AUSTRALIANCOMMISSIONON SAFETYANDQUALITYINHEALTHCARE

Operating Principles and Technical Standards for Australian Clinical Quality Registries

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MONASH University

Centre of Research Excellence in Patient Safety

The Australian Clinical Quality Registries project is one of the Australian Commission on Safety and Quality in Health Care's Information Strategy. For more information about the Information Strategy visit the Commission's website: http://www.safetyandquality.gov.au

The draft Operating Principle and Technical Standards for Australian Clinical Quality Registries have been developed in collaboration with the NHMRC Centre for Research Excellence in Patient Safety (CRE PS) at Monash University and the National E-Health Transition Authority (NEHTA). They have also benefited from external consultation and input from a range of clinicians, speciality groups and registry custodians.

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Introduction

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 (Figure 1). The purpose of a clinical quality register 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. Clinical quality registers can provide the most suitable and accurate method of providing monitoring and benchmark data and, where applicable, offer the greatest potential to improve health care performance across institutions and providers. Clinical quality registers should be focused on conditions and procedures where outcomes are thought to vary and where improvements in quality have the greatest capacity to improve quality of life and/or reduce costs.

The system or organisation governing the register is known as the *registry*.[1]
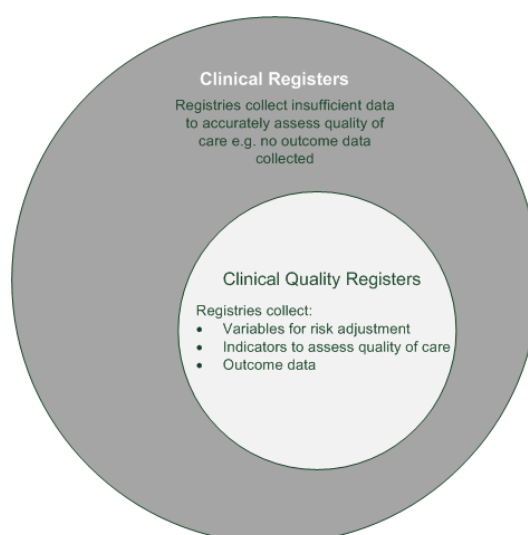
Figure 1. Clinical registers and clinical quality registers

Clinical registries are established and operated with the aim of improving patient care and outcomes through greater understanding of events, treatments and outcomes. The data collected by a registry over time are analysed and used to identify positive and negative trends and these analyses can be used, generally by clinicians, to lead to improvements in practice, and in medication and device usage.

There are a number of existing clinical registries and these are funded from a range of sources. Some registries are clearly contributing to valuable improvements in clinical practice and health outcomes and have strong support and participation rates within the relevant clinical profession. However, the existing clinical registries are quite variable; both in their ability to improve health care and in the quality of the information they hold and publish. They currently operate in a fragmented and inconsistent environment.

An Australian Clinical Quality Registry is a registry whose purpose is to improve the safety or quality of health care provided to patients. Australian Clinical Quality Registries build on data collected from events in daily health care and use this information to assess care provision and implement quality improvements where required.

It has been noted that:

▶ No national standard exists against which funding applications by clinical registries can be written or assessed.

▶ No routine processes exist to ensure that clinical registries improve safety and quality. For example, many registries take a significant period of time to collate data, reducing their ability to provide timely information to health care providers and to support clinical quality assurance and improvement.

▶ Registry processes, data and technology are neither uniform nor standardised, creating significant inefficiencies and hampering inter-operability with other information systems.

▶ Some registries collect data items that do not conform to national definitions, thereby limiting the utility and comparability of the data.

▶ Data quality, including completeness, is often compromised. Some registries seek information from the routine administrative collections to determine completeness or to match data with administrative collections (including hospital statistics or deaths) to extend or validate the registry information.

♦ Purpose and scope of this document

The Australian Commission on Safety and Quality in Health Care, the NHMRC Centre of Research Excellence in Patient Safety and the National E-Health Transition Authority (NEHTA) have collaborated to develop these operating principles and technical standards for Australian Clinical Quality Registries. These are registers that are:

▶ (potentially) national in coverage; and

▶ primarily focussed on supporting improvement in clinical practice, particularly clinical safety and quality.

A core function of Australian Clinical Quality Registries must be that they have the ability to improve clinical practice and health outcomes and be capable of accurately capturing the state of health care in Australia. For registers to meet their full potential in informing the state of health care in Australia, confidence is needed in the quality and relevance of the data. This document outlines a series of guidelines for the operation of Australian Clinical Quality Registries designed to help them achieve these goals.

Their purpose is to:

▶ Provide a means of improving existing clinical registers and enhancing the value of the information they provide;

▶ Provide guidance for the establishment and maintenance of new Australian Clinical Quality Registries aiming to measure quality of care; and

▶ Suggest a best practice model to which both new and existing Australian Clinical Quality registries should adhere.

Audience

These Operating Principles and Technical Standards are aimed at assisting those involved with or contemplating the development of clinical registries. This document is designed to assist:

▶ Organisations involved in the funding of clinical registers whose purpose includes the monitoring and/or benchmarking of quality of care;

▶ Individuals and organisations responsible for interpreting data derived from clinical registers; and

▶ Researchers and stakeholders contemplating the development of new Australian Clinical Quality Registries.

Outcomes

Australian Clinical Quality Registries complying with the principles and standards outlined in this document would:

▶ Have a clear purpose and scope

▶ Adhere to a standard governance model (including ethical standards and effective processes to ensure the clinical use and relevance of the registry)

▶ Adhere to privacy principles and legislation

▶ Adhere to information management principles, including publication of eligibility criteria and metadata

▶ Adhere to a uniform recommended technology approach (referring to standards rather than prescribing specific hardware or software)

▶ Use a standard technical design and leverage national infrastructure (where available) for key registry components to improve efficiency and security, to reduce cost of development and to increase comparability and interoperability of registries

▶ Involve the relevant national professional organisations, for instance in the areas of data custodianship and clinical practice advice

▶ Routinely analyse data and provide timely advice to clinicians and relevant stakeholders

▶ Provide annual reports which would include the registry's methods of altering practice and evaluating change

▶ Add value over and above that achievable through augmentation of existing routine data collections.

Using this document

This document sets out the operating principles and technical standards with which an Australian Clinical Quality Registry should generally comply.

This document has two major parts:

▶ *Part A: Operating Principles*; and

▶ *Part B: Technical standards*.

Part A: Operating Principles describes the principles that should be used to govern the structure, governance and operations of Australian Clinical Quality Registries.

Part B: Technical standards describes the technical standards that should be used in the development and operation of Australian Clinical Quality Registries.

The two parts are complementary and highly inter-related. Use of the technical standards makes the attainment of many of the operating principles more readily achievable.

Part B: Technical standards has two sections:

▶ *Part B: Technical standards – Architecture overview –* gives architectural context and vision for the short-term but also elucidates a longer term vision of how Australian Clinical Quality Registries may contribute to an e-health enabled healthcare system.

▶ *Part B: Technical standards – Standards Map–* lists existing technical standards that developers and managers of Australian Clinical Quality Registries should be aware of and, where appropriate, implement and comply with.

♦ Gaps in current knowledge

The role and position of Australian Clinical Quality Registries needs to be defined within the context of the broader safety and quality effort. We need to better understand:

▶ where Australian Clinical Quality Registries fit in the context of other quality and safety activities currently being used throughout the health system

▶ what criteria should be used to assess whether a registry should be implemented over an alternative approach; and

▶ what synergies exist between registries and other safety and quality activities. For example, it may be that registry data can be used as part of the national accreditation standards or national performance indicators.

In addition to understanding how registries fit into the wider quality and safety movement, the ways in which quality can be measured by registries and used to drive system improvement needs further research. The use of pre-determined quality process and outcome indicators, soundly based on the literature or at least on consensus judgements of experts, and embedded into registries is one approach to measuring quality.

In considering what measures to use to assess performance, clinical quality registries need to ensure they adhere to their purpose and avoid 'scope creep'. While measuring outcomes are important, in some situations there are limitations in only using direct outcome measurement, such as when there are long time lapses before outcomes are measurable, or when numbers are small, or there are questions about the adequacy of risk stratification, or about confounding.

Comparing patterns of care against best practice guidelines or protocols, either evidence based or developed through expert consensus, may be regarded as a proxy for direct outcome measures in some circumstances. Data on care patterns are more immediately available and may be less vulnerable to misinterpretation through random error or confounding. Viewed together with direct outcome measures, they can strengthen the evidence and indicate why outcomes may be sub-optimum. These process measures can also be used in research studies of associations of treatment with outcomes as a basis for setting/adapting care standards. Apart from care patterns, emphasis also may be placed on the performance of prosthetic devices, and registries used to locate people with prostheses that are subject to recall. In addition, apart from outcomes of care, complication rates and toxicity may be monitored to more broadly assess care safety and quality.

In addition to understanding what to measure, more work is needed to identify how data can be used to drive change at the clinical interface. Evidence suggests that quality improvement is driven by the production of outputs such as quality indicators from clinical registries and routine feedback to providers, teams within institutions, professional accreditation/auditing bodies, and the public. These outputs might include warning signals which trigger when performance falls below pre-determined

levels. The use of these data by multidisciplinary teams might facilitate quality improvement activities by identifying areas of need and assessing performance relative to efforts to improve care.

Registry managers need to identify the technical methods available for presenting data for quality appraisal and action. They also need to consider the importance and role of unexplained variance and outliers. How are small numbers that are vulnerable to random error addressed? How can the data be presented graphically or otherwise for ready interpretation by funders, service providers and consumers? What is the human environment needed to gain change? Where do the data fit with accreditation and credentialing? An Australian Clinical Quality Registry must focus on the use of registry data for clinical practice improvement and the importance of data use for system as well as individual practice improvement.

Australian Clinical Quality Registries have a key role in the monitoring and improvement of the quality and safety of Australian healthcare. They potentially provide a strong evidential base for determining the efficacy, safety and quality of providers, interventions, medications, devices and treatments. Many of the gaps in knowledge we have identified will be addressed over the next few years as Australian Clinical Quality Registries are further developed and examined in the context of the wider quality and safety agenda. This document provides the principles by which Australian Clinical Quality Registries can be developed to produce credible information and governed effectively to ensure that data is used effectively to drive quality improvement. The structures and governance of an Australian Clinical Quality Registry form a nexus that connects clinicians, administrators, peak bodies, jurisdictions and consumers. These connections can be used to build confidence and transparency in Australian health care and help ensure that our activities are focused on the patient.

An Australian Clinical Quality Registry must demonstrate potential for significant impact and relevance on quality and safety. The improvement should be expected to commensurate to cost and effort. The data collected, the subject matter or 'content' of a registry should be clearly relevant to clinical practice.

♦ Context

Determining the quality of our health care system

It is presently very difficult to measure the quality of care delivered by Australian hospitals and health services. On the few internationally comparable statistics, such as life expectancy and perinatal mortality, Australia ranks favourably against most other countries.[3] For example, the life expectancy of Australians ranks among the top five nations in the world.[6] However, these measures are heavily impacted by social circumstances that have little to do with the quality of health care delivered. Furthermore, despite these favourable results, there have been ongoing concerns that the quality of health care may not be of a uniformly high standard. The basis of this concern includes:

▶ The results of the Australian Quality in Health Care Study conducted in the early 1990s which revealed that adverse events were recorded at 16% of hospital admissions, with 51% of them considered preventable.[4] While there are inherent recognised biases and inconsistencies when attempting to determine preventability,[5] few would disagree that the extent of harm occurring in hospitals constitutes a significant problem. No subsequent large scale medical review has been repeated since this study was completed more than 15 years ago.

▶ · A number of high profile cases of alleged sub-standard care at major Australian hospitals, most of which had occurred after some years of unaddressed concern.[7–12] In the majority of these cases even very basic measurement and benchmarking would likely to have identified problems well before they reached a crisis point.

▶ Increasing evidence of substantial geographical variability in the care provided by some specialty areas within the Australian health sector.[13, 14]

▶ Limited evidence from administrative data suggesting considerable variability between hospitals in one jurisdiction in meeting quality indicators across a range of clinical areas including medical, surgical, mental health and obstetrics and gynaecology domains.[15]

In general, there has been very little systematic measurement of any aspect of health care in Australia. Most of the strategies designed to improve quality rely on qualitative approaches associated with such process as credentialing, medical record review, clinical audit, autopsy, incident reporting, coronial investigation, health complaints, hospitals accreditation, practice guidelines and patient satisfaction surveys.[16] Emerging methods include the use of clinical indicators[15] and statistical control charts.[17]

Without a credible system for monitoring outcomes within institutions there is little opportunity for managers or boards of management to be aware of how their services truly compare with those elsewhere or with pre-determined standards. Inquiries into adverse events have criticised the lack of a system for early detection of error and proactive monitoring of the system.[10]

The general lack of systematic measurement of the quality of the health system is analogous to trying to monitor an organisation's financial status without having financial data. The focus on clinical registers as tools to measure quality of care in an epidemiologically robust manner is part of an attempt to address these concerns.

