Amongst these are:
  - Clinical craft groups (e.g.bariatric surgeons, cardiologists, breast surgeons);
  - Clinical colleges;
  - State and Commonwealth Departments of Health;
  - Private insurers;
  - Medical indemnity insurers;
  - Patient advocacy and consumer groups.

Registry Data

- To be sustainable the data collected by a registry must be confined to a limited series of essential data items. Whenever possible, information should be restricted to one or two pages (see Figure 3).
- A typical registry will limit data collection to information that:
  - identifies the individual in sufficient detail to facilitate follow up;
  - describes the clinical condition and major co-morbidities;
  - describes health interventions such as surgical approach or type of radiotherapy;
  - collects prognostic factors required for risk adjustment;
  - describes key "process of care" that affects health outcomes (see below);
  - enables risk-adjustment of health outcomes;
  - describes the objective and 'patient reported' outcomes of care.
- In addition to being brief, the data items must be "epidemiologically sound" i.e.
  - routinely recorded in clinical records;
  - defined in a consistent fashion;
  - objective in nature (not requiring clinical judgement).
- To avoid suspicion of bias, data elements should be collected by a person independent of the practitioners involved in the patient's care.
- The minimum data-set of a registry may be considered to be a 'data-spine' to which additional items may be added for time-limited collection (see Figure 2).
- Web based systems facilitate data collection at sites as well as aiding data accuracy. They also reduce central registry costs.
- Registries provide an opportunity to capture patient-reported outcomes such as quality of life, complications, and impact of treatment on daily living. Patient outcomes are best collected directly from the patient, and often are captured via telephone.

Figure 2: Basic requirements for registry data elements



registries

are

a

data

spine

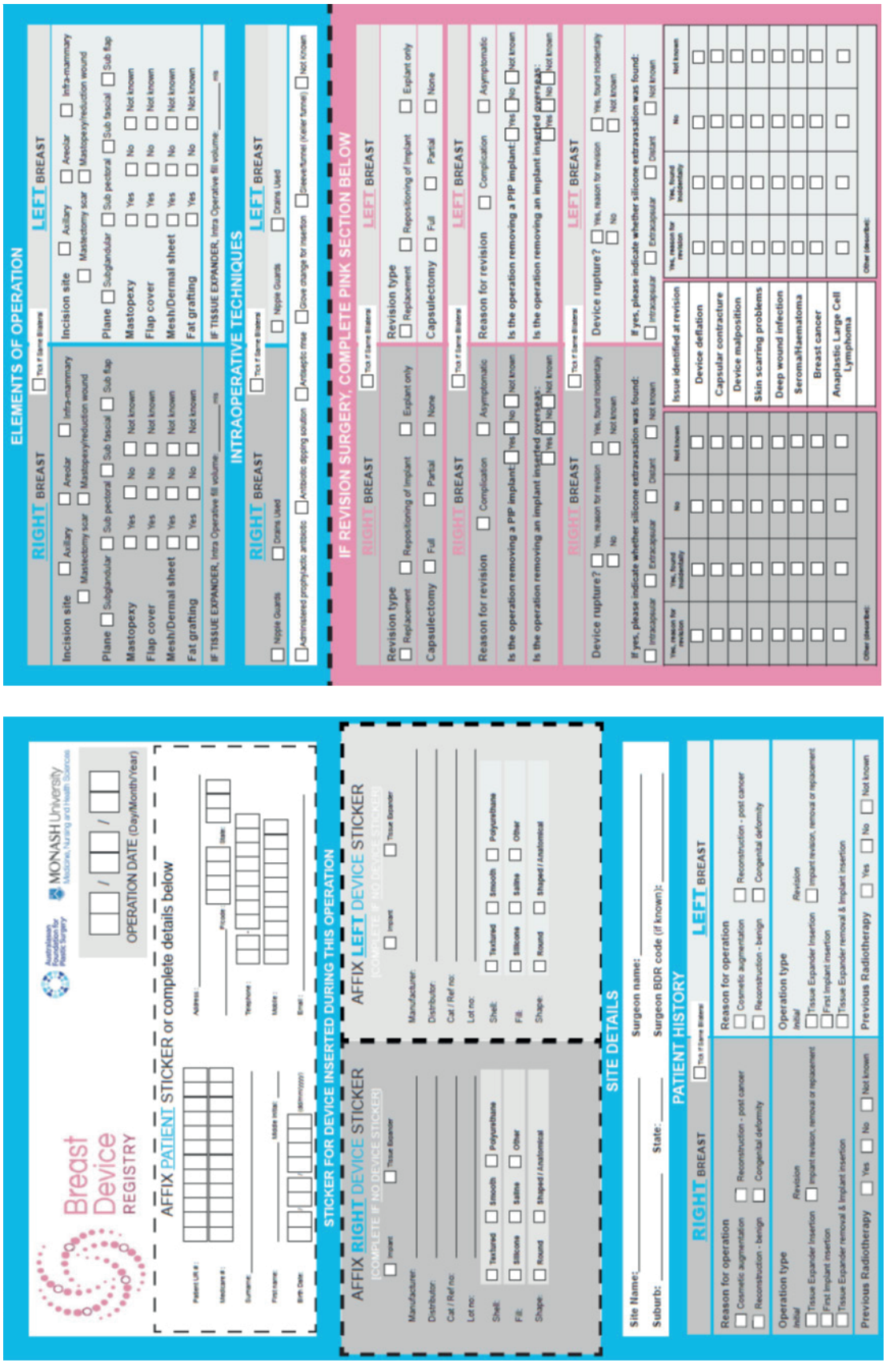
Minimal

Epidemiologically sound
- reproducible
- routinely recorded
- judgement free

Complete patient set i.e. no cherry picking

Identifiable*
- * When needed for determination of outcomes

Figure 3: Example of a case record form for a clinical quality registry (Courtesy: Breast Device Registry)



Process and outcomes measurements

Process of care measurement

- Clinical quality registries typically collect 'process of care' measures as well as clinical outcomes. These may include treatments provided, waiting times and investigations ordered.
- When clinicians and hospitals are made aware of differences in processes of care the variation in these measures typically declines. For this reason the "basket" of process indicators chosen should vary over time.

Outcome measurement

- Systematic measurement of clinical outcomes is a fundamental part of most registries. Clinical outcomes are useful for benchmarking only if the same data are collected in the same manner from every individual at the same time. Outcomes are typically measured at or beyond the time of clinical stability (typically within weeks or months of an intervention).
- Outcome measurement virtually always requires targeted data collection. It is rarely possible to obtain such data from routinely collected clinical or administrative data unless efforts have been made to schedule a systematic clinical review at a defined time after the illness or procedure. Exceptions are mortality and cancer occurrence which are systematically collected by death and cancer registries.
- In the past, many registries used overly simple measures of outcome such as survival to discharge, or survival to 30 days post-procedure. These measures have little sensitivity to difference in quality of care. With modern clinical management the likelihood of a person dying after surgery is primarily dependent on the severity of the underlying illness. Except in extreme cases even major differences in quality of care are unlikely to contribute substantially to the likelihood of death. Furthermore survival alone rarely captures the full intent of treatment which is primarily to return a person to good health.
- Patient reported outcomes are becoming an increasingly valuable outcome measure. They are commonly derived from brief telephone interviews conducted at defined times to determine the extent of recovery and overall quality of life. Typical questionnaires include the EQ5D, SF12 or ECOG status. Some registries have reported a near 90% success rate in telephone follow-up. Other approaches include mailed questionnaires and surveys delivered via mobile devices or email.
- In some cases recovery is best measured using disease specific questionnaires. For example, the EPIC26 collects details of urinary, bowel and sexual function following a diagnosis of prostate cancer (2). The Warlow questionnaire collects details of residual deficit following a stroke (3).
- Outcomes of chronic diseases are usually delayed for years or decades. They are less meaningful than outcomes of defined interventions because of the difficulty in ascribing outcomes to any recognisable component of the patient's care. Most chronic disease registries therefore collect only process measures or outcome surrogates (e.g. cardiac risk factors).