Measuring quality

The Institute of Medicine (IoM) defines quality as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [18] More nuanced definitions, incorporating elements such as appropriateness of care, cultural sensitivity, consumer satisfaction and experience, have subsequently been advanced.

In 1988, Donabedian proposed an approach for determining how to measure the quality of clinical care. Quality, he believed, could be measured by assessing either the processes of care or the outcomes of care. A third relevant component of quality is the structure or organisation of the clinical setting. [19]

Process indicators refer to the specific activities undertaken as part of the provision of care. They may include the use (or non-use) of various drugs and procedures or aspects of the organisation of care, for example, door to needle time for thrombolysis. Process measures can be used as measures of quality of care by comparing treatments given with recommendations in published guidelines or other standards.

Process measures are appropriate measures of quality of care for chronic illnesses such as in heart disease and diabetes when the long lag time between provision of care and the outcome diminishes the value of an outcome register. An example of the use of process measures to improve quality of care is provided by the US-based *Get With The Guidelines* program [20] in which compliance with best practice for management of patients suffering stroke and heart disease is measured and benchmarked.

Outcome indicators are measures used to assess the ultimate effects of treatments on health status. In ideal circumstances outcomes would be the only relevant measure of quality of care. However, there are only a limited number of healthcare interventions where the outcome occurs reasonably soon after the intervention and is predominantly determined by the quality of a defined episode of care. In most cases these are surgical or other procedural activities and it is in these situations where outcome measures have their greatest value. Clinical registries provide their distinctive contribution to quality improvement through their role in measuring and benchmarking outcomes. It is also recognised that outcomes can be given explanatory context and supporting evidence from process measures

Structural indicators are used to describe the attributes of a setting in which care occurs and the instrumentalities of which it is the product. It may also include administrative and related processes that support and direct the provision of care. [21] Structural determinants of quality of care include the adequacy of the building and equipment, the qualifications of the staff and credentialing systems in place to monitor this on an ongoing basis, and whether systems exist to systematically monitor care delivery.

Table 1 outlines some of the advantages and disadvantages of collecting outcome and process measures to assess the quality of care (after Willis *et al.* [22])

Outcome indicators	
Advantages	*Disadvantages*
• Integrate the impact of all factors influencing a patient's clinical course • Meaningful to patients, clinicians and funders • Effective method to investigate performance of proceduralists	• Applicable only when outcome follows relatively soon after intervention • Applicable only when outcome is substantially influenced by the intervention • Can be vulnerable to small numbers • Commonly requires risk adjustment to enable benchmarking • Often require direct contact with patients to ascertain outcomes • May be insensitive to occasional egregious events •
Process indicators	
Advantages	*Disadvantages*
• Most appropriate measure of quality of care for chronic conditions. • Useful, even with small patient numbers • Typically requires minimal risk adjustment • Important to measure adherence to best practice guidelines and a useful tool for driving quality improvement programs • Information potentially available immediately – no waiting time for outcomes to eventuate • Easily interpretable by clinicians	• May have only a minor impact on outcome. • Often a number of indicators may be necessary to generate a comprehensive picture of quality of care • Require constant updating to keep pace with changing guidelines and medical techniques • Often not collected systematically because of differences in definitions or methods of collection. • Assumes that there is a 'right' way

Table 1 Outcome and process indicators

Another approach used to measure quality of care is to determine performance amongst various dimensions of quality. Those most commonly used were proposed by the Institute of Medicine (IOM)[18] who recommended that health care be assessed according to the following criteria:

▶ *Safety*: avoiding injuries to patients from care that is intended to help them;

▶ *Effectiveness*: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit;

► *Patient-centred*: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions;

► *Timeliness*: reducing waits and sometimes harmful delays for both those who receive and those who give care;

► *Efficiency*: avoiding waste, including waste of equipment, supplies, ideas and energy; and

► *Equity*: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status.

Australian Clinical Quality Registries provide an effective means by which to measure these aspects of care.

♦ Role of Australian Clinical Quality Registries

This section describes the role of Australian Clinical Quality Registries, particularly in terms of how they can contribute to monitoring and improving Australian health care.

Monitoring and improving the quality of health care

An Australian Clinical Quality Registry must focus on the use of information to lead to clinical improvements in terms of safety and quality. Progressive extension of the scope and purpose of a clinical registry is to be avoided as it has been suggested such 'creep' undermines support and participation.

Clinical registries identify and investigate sub-optimum and variations in processes and clinical outcomes. Factors leading to such variability and sub-optimum practice can then be investigated further, often with targeted studies, with the ultimate aim of improving patient care. They can drive quality improvement in many ways: indirectly through the fostering of competition, or more directly through evaluating compliance with best practice guidelines and through informing policy areas such as regulation and pricing policy. Where data are collected on devices, registries also have a role to play in post-market surveillance and notification. Where they have been introduced at a state or national level, registries have become one of the most clinically valued tools for quality improvement.[23]

Registries improve care, in part by arming clinicians with information about how their outcomes benchmark with standards and other clinical outcomes, both locally and (sometimes) internationally. As long-term data repositories, registers have the ability to capture data on conditions or events which occur sporadically or rarely among populations. Longitudinal data also provide an ability to act as an early warning system if quality deteriorates.

A high quality of registry data provides credible information which engages the common desire of clinical teams to be the best. These data also provide the potential for units to learn from those with the best results. However, they can require considerable investment, and therefore should be focused on conditions and procedures where outcomes are thought to vary and where improvements in quality have the greatest capacity to improve quality of life and/or reduce costs.

Data output must be regarded as credible by clinicians if it is to drive change in practice. The introduction of teaching in epidemiology and biostatistics in undergraduate training across multiple health-related disciplines has meant that clinicians are increasingly astute at discerning the quality of information collected and reported in the literature. Data used to monitor the quality of care must be capable of taking into account the basic requirements of accuracy and reproducibility that underpin reliable clinical data. This, in turn, requires adherence to national standards and procedures typical of those widely utilised in clinical research activities.

Having good quality data is not, in itself, sufficient to improve quality of care. Systems must be in place to ensure that data is analysed in a timely manner with clinical interpretation on findings, and then fed back to appropriate personnel/bodies to ensure that appropriate action occurs. Register data should inform clinical practice, policy development and resource allocation.

The ultimate beneficiaries of clinical registries are patients, who will receive safer care. Data collected by registries should be made available to consumers in a manner that allows them to participate fully in decisions about their care. The role of consumers as stakeholders and in the governance of the system is an important. Consumers are more likely to support Australian Clinical Quality Registries if there is a sense of inclusion and a role for them in the governance and as recipients and beneficiaries of the analyses and reports. The opportunities for patients to know about the registry and its roles are fundamental considerations.

To maintain credibility and support of health professions the data should avoid providing information that is not of a high quality and has not had clinical interpretation, especially where this involves contrasts in the outcome results of different clinical service providers. Ongoing review is typically necessary to find the most appropriate output formulation. Attention must also be paid to reducing possible negative consequences of making data available without adequate disclaimers, and the potential to cause perverse incentives to occur such as the avoidance of 'difficult' cases.

Evolution of registries

Many of the major clinical registries established in Australia were initially developed as research resources, and have relied on the leadership of small groups of innovative clinicians and their practice specialties. This process has lead to Australia having some world leading registries, albeit mostly with limited funding and fragile governance processes.

The value of some clinical registers has been limited by such factors as unnecessarily extensive collection of data, poor quality control, inadequate governance procedures, and lack of provision of an appropriate level of funding to operate registries, or lack of linkage to an effective operator arm for gaining quality improvement in clinical practice. These often reduce their value for clinical quality improvement. With registries increasingly seen as a key driver of quality improvement, it is necessary to consider new approaches to the funding, organisation, and information and technical aspects of these resources.

With the increasing development of clinical registries, it is important that systematic consideration be given to issues such as minimum data sets, register governance, basic quality control and ethical issues.

Registries require considerable investment to develop and sustain. However, this cost needs to be matched with the costs savings and/or health quality improvements gained from the information supplied. For example, the National Joint Replacement Registry captures information on revision rates following hip and knee surgery. Over the past four years the proportion of hip and knee procedures that are revisions has declined from 14.8 to 11.1% and from 10.4 to 7.9% respectively. These declines are in large part attributable to monitoring systems incorporated into the registry design which detects poorly performing prostheses. The annual cost saving has been estimated at $44.6 million.[24] The cost of running the Registry is $1.5 million per annum.

To maximise the return on investment in registries, it is most beneficial to target diseases or procedures where there is likely to be variable and sub-standard performance and where poor outcomes may lead to poor quality of life or an increase in cost. An example could be renal transplantation where poor outcomes lead to patients having to revert to haemodialysis, providing a much inferior quality of life at considerably greater cost to the community.

Existing clinical registries have sometimes been limited as a result of the following factors:

▶ A lack of timely reporting, with some registries taking significant periods of time to provide reports;

▶ A lack of routine procedures for providing feedback and gaining improvement on the safety and quality of care;

▶ A variable and sometimes inadequate approach to governance;

▶ Variable approaches to data audit, especially with regard to the completeness of recruitment of the eligible population and assessments of the accuracy of the data collected.

In addition, there is no system in Australia to identify registers that have been developed. Furthermore, the data collection processes and technology are neither uniform nor standardised, creating significant inefficiencies and hampering their ability of registries to interact with each other and with other information systems. Finally, there are no national standards against which funding applications by clinical registries can be written or assessed.

Part A: Operating Principles

Anyone developing and implementing an Australian Clinical Quality Registry should be cognizant of the principles described here. It is not intended as a proscriptive list that every registry must comply with. Given the scope and purpose of a given Australian Clinical Quality Registry a varying subset of these principles may be relevant.

This part of the document provides recommendations on the development and implementation of new and existing Australian Clinical Quality Registries. They should be read in conjunction with the *Part B: Technical standards – Architecture overview* and *Part B: Technical standards – Standards Map* sections.

♦ Summary of Operating Principles

The following principles have been developed to provide a sound basis to underpin the establishment of future registers. The purpose of guidelines are to help clinicians and patients reach the best health care decisions. Guidelines recognise that specific circumstances may require a flexibility or range of approaches, as against standards that mandate a specific approach. [2]

This section summarises the principles for Australian Clinical Quality Registries. The following sections provide further details.

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-variates 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.

♦ Attributes of Australian Clinical Quality Registries

For clinical registries to be regarded as important tools for monitoring the quality of care, they should:

1. Collect data to serve a predetermined purpose;

2. Collect a core minimum data set of information about individuals treated in multiple locations;

3. Collect data that are epidemiologically sound, i.e. simple, objective, reproducible

4. Collect data easily and uniformly from the data source;

5. Collect outcome data from all or nearly all patients at a time when outcome is considered to be stable;

6. Collect sufficient clinical information to enable basic risk adjustment; and

7. Adopt an 'all or none' policy, i.e. units report data from all patients treated (where data collection is ethically permissible) if they wish to participate in the register to avoid introducing selection bias into the register population.

Each of these is described in greater detail in the following sections.

Purpose

When establishing an Australian Clinical Quality Registry, it is important at the outset to understand what questions the stakeholders may want answered through the register, both immediately and in the future.[25]

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. This will be determined by the core tasks of the registry. These may include activities ranging from the benchmarking of outcomes to compliance with guidelines or the monitoring of device safety.

While the purpose of the register may evolve as the registry is developed and implemented, it should be noted that broad changes in the purpose of a register will likely have a cascading effect on all dependent components of registry process and outputs.[26] For example, if the purpose of a register changes from a desire to assess the quality of clinical care provided to patients to one which primarily monitors service provision, then it is likely that data collection processes will change to reflect the change in direction. A greater focus will likely be placed on identifying tests and procedures while concomitant reduction in effort will likely be placed on assessing process and outcome measures.

Some common purposes for which clinical registers are established include:

▶ To monitor safety and quality of products and treatments;

▶ To determine clinical and/or cost effectiveness of treatment (including drugs, devices and procedures) across a population;

▶ To identify differences in the quality of care across a population and monitor this over time;

▶ To provide an infrastructure on which intervention studies can be established with relative ease;

▶ To provide information about incidence and prevalence and its variability (over time and place); or

▶ To identify new preventive opportunities for the disease or condition being studied.

Collect a core minimum data set

Some early clinical registers were designed as clinical research activities with extensive data requirements that have left an impression that contributing to registries is a highly burdensome task which is impractical to sustain long term. Ongoing collection of clinical data across multiple locations can be expensive and can be difficult to maintain unless it is simple and incorporated into routine clinical care. For this reason, it is important that Australian Clinical Quality Registries collect only the bare minimum of easily obtained data necessary to supplement ancillary administrative data systems to accomplish their task.