Quality control

- Because accurate registry data is critical for benchmarking, and because its use may impact on the reputation of clinical units, it is essential that the data be of high quality. To achieve this, a robust audit system is required, focusing particularly on the following areas:
  - Ensuring near complete ascertainment of patients from each provider (no "cherry picking");
  - Ensuring the accuracy of data reported to the registry through "source data verification" i.e. by matching data submitted to the registry with that in the clinical record;
  - Ensuring accurate data management within the registry coordinating centre.
- Data quality parameters including audit results and frequency of missing data should be reported routinely in registry reports. Extra scrutiny should be applied to units where the data collection processes appear to be inadequate.

Risk adjustment

When reporting the benchmarking of outcome data, it is important that outcome measures are “risk adjusted” to account for factors influencing the outcome that are beyond the control of clinicians. Risk adjustment is necessary because some clinicians or institutions are referred more advanced clinical cases than others.

Choosing which prognostic variables to adjust for may be difficult because some are partly under the control of clinicians e.g. cold-ischaemia time with kidney transplantation.

Risk adjustment is often imprecise because not all of the principal prognostic variables may be available. At other times the prognostic variables that are available may not have been subject to precise measurement. The imprecisions in risk adjustment must be taken into account when reporting the results of benchmarking. It is a reason why registry data is usually unsuited for providing precise league tables.

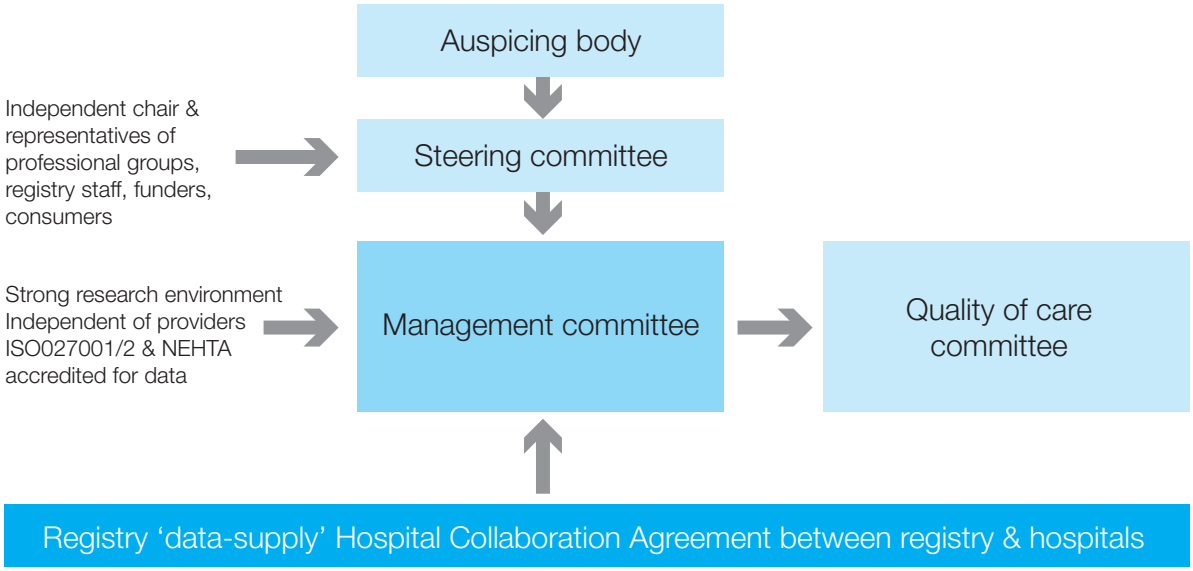
Data security

- Registry data must be housed in an environment which provides a high level of security. It must have an effective firewall to protect against threats from outside the organisation, and detailed procedures to protect against misuse of data. The data-protection plan must include human resource security, communications and environmental security, access control and information security incident management, as well as compliance with laws and regulations in regard to information management.
- Particular care must be taken when data are imported into and extracted from the registry. Identifiable data should always be transmitted through a secure file transfer protocol. When extracted from the registry identified data should only be stored on a secure networked data drive and should never be downloaded onto portable devices such as a USB or personal computer drives.

Registry governance

- The essential requirements for registry governance have been set out in the “Operating Standards for Clinical Registries,” published by the Australian Commission on Safety and Quality in Health Care (4). In many instances compliance with these standards will be included in the contract between the funder and the registry custodian. This contract becomes a fundamental document governing the registry’s operation.
- A key principle of registry governance is that the registry custodian should be independent from clinical providers. However there should be majority representation of the relevant clinical groups on the steering committee which provides oversight of registry operations. Most registry custodians will appoint a part-time clinical director to provide clinical leadership for the registry.
- Apart from clinicians, the steering committee typically includes a representative of the funders, a consumer, an epidemiologist and a biostatistician. With drug or device registries representatives of the professional body representing manufacturers should also be included. The Steering Committee will typically be chaired by a well-respected independent clinician and will formally report to the CEO of the institution housing the registry (because the CEO is formally responsible for delivery of the contract). However in most cases the steering committee acts with a substantial degree of autonomy.

Figure 4: Diagram of a typical registry governance structure



- The terms of reference of the steering committee include focus on the management of the registry, including the budget and deliverables. In particular the steering committee should oversee:
    - quality control and audit;
    - relationships between the registry and clinical providers
    - the management of quality of care issues arising from the registry data;
    - data access and research policies;
    - format and content of registry reports
- The registry should also have a management committee established by the registry custodian to manage day to day activities under the general direction of the steering committee. Members will include the clinical director & senior data manager/s. The role of this committee will be to implement:
    - data-collection and processing;
    - quality control and audit;
    - reporting;
    - processing requests for data.
- Registries must also have defined procedures to govern such issues as the management of outliers identified in registry reports. This is likely to involve liaison with a specialist college and/or institutional administrators. Analysis of outliers requires a rigorous review of the accuracy of the data and may involve careful analysis of the role of supporting services such as anaesthesia and ICU. Registries rarely have the capacity to undertake this level of investigation but must make sure that data are provided to those who can undertake this role within the hospital or specialist college. The designation of the person to whom data should be sent must be clearly documented in the Institutional Agreement.