Clinical registers are sometimes referred to as a 'data-spine' of core essential information. Additional collections over limited time frames can be added (as and when funding is available) to delve more deeply into specific questions.

As a general rule, the core information will include sufficient identifying information to allow a patient to be contacted for assessment of outcomes and for possible linkage to different databases. It will also include essential information about the condition or procedure leading to inclusion on the clinical register and information about co-morbidities or other factors needed for risk adjustment. In order to be used as a quality improvement tool, registries should consider collecting data to monitor adherence to important best practice principles. Simple outcome data are also required. Each of these issues is discussed in greater detail in *Data elements* on page 33.

Collect epidemiologically sound data elements

The core data set from an Australian Clinical Quality Registry must consist of data elements that are recorded in the same way using identical definitions across different institutions, and that different observers would record the information identically.

Age, sex, ICD codes are examples of epidemiologically sound information. By contrast, the saturation level of oxygen in the blood on admission to hospital is not epidemiologically sound because there is currently no standardised procedure under which it is measured.

Within Australia, METeOR is considered the authoritative repository for data standards as well as a strategic repository for other data standards.[27] A similar concept has been developed to define terms specific to conditions and diseases[28] and in other specialty areas.[29]

Uniformly collect data

Data elements must be capable of being easily and uniformly collected from the primary data sources at every site. For this reason, consideration needs to be given to the manner in which data elements can be collected systematically when registers are developed. The format in which data is captured should be standardised to enhance its ability to link with other databases. The National e-Health Transition Authority (NEHTA) has determined that within Australia there should be a standard exchange format for data.[30] This will be based on the Health level 7 (HL7) family of standards.[31] For further information, refer to *Part B: Technical standards*.

Over time, it should be possible to collect the essential data elements from administrative or routinely collected electronic data. This has the potential to greatly reduce costs and improve data quality. This is discussed further in the *Data collection* section.

Currently, the variability in hospital information technology systems and the lack of systematic recording of essential clinical data make this an aspiration rather than a short-term goal. It is necessary therefore for many registries to collect a significant proportion of clinical data from the written hospital records, typically by transfer onto web-based data entry screens by data collectors.

The manual component of data collection is currently the major limiting step in establishing new registers and explains why it is feasible to contemplate new Australian Clinical Quality Registries for only a limited number of conditions where differences in quality can have major impacts on quality of life or cost.

Ascertainment and follow-up

Outcome determination is the most fundamental requirement of an Australian Clinical Quality Registry and should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.

Some clinical registries collect data only for a short time period, such as for a single episode of care (e.g. most infection surveillance registries), while others follow patients until they no longer present for treatment (e.g. Australian Bleeding Disorder Registry) or die (e.g. Australian Cystic Fibrosis Data Registry[32]).

In the case of renal transplantation this may involve long-term follow-up monitoring for organ rejection. In the case of severe trauma a six month follow-up is needed for clinical stability to be measured. Shorter time frames may be appropriate in other settings, such as in the Intensive Care Unit where treatment survival to 30 days is commonly used. In general, measures which include functional or quality of life outcomes provide the most ideal measures.

Out of hospital outcomes are commonly determined by contacting participants at a defined time after discharge and asking a small number of key questions. An example is a questionnaire which classifies patients after stroke into three categories (dependent, independent with residual problems, and independent with no problems) using two simple questions.[33] Contact by phone may require considerable effort to find individuals and for this reason most registries undertaking this form of follow-up would collect information about a person's doctor, closest friend and closest relative to facilitate follow-up. Where telephone follow-up is impractical data linkage to other records may be an alternative. (For further information, refer to *Record linkage*.). This could include using the National Death Index where death by cause of death is an outcome of interest.

The outcome should be determined for the highest possible proportion of patients, i.e. 100% if at all possible. Otherwise, there is a high potential for biased results and, possibly, for manipulation. In situations where outcomes are not measurable on most participants it is questionable whether the expense of establishing a register is worthwhile. The length of follow up and the extent that outcome data is collected will depend on factors such as:

▶ *Cost*: Follow-up of patients via personal contact is particularly costly;

▶ *Burden*: The preparedness of patients to provide data is limited and easily exhausted. However in most cases the essential information can be obtained in a few simple well-planned questions;

▶ *Loss to follow-up*: In many instances, the greater the delay before outcome assessment the greater the likely loss to follow-up and the greater the risk of bias. Those patients missing from follow-up may be expected to differ from those who remain in contact. A number of studies have demonstrated that people with poor outcomes are less likely to participate in follow-up and that the longer the time lapse the greater the cumulative loss;[84–87]

▶ *Clinical stability*: In most situations it is necessary to wait until the outcome of a treatment or procedure has stabilised before an outcome can be measured. In many cases, particularly with surgical interventions this may be within several days, once the relief of symptoms can be assessed and the period during which the patient is at risk of major complications has passed. In other cases, such as with severe trauma, it may be necessary to wait for six months or so until clinical stability is reached.

Table 2 lists some example of outcomes collected by existing clinical registries.

Registries	Outcome
Australian and New Zealand Dialysis and Transplantation Registry	Survival Survival of the transplanted organ
Australian Joint Replacement Registry	Prosthesis revision surgery
Australian Bone Marrow Transplant Recipient Registry	Mortality Disease-free survival

Registries	Outcome
Victorian State Trauma Registry	In-hospital mortality
	6-month mortality
	6-month quality of life / return to work / function / pain
Australian Corneal Graft Registry	Graft survival
	Visual outcome
Australian and New Zealand Intensive Care Unit Society (ANZICS) Adult Patient Database	In-hospital mortality
Victorian Infection Control Nosocomial Infection Surveillance System (VICNISS)	Healthcare-associated (iatrogenic) infection

Table 2 Examples of outcomes collected

Selection bias

For Australian Clinical Quality Registries to ensure good quality data, meticulous attention must be afforded to ensuring that complete data are collected on all patients and that all eligible patients within a defined clinical population are included in the register. If clinical registries collect an incomplete set of patients from a clinical unit strong biases may occur. This would be most apparent if a unit reported only those patients with a favourable outcome ('cherry-picking' or 'gaming').

In general, no service should be allowed to contribute to a register unless they are prepared to allow all of their eligible patients to be reported. Selection bias (the purposeful or inadvertent exclusion of patients from inclusion) is best avoided through careful consideration of the recruitment strategy employed by the registry. Recruitment rates are typically low where eligible participants volunteer to participate in registers.[34]

Biases potentially created by incomplete reporting are best addressed by ensuring that the consent process facilitates inclusion of all patients into the clinical register and by having quality control processes in place that monitor the fraction of eligible patients reported to the registry. In general, no clinical area should be allowed to report cases unless they are prepared to allow all of their patients to be eligible for inclusion.

Summary

Australian Clinical Quality Registries should possess the following attributes:

- Australian Clinical Quality Registries should be developed with clear and precisely defined purposes;

- 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

- Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible;

- Methods used to collect data in Australian Clinical Quality Registries should be systematic, with identical approaches used at the different institutions contributing information;

- Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.

- 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.

- Australian Clinical Quality Registries must ensure that complete registry data are collected from the eligible population

♦ # Data collection

Data elements incorporated into Australian Clinical Quality Registries must be chosen to allow the essential variables to be collected with minimal burden. Data collection must not impact on the primary purpose of the health care visit/interaction which is for the provision of health care, nor must it be a burden or cost, time or financial, to the consumer. Data collection is made easier when information is recorded in clinical records or electronic databases in a standardised manner and is easily accessible.

Because registries collect information on a continuous basis, each data element requiring manual extraction adds significantly to the cost and potentially reduces the quality of the clinical register as a whole. For further information, refer to *Part B: Technical standards*.

Data capture tools

Data capture should be performed as close as possible in time to the relevant care event as this provides the best opportunity to ensure that all fields can be accurately completed. Missing data items are difficult to capture retrospectively, and is becomes even more difficult the further collection is removed in time from the care event.

Information for inclusion in an Australian Clinical Quality Registry is best collected from those parts of the medical record where data items are collected systematically, e.g. from pathology reports. The development of nationally uniform approaches, such as the recently introduced uniform national inpatient medication chart and structured pathology reporting, are a valuable aid to this type of data collection. This type of data can often be supplemented with information gained by placing a 'stamp' in a patient's notes or providing a brief data-collection form to be completed immediately after a procedure.

Commonly used approaches for data collection include paper-based forms, web-based data entry and personal handheld computers (Figure 2).
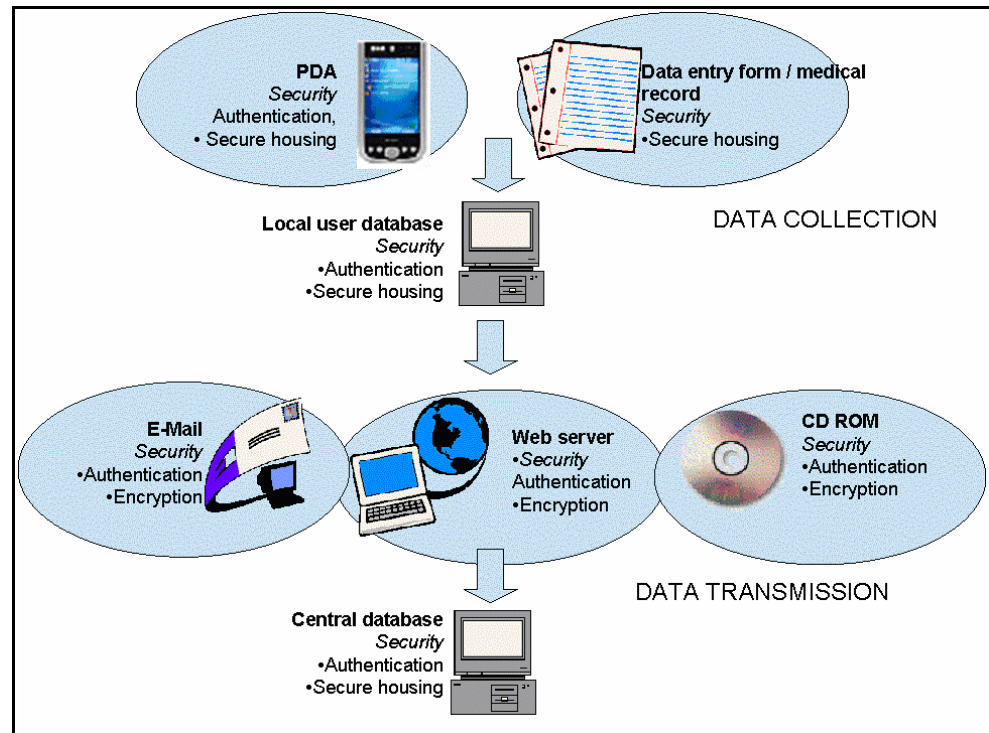
Figure 2. Data flows for clinical quality registries

The choice of which system to use will often be determined by where the data are captured and what resources are available in particular clinical settings, e.g. access to computers. Many registries use a hybrid of paper data collection forms and electronic data entry. Methods for optimising data collection from patients require further evaluation. Table 3 outlines some issues for consideration when collecting data using paper and electronic data capture tools.

Paper-based data capture	
Advantages	*Disadvantages*
• Generally cheap to produce and forms are (usually) easily accessible • Transportable, therefore often favoured by clinicians • Sending paper forms centrally for entry into the register can provide more consistent coding by specialist data entry clerks and economies of scale for personnel, equipment and expert input	• Transmission of paper forms to a central register may pose a security risk unless special arrangements are made (registered mail) • Storing of forms can be cumbersome and expensive in the longer term • Potential for forms to be lost/misplaced • Requires double data entry which is time consuming and expensive • Time delay in receiving data can impact on the timeliness of data being available to clinicians • Easy to leave fields blank (incomplete data) which impacts on data quality
Electronic data capture	
Advantages	*Disadvantages*
• Data is entered (potentially) only once thereby reducing opportunity for data entry / transcription error • Can incorporate various range and consistency checks to reduce data entry error • Produces an audit trail • Lends itself to automatically capturing data from other data sources (where this exists and is of good quality) through data linkage • Can be customised to minimise blank fields • If changes are to be made to the dataset, these can be done centrally and adopted into practice almost instantaneously where web-based systems are used • Enables strong security and auditing	• Requires resources and expertise to establish the data entry form and provide ongoing maintenance of the system • Computers and electronic data capture tools (if used) are required in contributing institutions • If system is browser-based, then it requires access to the world wide web in order to transmit data centrally • Transmission of data CDs/DVDs to a central register may pose a security risk unless special arrangements are made (registered mail). Encryption and other procedures should be used to secure the data. • Potential for data entry errors (but may be less than non-electronic capture methods)

Table 3 Paper and electronic data capture

Other aspects to consider with data collection include:

▶ Adequacy of training of data collectors, particularly encompassing the interpretation of data definitions, and adherence to the principles of good research practice (this can be complicated as many 'data collectors' are also clinicians);

▶ Supervision of data collectors at all stages of the data collection process;

▶ Security of confidential data; and

▶ Procedures to ensure that data are only used in ways agreed with those who provided it.

Timeliness

To be effective in driving change, clinical registries should:

▶ Collect data shortly after their occurrence and as close as possible in time to the point of care; and

▶ Provide reports as soon as possible after the episodes of care.

Delayed reporting lessens the clinical value of register data because it can be argued that the circumstances leading to the findings no longer apply.[35] An appropriate approach may be to provide a brief and immediate summary followed by a more detailed report after final checking and analysis. It is recognised that different registries may have varying conceptions of timeliness due to the clinical condition being addressed.

Standardised data elements

Where standard data elements and definitions exist for diseases and conditions, these should be used. The National e-Health Transition Authority (NeHTA) developed *Part B: Technical standards – Standards Map* to complement this section.[36] In it, they outline the suite of data specifications that have been developed to standardise various clinical concepts and foster interoperability in the health care settings. Table 4 outlines some established data standards and specifications to assist in ensuring the terminology is used consistently in the clinical and information technology context.

Data standard / specification	Description
International Classification of Diseases (ICD)	International standard for classifying diseases and other health problems recorded on health and vital records. ICD-10AM is currently used in Australia.[37]
National Health Data Dictionary (METeOR)	METeOR is Australia's repository for national data standards for health, housing and community services statistics and information.[27]
NeHTA National Products Catalogue (NPC)	The National Product Catalogue (NPC) will become the source and main repository of data for public health institutions seeking to purchase medicines, medical devices and other healthcare items. The NPC is a data repository - of product and pricing information.[38]

Data standard / specification	Description
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)	SNOMED CT is a comprehensive and precise clinical reference terminology. SNOMED CT presents clinically relevant information consistently, reliably and comprehensively as an integral part of producing electronic health records. SNOMED CT operates at many levels including history, examination, provisional diagnosis, test results, and treatment.[39]
Australian Medicines Terminology (AMT)	The Australian Medicines Terminology release is a national extension of SNOMED CT for use within Australian information systems to define and describe medicines and related concepts. The current release contains the products listed on the Schedule of Pharmaceutical Benefits.

Table 4 Data standards/specifications

Where standard definitions do not exist, terminology used within clinical disciplines should be used and clearly defined in the clinical register and by all data contributors. When different registries collect data about a common event, (e.g. blood transfusion) this should be done using uniform definitions and approaches, even if the extent of the data collection differs amongst the different registries (i.e. some registries may collect more extensive data about transfusion than others).

Even with the use of standard definitions, it is likely that registries operating over a long period of time will be faced with the possibility that data elements will change as systems and databases are revised. For example, in translating the International Classification for Diseases from the 9th to the 10th version a number of changes were made. It is expected that ICD 11 will be released in 2015. Registries need to consider the impact that these changes will have on collection and interpretation of findings within institutions over time. For further information, refer to *Part B: Technical standards*.

Data dictionaries

The methods used to collect data in registers should be systematic, with identical approaches used at the different institutions contributing information. Australian Clinical Quality Registries should maintain detailed documentation of all procedures. This should include a data dictionary, which is a catalogue of all data elements held in a database. The objectives of a data dictionary are to:

▶ Establish a core set of uniform definitions relating to the field;

▶ Promote uniformity, availability, reliability, validity, consistency and completeness in the data;

▶ Accord with nationally and internationally agreed protocols and standards, wherever possible; and

▶ Promote the standard definitions by making them readily available to people involved in the collection and use of the data from the data source.

Data dictionaries are a critical component of a registry and should be developed as the database is built. They typically contain a description of each element in the registry, the source of the variable, coding information and normal ranges if present.

The development of clinical registry data dictionaries should be overseen by each Registry Steering Committee (for further details refer to *Organisation and governance* on page 44). The data dictionary should be reviewed at least annually to ensure that it is up-to-date. Changes to the data dictionary should be ratified by the Steering Committee. Many registries publish their data dictionaries in the public domain, often on their website. Some examples include:

▶ The Australian and New Zealand Intensive Care Society's (ANZICS) Adult Patient Database data dictionary
   http://www.anzics.com.au/uploads/ANZICS_APD_Data_Dictionary.pdf

▶ The Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) data dictionary:
   http://www.anzdata.org.au/documents/pdf/ANZDATADictionary2008Jan.pdf

NEHTA recommends the establishment of a central portal for the publication of metadata. For further information, refer to *Part B: Technical standards*.

Existing data sources

Data items in clinical registers are usually obtained directly from the clinical record or through specifically designed data capture forms (or both). It may sometimes be possible to supplement this directly collected data with administrative data (defined as data primarily collected for funding and other administrative purposes, not for assessing quality of care[40]). Examples of administrative data include hospital admitted episode databases and billing sources.

Existing clinical systems, such as laboratory, operating theatre, radiotherapy and emergency department systems, may also be viewed as potential sources of data.

Administrative data offer the advantage of being systematically collected and likely to be available at lower cost.[13 40–46] In a limited range of circumstances administrative databases have been shown to approximate outcomes obtained using registers.[47 48] However, variability in hospital information technology systems and coding practices and the lack of recording of essential clinical data make the exclusive use of administrative data to measure quality problematic.[43 49–52]

Prior to establishing a clinical quality registry, and periodically throughout the life of the registry, there is a need for the registry Steering Committee to determine:

▶ whether the quality of administrative data is sufficient for the intended purpose to negate the need for the registry

> ► whether it is possible to improve the quality of administrative data such that they can be used to supplement registry data e.g. if they don't contain the required detail, can they be broadened to do so?

With further investment in improving the quality of datasets and in the establishment of electronic medical records, administrative data may add another dimension to the ability of registries to monitor quality of care. This will be further enhanced by investment in developing linkage options.

An Australian Clinical Quality Registry should attempt to leverage routinely collected or administrative data as much as possible where data are of a sufficient quality. Additionally, as the volume and/or quality or granularity of these collections changes, Australian Clinical Quality Registries should routinely re-evaluate their use of these data.

Record linkage

Currently there is no universal person identifier used in Australian health care. It is anticipated that by 2011 an Individual Healthcare Identifier (IHI) will be developed which will enable patients to be linked across multiple episodes of care with a high degree of certainty that it is the correct patient's details being linked (for further information refer to the *Unique Healthcare Identifiers (UHI)* section on page 69). In the absence of an individual healthcare identifier, linkage often relies on 'probabilistic matching' rather than inherently more accurate 'deterministic' linking.

For datasets to be linked using probabilistic matching, demographic details including name (last, middle and first), date of birth and gender need to be collected.[53] Because of unreliable reporting, non-uniqueness and changes over time, these fields are not always enough to definitively identify a person across multiple datasets and therefore are a potential source of inaccuracy.

Data linkage units have been or are being established across States and Territories in Australia to enable information housed in one database to be linked to other databases with due regard for data security and confidentiality concern.[54 55] Data linkage enables a multitude of clinical and non-clinical data sources to be linked. Figure 3 provides an example of the various data sources which are linked in Western Australia.[56]
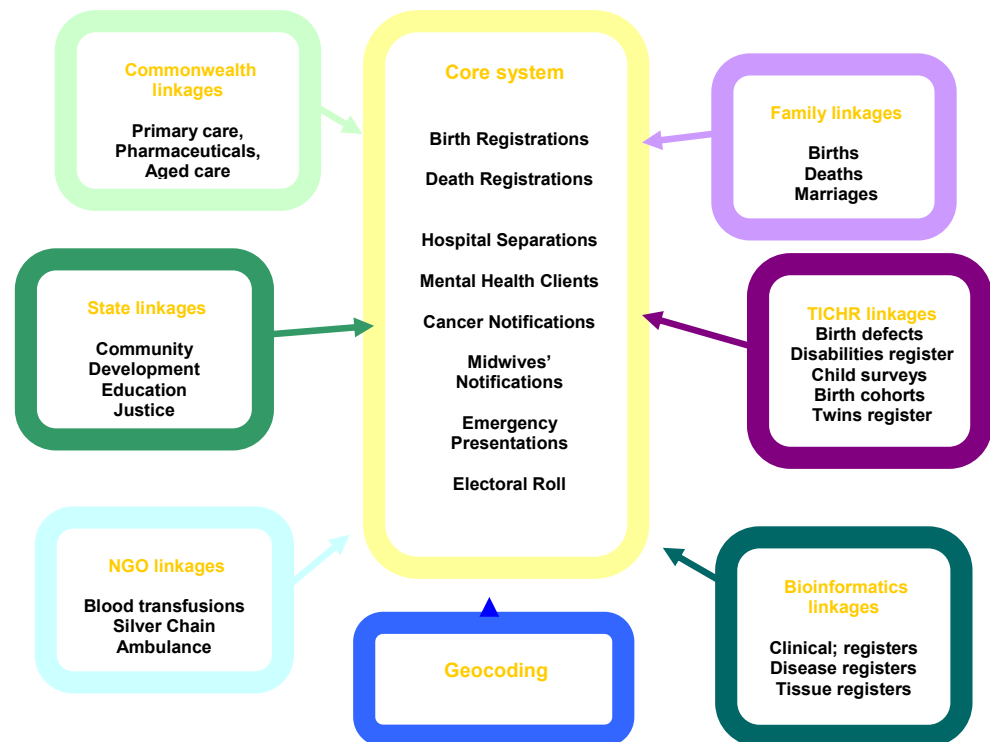
Figure 3. Western Australia Data Linkage System

There is considerable value to be gained by linking data from different sources. Each Australian Clinical Quality Registry should examine what opportunities exist to obtain broader safety and quality data through data linkage exist

For example, linking Australian Clinical Quality Registries with the National Death Index provides a powerful tool to assess longer term outcomes which would otherwise not be feasible to collect. As another example, the linkage of the Victorian Cardiac Surgery Register with the Victorian Infection Control Nosocomial Infection Surveillance System Registry has made it possible to examine variation in the rate of surgical wound infections after cardiac surgery.[57][58] Detailed linked data from these registries provides information that could not have been derived from either register alone.

Although linkage of data amongst different registers is often valuable, there are considerable challenges involved in linking register data with information from secondary data sources. These include:

▶ The need to comply with privacy and confidentiality constraints. Where data are linked, the minimum ethical and privacy standard that must be applied is the higher ethical and privacy standard;

▶ Possible uncertainty about the accuracy, completeness, reliability and validity of the secondary data source;

▶ Difficulty in determining which data should be used when databases provide disparate information. A study by Parker *et al* demonstrated that, when a clinical cardiac surgery register was compared with an administrative database to identify coronary risk factors, there was poor agreement (as reflected by a kappa score of less than 0.4) for the following fields: presence of morbid obesity, acute renal failure, heart block, dysrhythmia, and mitral insufficiency;[59]

▶ The lack of standardised definitions used across databases. The ability to link data is particularly problematic when databases do not use consistent language or definitions; and

▶ Cost associated with undertaking data linkage, which are rarely built into registry budgets.

Currently we are limited in our knowledge of the registers that have been developed, and of their attributes. There is a need to establish a register of clinical registries, in much the same way as has already been done in the UK[64] and recently trialled in Australia.[60]

Summary
With regard to data collection, the following principles should be observed:

- 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;

- Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors;

- Data should be uniformly and easily accessible from the primary data source;

- Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and allow maximum benefit to be gained from linkage to other registries and other databases (if approved by relevant ethics committees);

- 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.;

- 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;

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

♦ Data elements

Information collected by Australian Clinical Quality Registries may be regarded as a data-spine which other specific studies can be attached to, rather than a collection of comprehensive data suitable for answering a large range of possible future questions. As a result of the need to have a minimalist approach to data collection, it is recommended that the process of deciding on the core dataset be undertaken by a team which includes clinical experts, health informaticists and epidemiologists. Data elements need to be carefully considered in relation to the purpose for establishing the registry.

Because the success or failure of a clinical registry is often determined by the burden of data collection, clinical registries should focus on collecting:

- ▶ Identifying information;
- ▶ Key clinical information; including information required for risk adjustment and for measuring aspects of care delivery;
- ▶ Process of care measures; and
- ▶ Outcome data.

Identifying information

Individually identifiable information (personal information) is defined in the Commonwealth Privacy Act 1988 (s6) as:

Information about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.
<div align="right">*Privacy Act 1988 (Cth) s6 61*</div>

Australian Clinical Quality Registries may need to collect individually identifiable patient or subject information for the following reasons:

- ▶ To enable outcome information to be collected when this requires personal contact with patients
- ▶ To enable linkage to administrative and/or other databases.
- ▶ To track people through multiple episodes of care and sometimes across multiple institutions; and/or
- ▶ To facilitate data quality checks to be undertaken, e.g. by comparing registry data with information held in medical records.