Ethics

- Until recently ethics committees have required individual patient consent for the pooling of identified data by outside institutions. Without individual consent the uses of clinical data are governed by the Privacy Acts which heavily restrict the use of 'non-consented' data in each State. However, many ethics committees have now changed their attitude towards clinical registry data in recognition of its important role in quality improvement.
- With most registries it is impracticable to seek individual consent from every participant (day, night and weekends) to allow their clinical data to be included in a registry. If individual consent was sought only a fraction are likely to actively volunteer to participate. For example in a stroke registry in Canada only 40% of those invited agreed to actively sign up to participate (5). A participation rate of this level allows a strong potential for biased inclusion by allowing institutions to selectively enter participants most likely to show the institution in a good light. Clinical quality registries established in this fashion would have little credibility amongst clinicians or administrators.
- The large majority of Australian ethics committees now allow bona fide registries to operate with opt-out consent. In Australia, a review of the ethical framework for clinical registries identified that 75% adopt an opt-off consent model (6). In these cases, permission is provided for registry custodians to provide participants with an information sheet describing the registry and how individual's data will be handled. A 1800 number is provided to allow participants to opt-out being included. Typically less than 2-3% will ask for their information to be excluded, a figure which has little impact on the validity of the registry data.
- When asked to approve opt-out consent, the ethics committee will typically weigh up the following:
    - The degree to which the public interest in having the registry outweighs any impingement on individual privacy;
    - The efforts to which registry staff will go to ensure that all participants receive a copy of the plain language information sheet (with the 1800 number for withdrawal prominently displayed);
    - The degree to which the information collected by the registry is sensitive (e.g. HIV status);
    - The security of the data collection centre (including the capacity of the registry custodian to maintain large secure databases);
    - The degree to which the registry governance and organisation meets the requirements of the guidelines established by the Australian Commission on Safety and Quality in Health Care.
- Another sensitive ethical issue relates to the follow-up phone calls used to determine outcomes. It is important that follow up staff are briefed in the use of a standard script when conducting the phone call and are provided with information on how to handle sensitive situations. These procedures should be considered and endorsed by the Steering Committee when the registry is being developed. It is also important that follow up staff are provided with a mentor and capacity to de-brief should the necessity arise.
- Patients must be made aware of the fact that they will be telephoned (where applicable); this should be prominently displayed in the patient explanatory statement.

Institutional agreements

- Formal agreements should be put in place between the registry custodian and the institutions and providers supplying data to the registry. These agreements should commit the registry custodian to maintaining the security of data provided, and to providing regular reporting within specified timeframes. The institution should agree to provide the data required in a timely and accurate manner, and participate in specified auditing activities.
- Registry custodians must be aware of the legal obligations that accompany registry activities. Legal issues may arise if there is no follow-up of serious adverse findings or if an individual unit or practitioner is disadvantaged through inappropriate reporting.

Registry reporting

- Clinical quality registries provide clinicians with feedback on their performance and allow them to compare their results with those of other providers. Without such feedback clinicians typically practice in isolation without the information needed to stimulate self-improvement. By providing benchmarking, data registries provide the feedback that facilitates a cycle of continuous improvement. Units whose performance has deviated below par commonly request a review by outside consultants to identify areas for improvement.
- The feedback of performance data to clinicians may achieve a number of additional goals, including:
    - stimulating competition;
    - identifying variation in outcomes (typically a flag for concern);
    - identifying best performing units so that others can learn from them;
    - identifying treatments given that were non-compliant with accepted guidelines;
    - providing early warning if outcomes begin to deteriorate;
    - flagging persistent poor performers.
- Other analyses available from registries include:
    - process data (eg door to needle time) describing the performance of components of the systems of care;
    - measuring access to care in different geographical areas or amongst different socio-economic groups;
    - performance data to monitor the progress of trainees and assist credentialing;
    - monitoring trends in health service utilisation;
    - monitoring medium and long term safety of drugs, devices and surgical procedures.
- Benchmarking results are commonly presented in the form of funnel plots where results of an individual unit are compared with the risk adjusted results from other similar units (figure 5). Boundary lines indicate where the outcomes are within one, two or three standard deviations of the average. The boundaries splay outwards to accommodate units with low procedure volumes where greater fluctuation may occur by chance. Typically the reports involve partial blinding, i.e. the results for the relevant institution are provided but the identity of other institutions is concealed.
- Life tables provide an alternative approach to presenting benchmarking data as shown in figure 6. The figure shows graft survival after organ transplant for 6 centres. The median is shown in blue and the results for a single centre in red. This display has the advantage over the funnel plot of presenting performance over a period of time.
- Registry data is generally well respected and acted on seriously by clinician groups. One fundamental advantage over other quality assurance programs stems from the engagement of clinicians in the design and interpretation of the data and their resulting respect for the results. There are many examples from Australia and overseas where feedback of benchmarking information has led to a substantial improvement in clinical results.
- There is a strong rationale to delay the public identification of specific units until there is a high level of confidence in the accuracy of data and in the risk model used to adjust outcomes.

Figure 5: Registry reporting - example of a funnel plot showing percentage positive margins following cancer surgery

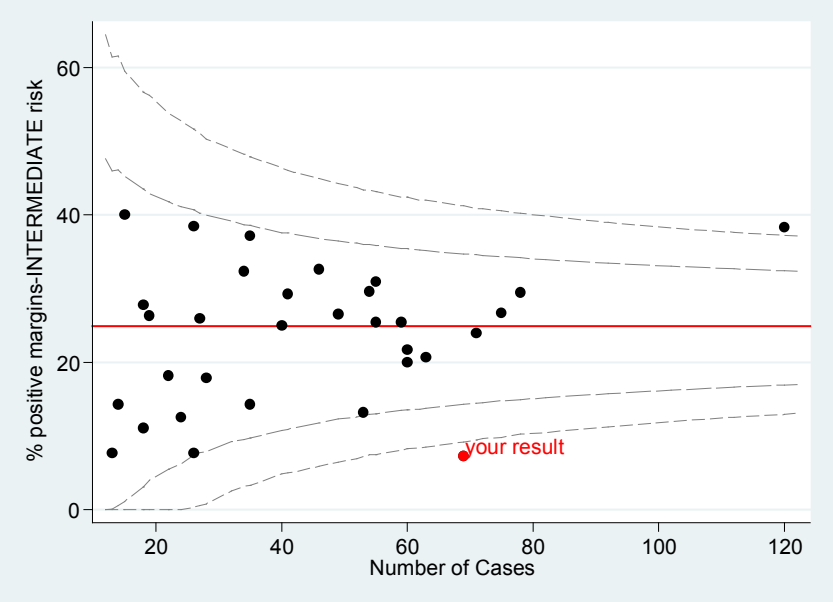
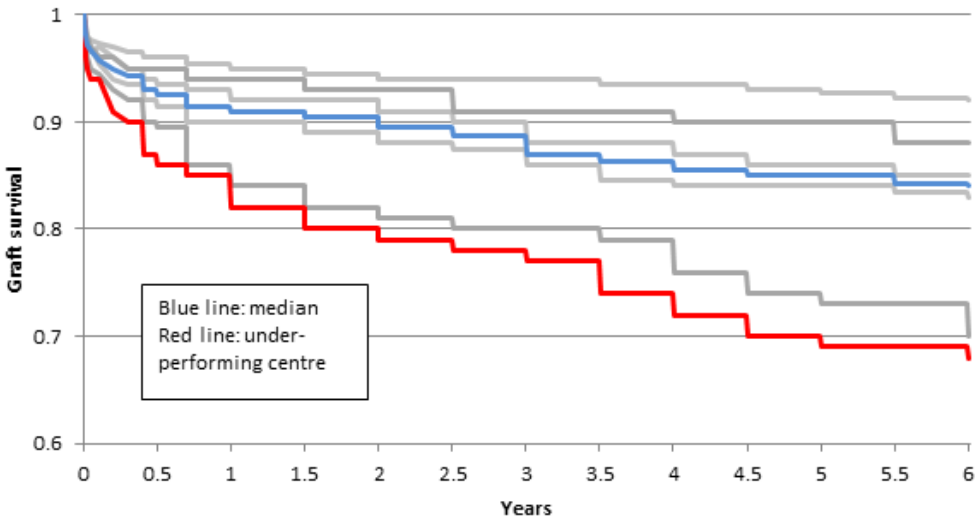


Figure 6: Illustrative example of graft survival after organ transplant for 6 centres



Funding models

- 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. There are often strong incentives for participation including:
    - commitment from clinicians;
    - a requirement of boards of management and quality committees;
    - a requirement by private hospital insurers;
    - requirements for credentialing by specialist colleges;
    - premium discounts or penalties from medical indemnity insurers.

Data collection activities may include undertaking the follow up of subjects, entering data into the web portal, handling data queries and participation in audits.