Identifying information may also be accompanied by other information to allow patients to be tracked into the future. For example, where longer term outcomes are required it may be appropriate for a registry to collect information about the individual's next of kin, usual general practitioner and/or a friend.

Registries may also collect information capable of identifying the providers of clinical services, potentially including the identity of individual units and individual clinicians.

Identifiable and re-identifiable

Linkage of data from registers containing identifiable data to other data sources must be undertaken using procedures that ensure the confidentiality of an individual's data. One approach to achieving this goal is to create a secondary or link key which can replace the identifying information prior to transmitting data to a third party for data file linkage.[62] In effect, the link key enables identifying information to be removed before it is transmitted to a third party. The link key is unique to each specific individual and is used only for data linkage purposes. The link key should be retained in a secure database so that at a later stage the data can be re-identified if necessary.

Key clinical information

Key clinical information collected by a registry might include elements such as:

▶ Dates of admission/operation/discharge;

▶ Principal diagnoses and co-morbidities;

▶ Results of key diagnostic tests;

▶ Principal treatments provided;

▶ Elements of clinical care provided; and

▶ Information required for risk adjustment.

This type of information must typically be extracted from a patient's clinical record or from specific data-collection forms completed during (or after) the patient's treatment or may come from routinely collected or administrative data.

Process of care measures

In maximising the ability of Australian Clinical Quality Registries to improve quality of care, consideration should be given to measuring compliance with core best practice principles. For this to occur data must be reliable and reproducible. The patterns or processes of care measured should have established links to outcome. Examples of process measures include times from arrival in an emergency department to the administration of a definite treatment such as thrombolysis for stroke or an intervention for myocardial infarction. Analysis of these variables may provide useful information to examine the reasons for differences in outcomes.

Clinical quality registries established in Sweden provide excellent examples of how process measures can be incorporated into registers. The Swedish Stroke Quality Registry collects process measures to identify the:

▶ proportion of patients admitted to a stroke unit;

▶ proportion of patients who receive a CT scan;

▶ treatment in the acute phase and at discharge (= secondary prevention); and

▶ length of hospital stay.[63]

Outcome measures

The type of outcome data collected will depend upon the purpose for which the register has been developed. It is sometimes necessary for the treating clinician to determine the outcome and in these circumstances it is important that, wherever possible, the outcome of interest be an objective measure such as transplanted organ survival or death.

In some instances objective outcomes measures are not possible, such as in the case of quality of life measurement. In these instances, standardised, validated, established tools such as the Health Survey Short Form[12 64 65] or the SF-8 Health Surveys[66] administered by an independent party might be appropriate.

Summary
With regard to determining data elements the following principles should be observed: • Australian Clinical Quality Registries should collect individually identifiable patient or subject information; • 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; • Where possible, outcome 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

In determining whether quality of care differs across health care settings, it is important to ensure that Australian Clinical Quality Registries adjust for variation in patient outcomes that result from differences in patient characteristics that are outside the control of the healthcare providers. Some clinical units attract patients whose conditions are more advanced or who are more prone to worse outcomes because of concomitant illnesses. When outcomes are compared amongst institutions or when attempts are made to investigate poor outcomes, it may be appropriate that these factors are taken into account by applying appropriate statistical adjustments. Risk adjustment is the statistical process of identifying and adjusting for variation in outcomes resulting from differences in patient characteristics or risk factors.

A challenge when undertaking risk adjustment is to identify the epidemiologically sound risk-related variables that have a fundamental impact on outcome and are easily accessible to the data collectors. Sometimes the most important variables which might account for differences in clinical outcomes are either not recorded systematically in clinical records or are not able to be easily extracted, resulting in very limited risk adjustment. In these situations comparative measures of clinical performance may be unsuited for any other purpose other than the identification of extreme 'outliers' or 'unexplained variance'.

Determining the variables to be taken into account during risk adjustment requires judgment, since many potential adjustment factors are either difficult to measure accurately or may only be partly under the control of the treatment team. For example 'cold ischaemia' time (which refers to the length of time between harvesting a kidney from a donor and transplanting it in the recipient) is an important determinant of outcome after renal transplantation. It may be prolonged because of factors outside the control of the clinician.

Commonly only a few of the most obvious co-variates are suited for routine collection and usable as risk adjustment variables. This is one of the reasons why benchmarking comparisons are rarely precise.

An alternative to risk adjustment is to report data within individual risk strata. For example, renal transplantation is compared across institutions using patients regarded as having a low risk of rejection: those who are recipients of primary cadaveric grafts, non-diabetic, non-Aboriginal, non-Maori, non Pacific-Islander and aged between 20 and 54 years at transplant. However, this approach may have the disadvantage of eliminating from the benchmarking the more challenging cases, where outcomes are more likely to be variable and where trends in management need to be tracked.

Summary

With regard to risk adjustment the following principle should be observed:

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

♦ # Data security

In accordance with the Privacy Act first introduced in 1988, personal information collected on individuals must be held in a secure manner. While this Act initially related only to data collected on patients in the public health system it was extended in the Privacy Amendment Act (Private Sector) Act 2001 to also protect personal information held by private sector organisations. The following important documents developed by the National Health and Medical Research Council (NHMRC) provide guidance on the appropriate collection, storage and transmission of data:

▶ *Guidelines to assist researchers in understanding their responsibilities under the Privacy Act 1988*;[67] [68]

▶ *Guidelines for genetic registers and associated genetic material*;[69]

▶ *The Australian Code for the Responsible Conduct of Research*[70] (issued jointly with the Australian Research Council and the Australian Vice-Chancellors' Committee);

▶ *The National Statement on Ethical Conduct in Human Research*[71] (issued jointly with the Australian Research Council and the Australian Vice-Chancellors' Committee).

Registry custodians must familiarise themselves with and ensure that they comply with their obligations under the Privacy Act and documents listed above. This will be further discussed below and in the *Ethics and privacy* section on page 51.

Secure data housing

As part of their governance procedures Australian Clinical Quality Registries are required to address issues relating to the storage of information during the life of the clinical register and after it has ceased to operate. Register data for an Australian-based registry should be stored in Australia. Where registries collect data from multiple institutions, there must be a policy and agreement established within each institution covering storage of data.

The *Australian Code for the Responsible Conduct of Research* provides principles of responsible and accountable research practice, and addresses the responsibility of institutions and researchers in the area of data and record management, publication of findings, governance and dealing appropriately with allegations of research misconduct.[70] The Code dictates that:

▶ Data must be kept in a safe and secure storage place, even when not in use;

▶ Primary research records such as paper forms must be afforded the same level of protection as analysed research data;

▶ Data must be stored in a durable, indexed and retrievable form;

▶ A catalogue of data must be maintained in an accessible form; and

▶ Records must be maintained in accordance with ethical protocols and relevant legislation.

Fundamental aspects of secure data housing would include:

▶ Appropriate off-site backup procedures

▶ Disaster recovery procedures, including failover and redundancy

▶ Regular and adequate testing of all data security procedures.

ⓘ A general principle is that registers holding information on Australians should maintain the register in Australia.

Authentication

Australian Clinical Quality Registries should be established with secure access controls to ensure that only authorised people have access to pertinent information on the database. The register must be password-protected at an individual level. An audit trail should exist to ensure that data cannot be tampered with in the absence of a process for tracking any changes made. For further information, refer to *Part B: Technical standards*.

Secure transfer and messaging

The transmission of data from the local clinical environment to the central register repository can occur via a web-based system, electronically or using a manual system (Figure 2). Principles of data transmission are that:

▶ Data should be transmitted in a secure manner. This includes encryption of data and access to data only after authentication is provided;

▶ Data transmitted via a postal system must be registered and addressed to a specific person who will take responsibility for ensuring the arrival of the data.

Where possible, every effort should be made to enable web-based transmission of data. An outline of security requirements for transmission of data are outlined in Figure 2 and are addressed in more depth in *Part B: Technical standards*. Importantly, transfer of data over the internet requires that data flowing between the browser, web server and the database server, should be encrypted to 128 bits via Secure Sockets Layer. For further information, refer to the *Part B: Technical standards*.

Summary
With regard to data security the following principles should be observed: • To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems. • The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines; • The institutional policy principles set out in *Part B: Technical standards* should be met.

♦ Data quality

The potential use of Australian Clinical Quality Registry data for benchmarking outcomes, providing volume quality assessment, assessing compliance with best practice guidelines, identifying preventive measures to reduce harm and undertaking outcome prediction and cost-benefit analysis will mandate the need for register data to be timely and accurate. To maintain the confidence of providers and consumers (and jurisdictions, funders and other stakeholders) in the accuracy and reliability of the information provided, Australian Clinical Quality Registries must have a robust quality assurance plan and regularly publish information demonstrating its effectiveness. Collection of data from widely dispersed sites is a well-established risk factor for poor quality (and sometimes fraudulent) data. A continuing focus on data quality is a fundamental requirement of an Australian Clinical Quality Registry.

Data quality assurance plans for an Australian Clinical Quality Registry must demonstrate:

▶ Completeness of population ascertainment;

▶ Accuracy of data provided to the Australian Clinical Quality Registry;

▶ Accuracy of data entry, coding and analysis; and

▶ Timeliness of data collection and reporting.

A similar approach has been taken in the United Kingdom where eleven quality criteria have been proposed against which databases including registries should be assessed.[72] The criteria proposed are:

1. To what extent is the collection representative of the population at risk?

2. Which patient groups, if any, should be represented but are not?

3. How complete is recruitment of the eligible population?
   a.   How and when was completeness last determined?

4. What variables are included in the database (Identifiers, condition, intervention, major known confounders, outcome)?

5. What percentage of variables are at least 95% complete?
   a.   How and when was completeness last determined?

6. What percentage of variables have clear definitions laid out in a document such as a data manual?

7. What percentage of variables have clear rules on how to code them in the database laid out in a document such as a data manual?

8. How standardised is the coding for conditions and interventions?
   a.   How and when was reproducibility last tested?

9. Was the person assessing the outcome independent and 'blinded'?

10. To what extent are data validated?

11. Is there any bias associated with the outcome collected by the database?

Ascertainment

The proportion of eligible people entered onto the clinical register is a key quality measure which must be ascertained by determining the number of cases recruited on to the register as a proportion of all eligible cases from the participating institutions. This can be done by comparing the register holdings with external data sources. For example, numbers of patients entered into the cardiac surgery register should be regularly and at scheduled intervals, compared with numbers from administrative databases. This is likely to require periodic matching of register data against information held in local or external databases. Other approaches could include modelling and use of known prevalence or incidence data, modelling or comparison with existing administrative or payment databases, etc.

Accuracy

It must be recognised that data entry errors are not infrequent. One audit of data entered into an orthopaedic register in the UK identified that nearly 40% of records were incomplete.[73]

Data errors may be the result of:

▶ systematic (type 1) errors, e.g. programming errors, unclear or ambiguous definitions, violation of the data collection protocol; or

▶ random (type 1) errors, e.g. inaccurate data transcription and typing errors, illegible handwriting in the patient record. [74] [75]

Figure 4 illustrates some of the types and causes of data error identified in a review of data entered into a National Intensive Care Evaluation Registry.[75] It demonstrates that data captured automatically was more accurate yet less complete than that captured manually.

Automatic data collection

| Patient data |

Data entry ← Incomplete: 4.0%

Electronic patient record (PDMS)

Inaccurate: 4.8%
Incomplete: 3.3%

Extraction ← Inaccurate: 1.7%
Incomplete: 1.4%

Inaccurate: 0.6%
(Corrected: 0.8%)
(Completed: 1.9%)

Local registry database

Data errors:

Manual data collection

| Patient data |

Documentation

Paper patient record

Data collection

Case Record Form

Data entry

Local registry database

Incomplete: 3.6%

Data transfer ← Inaccurate: 0.9%
Incomplete: 0.6%

Data transfer

Central registry database

Automatically collected data
Inaccurate: 2.0%
Incomplete: 6.0%

Manually collected data
Inaccurate: 4.6%
Incomplete: 5.0%

Figure 4. Types and causes of errors.
Reproduced with permission from Arts *et al.*[75]

Strategies to reduce systematic and random errors include:

▶ Establishing data dictionaries (see section 5.4);

▶ Establishing regular meetings with and shadowing data collectors to identify problems with and inconsistencies in data that has been collected;

▶ Providing ongoing training for data collection and coding;

▶ Cross-checking data with other data sources ('triangulation') to assist in determining data completeness; and

▶ Incorporating range and consistency checks in the data collection process.