- 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.
- 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.
- 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.
- Additional information may be sought from a registry to answer specific questions that cannot be adequately addressed by the minimum data-set. This additional data may be collected from a random sample of the clinical providers or for a short period from all participating units. Such additional data collection is typically funded by specific grants.

Cost Effectiveness

There is emerging evidence of substantial cost savings resulting from clinical quality registries. 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 (7).

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

- 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.

Priorities for clinical quality registries

Clinical quality registries are of most value in areas of clinical practice where an intervention or a pattern of care is discrete and well defined e.g.:

- Surgical procedures or other clinical interventions, e.g. coronary angioplasty;
- Device implantations;
- Acute episodes of care, e.g. admission to an intensive care or burns unit;
- Discrete diseases, e.g. multiple sclerosis;
- Obstetrics.

Registries are generally not useful in monitoring non-discrete conditions such as hypertension or diabetes where the borderline between who is and is not eligible for inclusion on the registry is unclear.

Highest priority for clinical quality registry development are high cost/high significance procedures where:

- there is known to be significant variation in clinical management or clinical outcomes;
- the variation leads to a substantial increase in costs or reduction in quality of life (8);
- it is important to monitor medium or long-term safety.

Clinical research based on registries

Registries are developing as a major resource in support of clinical research. Typically, researchers require a grant to provide resources for additional data collection. Ways in which registries are being used for research include:

- By supplementing the information provided by clinical trials. Unlike clinical trials which focus on a very carefully defined population, typically with little co-morbidity and few other medications, registries portray the experience with an intervention in real life. Although limited in their ability to determine efficacy, registry alternatives are especially valuable in determining whether the frequency of adverse effects is in keeping with that identified in the clinical trials.
- By providing well documented cohorts which are effective in determining predictors of prognosis, or risk factors for poor prognosis.
- By providing cases for case control studies that are useful for determining aetiology of, or risk factors for disease. This requires the administration of questionnaires to cases, and matched controls.
- Linkage to bio-repositories from which new prognostic markers or new diagnostic agents can be discovered.
- As a basis for inexpensive clinical trials (given that outcome measures are supplied routinely, the only additional requirement is an initial randomisation step (9)).

Access to registry data for research purposes should be governed by a formal data-access policy under the direction of the Steering Committee. This policy should provide for a rapid and systematic approach to the review of applications. Requests for access to data should be accompanied by relevant ethics approval certification.

Future developments and opportunities

An ongoing registry program is likely to develop by inclusion of at least some of the following elements:

- Linkage to personal electronic records and administrative data sources e.g. cancer registrations, pharmaceutical prescribing, hospital admissions and emergency department presentations. This will progressively reduce the data-burden on registry administrators;
- Linkage to bio-repositories containing blood and tissue samples in order to improve predictions of prognosis and better knowledge about responses to therapy;
- Increased coverage of new surgical procedures and implantable devices in order to improve knowledge of medium and long-term safety and facilitating recalls;
- Development of rare disease registries to help improve research into neglected conditions;
- Provision of registry services (especially benchmarking) to international clients, private hospital chains, credentialing bodies etc;
- Provision of special reports on subjects such as trends in resource utilisation, access to treatment, cost-effectiveness, long-term safety and credentialing/training needs.

Registry Developments

Australian registry developments

Some important milestones in the establishment of national registries:

1969: Australian and New Zealand Dialysis and Transplant (ANZDATA) registry established to provide feedback on survival following dialysis and transplantation

2000: National Joint Replacement Registry first annual report produced

2001: The Victorian State Trauma Registry (VSTR) was established with funding from the Department of Human Services and the Transport Accident Commission (TAC). The VSTR is managed by the Victorian State Trauma Outcomes Registry and Monitoring Group (VSTORM)

2005: The Australian Society of Cardiac and Thoracic Surgeons (ASCTS) national cardiac surgery database developed

2008: Pilot prostate cancer registry developed

2008: Development of national Operating Principles for Clinical Quality Registries by the Australian Commission for Safety and Quality in Health Care (ACSQHC)

2009: Validation of Operating Principles by six Australian clinical quality registries

2010: Expert group established to assist the ACSQHC develop a national registry program

2012: Private funding of a cardiac procedures registry

2013: Budget announcement for funding to be provided for two high risk implantable device registries on breast implants and implantable cardiac devices.