In addition to back-end data cleaning and front-end logic checks of data, accuracy of information may be validated by field audits or by sending queries back to collecting institutions for assessment and clarification.

Field audits typically involve matching reported data with clinical records in a random sample of cases. This type of audit should cover all units reporting data, but may be targeted to areas where data quality problems have emerged or are suspected. Typically at least 1-2% of reported cases should be audited annually. The sample size needs to be adequate to produce reliable measures of data completeness and accuracy. Further, the audits need to be frequent enough such that data quality lapses are promptly identified. The value of audit is partly preventive, i.e. to signal to data collectors the importance of accuracy.

Completeness of data fields should be determined on a regular and frequent basis by the data management centre and be fed back immediately to data collectors to enable them to rapidly retrieve outstanding data items. Statistical reports of the performance of individual data collectors should also be provided to each individual involved.

Within the data centre, the accuracy of data entry from paper-based recording forms should also be regularly monitored using strategies such as double entry of a random sample of cases. This technique will identify whether data is interpreted differently by data entry staff.

Timeliness

Reporting timelines are important if the data from Australian Clinical Quality Registries is to have relevance to current clinical practice and to be effective in quality improvement. These should be agreed to as part of the registry funding agreement and monitored by the registry Steering Committee. Adherence to timelines however requires that a registry is supported with adequate funding and staff.

Summary
To ensure data quality, the following principles should be observed: • Australian Clinical Quality Registries should report as a quality measure the percentage of eligible patients recruited to the clinical registry; • Australian Clinical Quality Registries should have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected; • 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; • Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks; • 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

This section describes the organisational and governance issues that any Australian Clinical Quality Registry needs to consider.

In most instances the registry should be a legal entity, possibly as a limited liability company, with a board including representation from clinicians, national peak bodies, jurisdictions, funders and consumers.

Corporate and clinical governance

Many registers were initially developed as research projects and consequently developed policies primarily designed to manage research data. However, with the increasing focus of registries on quality assurance and benchmarking, together with the rise of alternative sources of public (and/or private) funding, different approaches to governance and accountability are required. It is increasingly important that individuals involved in managing and overseeing an Australian Clinical Quality Registry are aware of their responsibilities and scope of practice. However, to date, no general guidelines for establishing and governing registries have been published in Australia.[76]

Australian Clinical Quality Registries must be able to demonstrate well-organised and well-documented governance structures incorporating representation from stakeholders, including consumers, clinicians, jurisdictions, funders, researchers, and policy developers. In demonstrating the application of good corporate and clinical governance, registries must:

- ▶ Be run efficiently;

- ▶ Meet their fiscal responsibilities;

- ▶ Operate within legal constraints, particularly with regard to data security and confidentiality;

- ▶ Meet corporate and clinical goals related to the purpose of the register;

- ▶ Monitor outcomes and deal appropriately with clinical issues arising from the data analysis;

- ▶ Be appropriately managed by people who have clearly identified roles and responsibilities. This includes having documented and standardised practices and procedures for data collection, lodgement, storage, and data management;

- ▶ Have established data access policies and procedures, for both registry staff and third parties; and

- ▶ Have processes for demonstrating the engagement and commitment of all relevant stakeholders.

One of the most important tasks of the governing body is ensuring that data output is reviewed on a regular and timely basis and that quality of care issues are addressed appropriately. Analysis of data must include a clinical interpretation of the findings. Australian Clinical Quality Registries must have in place a structured process for peer review and feedback to organisations that ensures that action is taken. The Steering Committee will be responsible for monitoring and ensuring that this occurs.

The challenges of clinical data collection, quality control, data security and statistical analysis will generally require that Australian Clinical Quality Registries be established in a strong research environment which has experience in maintaining large data sets. A registry should develop links to experts in the key areas of biostatistics, clinical medicine, quality, management and clinical epidemiology.

Accreditation

Institutions providing data to Australian Clinical Quality Registries should be acknowledged in the accreditation process. The support of medical colleges and other relevant specialty groups is also essential if a registry is to function effectively. Certain specialty groups strongly recommend that their members contribute to registers as part of their Continuing Professional Development (CPD) Program.[77]

Australian Clinical Quality Registries are often useful in supporting training and credentialling by supplying data on numbers of procedures undertaken and associated outcomes, and through identifying institutions suitable for supporting training activities. In addition to being used at an institutional level, these data can also be used by individual clinicians to provide evidence of their experience and the quality of their work. Health insurers may also require a contribution to certain registers as part of their funding agreements.

Governance structures

The registry governance structure should comprise a Steering Committee, responsible for the clinical register and for promoting its activities. In addition, a Management Committee should be established to take responsibility for managing day-to-day aspects of the registry. Some registries use working parties to undertake targeted work in a given area. For example, working groups within an Infection Surveillance registry might focus on nosocomial pneumonia or surgical site infections in orthopaedics or paediatrics.

For some smaller registers, the role of the Steering Committee and Management Committee can be combined, provided that the group meets on a regular basis.

In addition to these structures, registries must have an independent complaints system in place to provide confidence that perceived misuse or inappropriate use of data can be investigated. In most institutions, the Institutional Ethics Committee (IEC) will undertake this role (for further information on the role and responsibilities of ethics committees refer to the *Ethics and privacy* section on page 51).

Steering Committee

A Steering Committee should be established to oversee the governance of the Australian Clinical Quality Registry and to maintain the confidence of all parties. Its focus should be on providing strategic direction and ensuring deliverables are met for the Australian Clinical Quality Registry. The specific roles of the Steering Committee are to:

► Provide oversight over all the Australian Clinical Quality Registry's activities, including that of the management committee;

► Provide ongoing review of the objectives of the clinical register and the Australian Clinical Quality Registry's effectiveness in meeting them;

► Establish policies to address issues of clinical interest or significance that may arise from time to time. These will include matters related to quality of care;

► Facilitate policy support for issues identified by the Management Committee;

► Provide advice on the Australian Clinical Quality Registry's management, organisation, scope, development and funding;

► Monitor the quality of the Australian Clinical Quality Registry's data quality management processes and timeliness of reporting;

► Develop and monitor policies for access to data and responses to quality of care issues identified;

► Review and advise on output from the clinical registry;

  ► Review and provide comment on reports published by the Australian Clinical Quality Registry;

  ► Provide advice on the collection and interpretation of data;

► Review all research and data requests for identified or identifiable data.

► Review publications arising from the Australian Clinical Quality Registry; and

► Review and advise on communication strategy, including communication with consumers.

The Steering Committee should meet more than once annually and have provision for the calling of extra ordinary meetings as required. Formal Minutes of meetings must be taken. Membership should comprise:

► Senior clinicians in a leadership role with the relevant specialty group;

► Representation from the funding body and/or appropriate jurisdiction;

► Senior staff from the Management Committee;

► Community or consumer representative(s);

► Any group involved in providing care in the subject area;

► The key national professional organisations must be party to the clinical registry.

The Chair of the Steering Committee should typically be a senior and distinguished and independent clinician researcher.

Management Committee

The Management Committee is responsible for managing day-to-day aspects of the clinical register. Data quality measures should be reported regularly to the management committee. The specific roles of the Management Committee are to:

▶ Be responsible for the administration of the management, staffing and budget in the Australian Clinical Quality Registry;

▶ Ensure that the data collection and data quality processes function effectively and that issues arising are dealt with in a timely and effective manner;

▶ Arrange for timely and appropriate statistical analysis, reporting and publication of Australian Clinical Quality Registry data;

▶ Review Australian Clinical Quality Registry data regularly and undertake necessary follow-up in accordance with policies ratified by the Steering Committee;

▶ Report back to the Steering Committee to ensure suitable resources are provided to facilitate action on policy-related issues;

▶ Ensure compliance with requirements of ethics committees and all relevant legislation;

▶ Provide reports and liaise as necessary with bodies providing funds to the clinical registry;

▶ Ensure that the finances of the Australian Clinical Quality Registry are audited annually in accordance with appropriate standards and that the audited statements are provided to the Steering Committee; and

▶ Develop and provide support for the function of the various scientific working groups.

The Management Committee should convene at least monthly and have provision for the calling of extra ordinary meetings as required. Minutes of these meetings should be taken. Membership should comprise at least:

▶ Two clinical specialists; and

▶ Two representatives from the data management centre.

Working groups

Working Groups are composed of a small, functional number of clinician-researchers with special interest in specific areas related to the clinical registry. They should be supported by a member of the data centre charged with coordination of the group. Their membership may alter as the focus or interests of the groups change.

Addressing quality of care

Between 1988 and 1994 the mortality rate for children undergoing complex cardiac surgery at Bristol Royal Infirmary was roughly double that elsewhere in the United Kingdom in five out of seven years. An independent investigation into the statistically significant excess death rate identified that, for much of that time, cardiac surgeons were contributing data to a register and were aware of their poor performance relative to other centres in the UK. This information was not made available to those in a position to initiate action and, as a result, deaths which could have been prevented were not.[78][79]

These findings highlight the need to not only have formalised reporting requirements, but to ensure that feedback processes exist to ensure that data are appropriately actioned. An escalation protocol must be developed and ratified by the Steering Committee including provision to notify the senior executive personnel within the practicing institution in the event of ongoing poor performance. Actions and processes to address poor performance need to be agreed upon, accepted and executed to ensure improvements in the delivery of patient care. It is important that the appropriate peak bodies and jurisdictions are involved so as to ensure appropriate corrective actions can be taken in a timely manner.

Summary
To ensure that Australian Clinical Quality Registries are well organised and governed, the following principles should be observed: - Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output;   - 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

A key role of the Steering Committee is to establish data access and reporting policies. These policies must take into account the requirements imposed by Institutional Ethics Committees and legislation.

The body responsible for the governance of the Australian Clinical Quality Registry should be a legal entity; that is an individual or organisation legally permitted to enter into a contract, and can be sued if it fails to meet its contractual obligations. The legal entity will generally be the administering institution which manages the funds provided to establish and maintain the Australian Clinical Quality Registry. This needs to be made explicit in any Contract and /or Funding Agreement established between the various parties associated with the registry.

It is generally the responsibility of the Steering Committee to provide advice on the collection and interpretation of data and to review publications arising from the Australian Clinical Quality Registry and advise on their scientific quality. The Steering Committee may wish to restrict the distribution of data pertaining to identifiable institutions until it is confident that the data quality is sufficiently accurate and that it has appropriate legal protection. The process and criteria for publishing Australian Clinical Quality Registry data needs to be made clear to all parties including those providing information to the Australian Clinical Quality Registry.

Research use

An important consideration when establishing an Australian Clinical Quality Registry is determining who should have access to data developed from the register. When Australian Clinical Quality Registries are publicly funded it is important that information is made available to the range of parties stipulated by the funding organisation, and agreed to by the institutions or other parties providing data. Sometimes this access may also be influenced by the requirements of relevant legislation (including the Public Health and Freedom of Information Acts).

For Australian Clinical Quality Registries to contribute to knowledge and be of benefit to consumers, data should be interrogated for research purposes. However, data access needs to be closely monitored to protect the personal health information of register participants and ensure that they are not harmed in any way: physically, psychologically, spiritually or emotionally. For this reason, all requests for data access should be made through the Steering Committee and receive Institutional Ethics Committee (IEC) approval. In the absence of a national ethics committee, it is acknowledged that where data are being sourced from multiple institutions this process is both protracted and often duplicative. The development of the National Ethics Application Form (NEAF) aims to reduce this burden.[80]

In addition to the need to consider ethical issues associated with requests for data from an Australian Clinical Quality Registry, policies should be developed and endorsed by the Steering Committee to guide processes and costs to be charged (if any) to researchers and for-profit organisations wishing to have access to register data. It is important that a formal contract be developed between the registry and the researcher, detailing conditions of use of the data.

Researchers should also make available to the Steering Committee manuscripts for consideration for publication prior to submission. This is not to veto any publication but rather to assess the rigour of the study design and analysis, and to ensure that data are not misrepresented.

Summary
With regard to data custodianship, the following principles should be observed: - Custodianship of data needs to be made explicit in Contract and /or Funding Agreements;   - Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data;   - 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

All Australian Clinical Quality Registries need to aware of and compliant with the relevant legislation and regulations, Commonwealth, state and territory, that are applicable.

With the exception of instances where data collection has been mandated through legislation or enabled through regulation or legislation without patient consent (e.g. cancer registries, Creutzfeldt-Jakob disease registry), a requirement of registries is that approval for the collection of data at each site is given by an Institutional Ethics Committee (IEC).

This section discusses existing legislation and issues relating to obtaining consent from clinical register participants.

Legislation and guidelines

Personal information held by registries is protected by both Commonwealth and State Privacy Acts. The Privacy Act, established in 1988, aims to protect information held by federal government departments and agencies. The Privacy Amendment (Private Sector) Act, passed in 2001, aims to protect personal information held by private sector organisations. Under the Privacy Act there are two sets of privacy principles; one which applies to the Commonwealth public sector (Information Privacy Principles (IPPs)) and the other which applies to the private sector (National Privacy Principles: NPPs). The Australian Law Reform Commission reported to the Commonwealth Government on privacy legislation in mid-2008. The Commonwealth's response is not expected before the end of 2009.

In addition to these Privacy Principles, most States and Territories have also enacted their own privacy legislation that applies to State public sectors. The criteria for protection and its extent vary between the different States and Territories making it important that clinical registries check on the protection available in their jurisdiction. Table 5 outlines Privacy Acts and Principles within the States and Territories current as of 2008. It should be noted that these may change, so when establishing a register it is imperative that registry custodians seek advice on Acts and Principles which deal with confidentiality of identifiable data which might be of relevance to them.

Jurisdiction	Act	Principles
New South Wales	Privacy and Personal Information Protection Act 1998	Information Privacy Principles (IPPs)
	Health Records and Information Privacy Act 2002	Health Privacy Principles
Victoria	Information Privacy Act 2000	Information Privacy Principles (IPPs)
	Health Records Act 2000	Health Privacy Principles
Queensland	Non-legislative scheme incorporating NPPs into Queensland	National Privacy Principles (NPPs)

Western Australia	No current privacy scheme	
South Australia	Has issued an 'administrative instruction' that government agencies should comply with IPPs	Information Privacy Principles (IPPs)
Tasmania	Issued the IPPs based on the Federal version	Information Privacy Principles (IPPs)
Northern Territory	Information Act 2002	Information Privacy Principles (IPPs)
Australian Capital Territory	National Privacy Act applies Health Records (Privacy and Access) Act 1997	National Privacy Principles (NPPs) The Privacy Principles

Table 5 Privacy Acts and Principles

Under the Privacy Act 1988, the NHMRC is authorised to issue guidelines to protect the privacy of personal information and health information which may be used for the purposes of research. Two sets of guidelines have been developed:

▶ The *S95 Guidelines*, which provide a framework in which medical research involving personal information held by Commonwealth public sector agencies should adhere to ensure that information is protected against unauthorised collection, use or disclosure;[68] and

▶ The *S95A Guidelines* which provide a framework in which medical research involving personal information held by private sector organisations or institutions should be conducted to ensure that information is protected against unauthorised collection, use, and disclosure in the conduct of health service management activities. [67]

When registers are proposed, Institutional Ethics Committees must consider which Acts apply (State/jurisdiction, Commonwealth or both), whether the registry conforms to the relevant Privacy Principles and apply the S95 and S95A Guidelines. The S95 and S95A Guidelines are used mainly in cases where consent from participants to use their data cannot be obtained.

The *National Statement on Ethical Conduct in Human Research* has been developed jointly by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee to provide clear guidance for those conducting research and those involved in its ethical review.[81] It outlines values and principles of ethical conduct, risk in research, the role of consent, ethical considerations specific to research methods, fields and participants, and processes of research governance and ethical review. Registry personnel should be familiar with the National Statement and comply with requirements outlined in the document.

Consent

The issue of consent is complex, and for this reason requires careful consideration of relevant Acts, guidelines, and the National Statement by ethics committees. There are two methods by which consent can be obtained. This can generally be either by:

1. Asking individuals to register their willingness to be included on an Australian Clinical Quality Registry (opt in); or

2. Presuming that an individual will be willing to be included on an Australian Clinical Quality Registry unless they lodge an objection (opt off).

In some circumstances personal information including health information can be collected without consent for health and medical research. Apart from legal mandate or legal authorisation, only an Institutional Ethics Committee (IEC) has the ability to waive the requirement for consent for medical research using personal information. For this to occur, ethics committee members must be satisfied that all of the following apply:

▶ Involvement in the research carries no more than a low risk;

▶ The benefits of the research justify any risks of harm associated with not seeking consent;

▶ It is impracticable to obtain consent;

▶ There is no known or likely reason for thinking that participants would not have consented if they had been asked;

▶ There is sufficient protection of their privacy;

▶ There is an adequate plan to protect the confidentiality of data;

▶ In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them; and

▶ The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled and the waiver is not prohibited by State, federal or international law.

It has been repeatedly demonstrated in quality improvement programs that requiring specific permission in advance from potential research participants (opt in) will lead to the collection of a relatively small fraction of eligible cases and the resulting data will have no credibility for quality improvement.[34 82–86]

To overcome the problems associated with low participation rates resulting from voluntary recruitment of research participants, while still allowing an exclusion for those who are actively opposed to participation, Australian Clinical Quality Registry custodians commonly request IEC approval for an approach whereby potential participants are provided with information about the register and provided with an option to not participate without incurring any cost (opt off). Specifically, potential register participants must be provided with clear and easily interpreted information detailing:

▶ The purpose of the Australian Clinical Quality Registry;

▶ That their identity and some specific clinical information will be retained in the Australian Clinical Quality Registry unless they contact the registry to lodge their objection;

▶ How information contributed to the Australian Clinical Quality Registry will be used, including how data may be linked and shared;

▶ That a decision not to participate in the Australian Clinical Quality Registry will incur no penalty, either financially or in respect to the care they will receive;

▶ How they may lodge a complaint through an independent complaints process.

Options by which people can notify the Australian Clinical Quality Registry should they not wish to participate in the register include via free-call telephone number, web-based systems or return postage paid forms distributed with the registry information leaflet. A period of two weeks should lapse before data are made available to the Australian Clinical Quality Registry.

It is recommended that this form of opt off consent be a standard approach taken upon the establishment of new registers and that an education process be established to inform IECs of the appropriateness of this approach when considering new Australian Clinical Quality Registry applications.

Care must be taken to avoid confusing safety and quality monitoring with research with regard to customary approaches to consent. Australian Clinical Quality Registries need to understand the legal environment and the legal options for gaining complete coverage for this monitoring. The issues of bias from sub-optimal coverage, or of missing rare but crucial sentinel events, needs to be understood. Even when registry data collection is legally compelled or authorised, ethics committee approval may be important to lend credibility to the data collection processes, provision of information to patients about the use of their data, etc.

Research

Consent for establishment of an Australian Clinical Quality Registry should be considered separate from consent for research projects arising from register data. Where research projects are undertaken using register data, IEC approval must be sought unless the activity falls within the scope of a quality assurance activity. A quality assurance activity is one in which the primary purpose is to monitor, evaluate or improve the quality of the health care delivered by a health care provider (constituting an individual, a service or an organisation). The National Health and Medical Research Council have outlined conditions under which quality assurance activities would not require independent ethical review;[87] namely provided:

Both:

a. The activity is undertaken with the consent of patients, carers, health care providers or institutions involved
or
Is consistent with NPP 2.1 (a) which states: 'An organisation must not use

or disclose person information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless'…' both of the following apply:
1)   The secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;
2)   The individual would reasonably expect the organisation to use or disclose the information for the secondary purpose;

and

b.   It is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

Additionally, such activities may not require independent ethical review if legally mandated or legally authorised.

If it is anticipated that Australian Clinical Quality Registry data will be used as part of ongoing quality assurance activities within institutions, then this should be made known to potential registry participants in information material made available to them.

Qualified Privilege

In undertaking quality assurance activities there is a risk that quality of care issues may be identified. In the interest of ensuring frank and open discussion of findings from quality assurance activities without fear of litigation, organised committees overseeing quality assurance activities may apply for a legislated protection of Qualified Privilege. Register custodians should consider applying for protection in this way.

The criteria for protection and its extent vary between the different States and Territories making it important that clinical registries check on the protection available in their jurisdiction. Using New South Wales as an example, though, qualified privilege affords the protection for:

▶   The confidentiality of documents and proceedings of the Committee;

▶   The protection of those documents and proceedings from being used in legal actions; and

▶   The protection from liability and indemnity for present and former members, of the Committee, who were acting in good faith in carrying out their responsibilities.[88]

Committees seeking qualified privilege must demonstrate that:

▶   The public interest in gaining health care professionals participation outweighs the community's interest in accessing information; and

▶   That there will be an improved standard of patient care arising from the Committee's activities if it was able to operate under a guarantee of privilege.[88]

To the extent that an Australian Clinical Quality Registry is engaged in quality activities it may be protected by the existing legal regime depending upon its relationship to the unit or group which is the subject of the quality activity. As an example, data from registers collected within an institution and discussed at that institution's quality assurance committee would be protected from disclosure provided the committee had sought and been afforded qualified privilege.

Currently in Australia, it is not commonplace for committees overseeing registry function to have sought this legislative protection. Without this protection, Courts have the power to compel information from clinical registries. This is in contrast to the United Kingdom where the Health and Social Care Act 2001 has explicit provisions protecting register data from disclosure.

Summary
With regard to ethics and privacy issues, the following principles should be observed for those Australian Clinical Quality Registries in which data collection has not been mandated or enabled through legislation or regulation: • Institutional Ethics Committee approval must be obtained to establish the Australian Clinical Quality Registry (except where legally mandated or legally authorised); • Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*; • Participants or their next of kin should be made aware of the collection of 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. • 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.

♦ Outputs

Australian Clinical Quality Registries need to report rapidly on information they collect, to those institutions and individual clinicians contributing data, to regulatory bodies, to jurisdictions, to funders and to the wider community. A common problem with registries has been the delay in reporting information. Although time is required to ensure completeness and accuracy of data collection, Australian Clinical Quality Registries should give consideration to rapid feedback of interim data.

In discussing the reporting requirements of Australian Clinical Quality Registries, this section covers methods for analysing data and reporting requirements which must be in place to ensure that data are adequately reviewed and appropriately actioned.

Data analysis

Analysis of Australian Clinical Quality Registry data may include:

► Descriptive reporting of significant process variance

► Benchmarking;

► Volume quality assessment;

► Assessment of compliance with best practice guidelines;

► Post-market surveillance of devices and of new and existing technology;

► Assessment of outcome prediction;

► Preventive measures demonstrated to reduce harm; and

► Cost-benefit assessment.

Benchmarking

In a report written by the Society of Cardiothoracic Surgeons of Great Britain and Ireland it was stated that, "In order to measure the quality of any service industry some sort of benchmarking and performance assessment is the first step and is unavoidable". [89]

Registers are an ideal source of data from which outcomes can be measured and results compared amongst different institutions, within Australia and overseas. Interpretable results require that case ascertainment is complete (from the participating institutions), valid outcome data is obtained and adequate risk adjustment undertaken.

Statistical process control charts and box-plot diagrams provide two examples of ways in which data can be displayed for benchmarking purposes. Figure 5 is an example of a statistical process control chart. Figure 6 is an example of a box plot used to compare and measure distribution of measurement values of different units.

Statistical process control charts provide a continuous display of observed versus expected performance for conditions and therefore potentially offer a more effective means of monitoring practice, provided that analyses are conducted at relatively short time periods.[90]
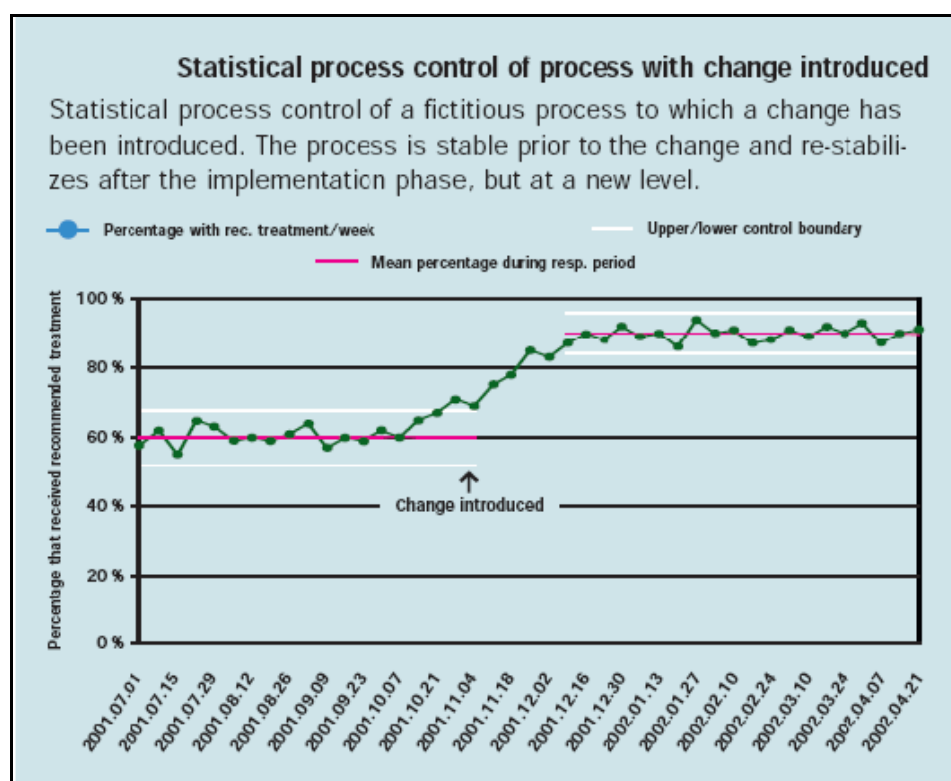