2013: Consultation paper released by the National Health and Medical Research Council introducing 'opt out consent' as a consideration for low risk research in the National Statement for Ethical Conduct in Human Research (10).

Overseas Developments

Some important milestones in the development of international registries:

1977: UK National Cardiac Surgery Database established to compare clinical performance and health outcomes following cardiac surgery

1979: Swedish hip arthroplasty registry developed with population coverage

1988: The New York State Cardiac Surgery registry was developed to monitor survival variation following cardiac surgery

1990: Hospital-level data publicly released by the NY State Cardiac Registry

1991: Surgeon-level data released by the NY State Cardiac Registry

1994: Swedish national stroke registry established to monitor outcomes following stroke

2002: Bristol Royal Infirmary Inquiry Report released detailing a lack of capacity by the UK Cardiac Surgery registry to detect problems at Bristol. The result was an overhaul of the registry program and greater commitment to public reporting of benchmarked outcomes.

2007: ACTION Registry-GWTG established by the American Heart Association to assess compliance with evidence-based guidelines for patients with acute coronary syndrome

2007: The Agency for Healthcare Research and Quality released the report "Registries for Evaluating Patient Outcomes: A User's Guide" to support groups wishing to establish clinical registries

2012: AHRQ released the Registry of Patient Registries to tabulate existing registries in the US

In Sweden, there are now over 90 government-supported registries covering 25% of health expenditure. A 2009 review by Boston Consulting concluded that a further $70 million investment would reduce annual growth in healthcare cost by 4.7% – 4.1%, and save $7 billion over 10 years. They further noted that effective registries required active engagement of clinicians, high quality data and high levels of transparency (7).

References

1. Gliklich R, Dreyer NA, Center OD. Registries for Evaluating Patient Outcomes: A User's Guide. Rockville, Maryland: Agency for Healthcare Research and Quality, 2010.
2. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. Urology. 2000;56(6):899-905.
3. Warlow CP, Dennis MS, van Gijn J, Hankey GJ, Sandercock PA, Bamford JM, et al. Stroke: A Practical Guide to Management. 2nd edition ed. Malden, Massachusetts: Blackwell Science; 2001.
4. Australian Commission on Safety and Quality in Healthcare. Operating Principles and Technical Standards for Australian Clinical Quality Registries. 2008.
5. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. N Engl J Med. 2004;350(14):1414-21.
6. Evans SM, Bohensky M, Cameron PA, McNeil JJ. A survey of Australian clinical registries: can quality of care be measured? Intern Med J. 2011;41(1a):42-8.
7. Larsson S, Lawyer P, Garellick G, Lindahl B, Lundström M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Affairs. 2012;31(1):220-7.
8. McNeil JJ, Evans SM, Johnson NP, Cameron PA. Clinical-quality registries: Their role in quality improvement. Medical Journal of Australia. 2010;192(5):244-5.
9. Lauer MS, D'Agostino RB. The randomized registry trial - the next disruptive technology in clinical research? N Engl J Med. 2013;369(17):1579-81.
10. National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee. National Statement on Ethical Conduct in Human Research, Australian Government, Canberra: 2007 (Updated May 2013).

MONASH University

GROUP OF EIGHT

Further information

School of Public Health and Preventive Medicine
Alfred Centre,
99, Commercial Road,
Melbourne, Vic 3004, Australia
Telephone: +61399030555
Facsmile: +61399030556

CRICOS Provider: Monash University 00008C. MMS363798