Figure 5. Example of a statistical process control chart
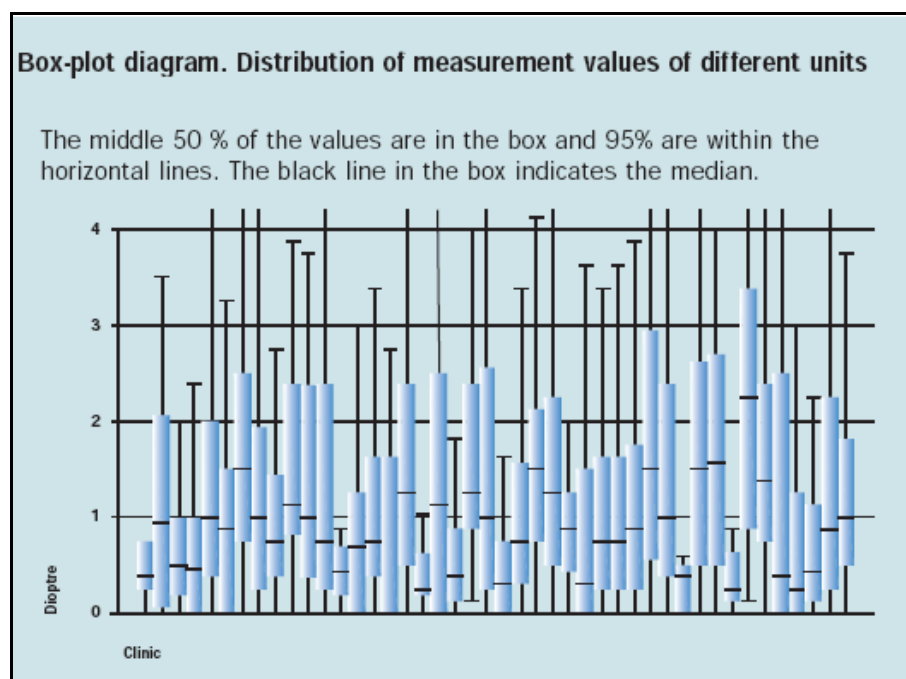Reproduced with permission from *Handbook for Establishing Quality Registries.*[23]

Figure 6. Example of a box plot
Reproduced with permission from *Handbook for Establishing Quality Registries.*[23]

Volume quality assessment

Register data has been valuable for defining the numbers of procedures required by individuals and units to achieve optimal results.[91–93] Figure 7 demonstrates the relationship between numbers of angioplasties and bypass surgery and patient mortality rates by physician. In this example, it is apparent that physicians performing more than 50 procedures per year and hospitals performing more than 200 procedures per year demonstrated reduced mortality compared to those performing fewer procedures.[92] Register data has also been used to monitor the relationship between volume and complications at an individual and hospital level (Figure 8).
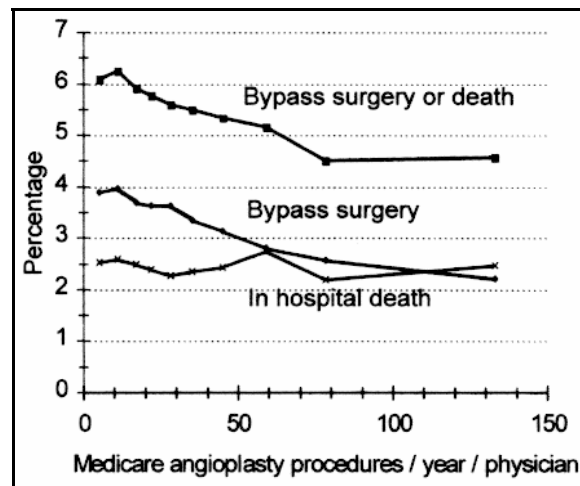

Figure 7. Volume quality assessment: rates of bypass surgery and death after angioplasty according to the annual volume of Medicare angioplasties performed by the treating physician.
Reproduced from Jollis JG, Peterson ED, Nelson CL *et al*. *Circulation* 1997; 95(11):2485–91
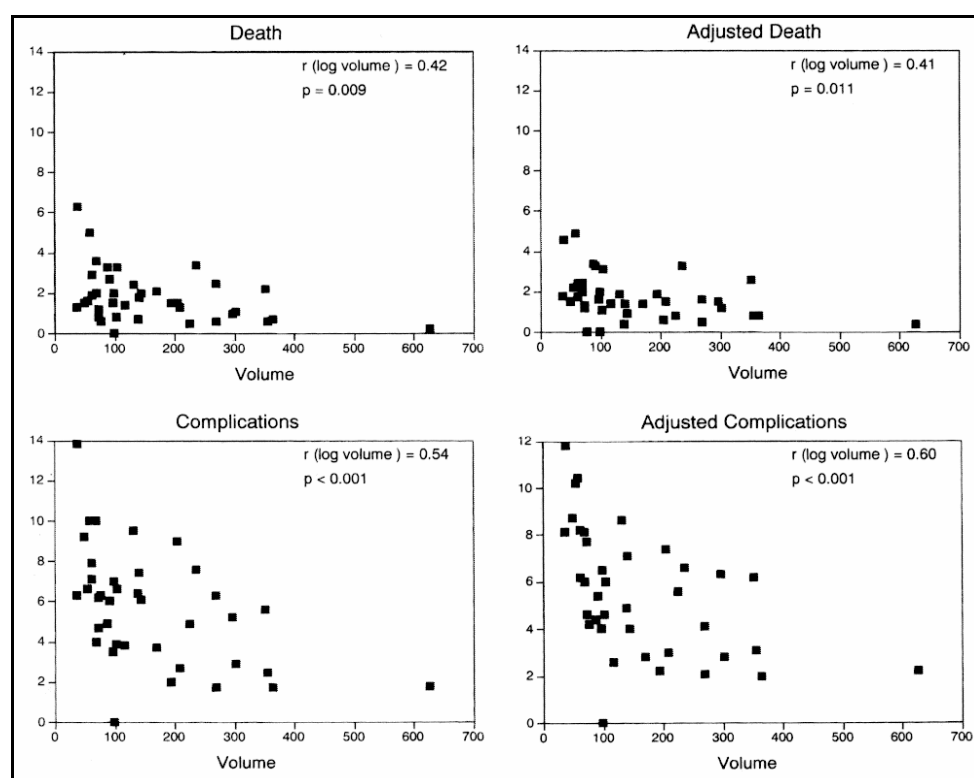
Figure 8. Relation of operator volume to (A) incidence of death, (B) adjusted incidence of death, (C) incidence of major complications, and (D) adjusted incidence of major complications.
Reproduced from Ellis SG, Weintraub W, Holmes D *et al. Circulation* 1997; 95(11):2479–84.[93]

Compliance with guidelines

Registries that collect information on aspects of disease management are useful for assessing compliance with published treatment guidelines. They provide valuable information to allow variations in practice to be investigated. For example, the Australian and New Zealand Dialysis and Renal Transplantation (ANZDATA) registry has been used to assess how well implemented standard guidelines were for the management of iron levels in patients with chronic kidney disease who were dependent on dialysis.[94] Factors identified in units achieving high level of compliance with guidelines (such as the use of nurse-driven iron management protocols and iron management decision aids) can then be translated and applied to those units demonstrating poorer management of patients.

Surveillance

Some registers are established primarily to provide post-market surveillance of medical devices and technologies in the clinical setting. The Australian Orthopaedic Association Joint Replacement Registry is an example of one such register. The principal measure of outcome in this register is revision surgery.

Other registries may be ideally suited to monitor products or devices as part of their role in safety and quality improvement. This is likely to be an increasingly important role for registries in addition to their other functions. The Cardiac Surgery registry, for example, collects details on the type of valve replacement prostheses inserted during cardiac surgery. [95] Should analysis identify one type of valve as having a higher complication rate than others, then further action could be initiated. Similarly, if a safety alert was initiated a registry could provide a listing of potentially affected individuals.

The strength of the data provided by registries is similar to that of other observational datasets in that it is generally less rigorous than clinical trials and potentially more prone to bias and confounding. Considerable attention must be paid to data quality to minimise these adverse influences. However, registries do have the strength of potentially greater representativeness of the patient population being treated and routine clinical settings, and provide a longer duration of surveillance than is typically available from a clinical trial.

Outcome prediction

Register data may be used to help identify previously unverified factors that exert a measurable impact on outcomes. This was demonstrated when the Victorian State Trauma Registry was used to investigate factors associated with mortality and extended stay in Intensive Care Unit in patients who had sustained blunt trauma.[96] It was shown that the Glasgow Coma Scale motor response and respiratory rate determined during pre-hospital triage were both independent predictors of mortality and length of stay in the Intensive Care Unit. The impact of this finding is that these two variables are now considered important criteria for triaging patients out of the hospital environment. Similarly, the ANZDATA registry was used to assess the impact of geographic variance in access to renal transplantation[97] and to show that people living in disadvantaged areas were more likely to have delayed referral to see nephrologists.[98]

Preventive measures

Data from registers have been extensively used to investigate factors contributing to the development or progression of diseases and illnesses. Identification of risk factors provides information that is useful for disease prevention. Cases collected from registers are compared with data from matched controls in case control studies to identify potential causal factors for the disease in question. Examples include studies to identify risk factors associated with operative procedures,[99 100] suicide [101 102] and the development of cancers.[102]

Cost-benefit assessments

Data from registers may also be useful for collecting information about current management approaches and their costs. Cost-effectiveness analysis is increasingly being required to focus services and procedures delivered in an increasingly complex environment. Studies such as those investigating the cost effectiveness of the establishment of stroke units compared to conventional care for patients suffering strokes have used data from registers.[103] Longer term studies evaluating costs associated with the management of patients can also be assisted by the use of clinical register data.[104]

Reporting

Australian Clinical Quality Registries have a fundamental requirement to report without delay on information they collect to institutions and clinicians and to the wider community, including jurisdictions, funders and consumers. The requirement that Australian Clinical Quality Registries must have a formalised process to address quality of care issues has been described (for further details, refer to the *Organisation and governance* section). At a central registry level, data must first undergo peer review to validate analyses. Data must then be fed back to institutions and contributing clinicians, prior to wider release of data.

Peer review

Peer review of register data is fundamental to ensuring the validity of findings. A formal mechanism should exist within Australian Clinical Quality Registries to ensure that, prior to release of information, data are assessed by a number of clinicians specialising in the area being measured. It is the responsibility of the Steering Committee to monitor this process. The role of the peer reviewers is to consider whether any assumptions or biases have been introduced in the analysis of data. Where outliers or unexplained variance exist, the peer review process should provide a clinical context which might explain the findings. A finding of the peer review might be to request closer inspection of cases. Institutions contributing to Australian Clinical Quality Registries must be committed to investigating anomalies in findings to determine causation.

Wherever possible, the reviewers should be blinded (the clinicians should not know the identity) to both the institution and/or clinician being studied.

Feedback

An Australian Clinical Quality Registry should supply regular reports to contributing clinical units that will allow as close as possible to real-time monitoring of key outcome and/or process measures and retrieval of past reports.

Local contributors should also receive:

▶ A standard suite of reports comparing their performance against the aggregated national data, and possibly also against other jurisdictions and peer groups. This suite will typically contain risk-adjusted outcome data and adherence to guidelines (process measures where collected);

▶ Details of missing variables and outliers to enable data quality checks to be performed;

▶ Information on how to distinguish data which has gone through rigorous quality checks against that which needs to be verified.

The provision of full access to a contributor's own data and the associated reports (ideally via real-time web-based access data access and reporting mechanism) can also act as a key benefit and driver for participation.

The broader reporting framework should include:

▶ Reports on the performance of registries at least annually;

▶ Information about the clinical register specifications, including eligibility criteria and database coverage to enable others to approach the registry to undertake analysis or linkage;

▶ Contributions to national safety and quality reporting, including the key methods and indicators demonstrating the impact of the Australian Clinical Quality Registry upon clinical practice.

Delays or restrictions on the public reporting of clinical registry findings may occur for a number of justified reasons:

▶ Data relating to identifiable institutions need to be assessed to ensure sufficient accuracy prior to release;

▶ Data need to be properly interpreted in a clinical context. Where outliers or unexplained variance exist, there needs to be investigation to determine causality.

Public reporting

Australian Clinical Quality Registries should disseminate aggregate findings to the wider community. An annual report should be produced and be publicly accessible. It should include:

▶ Reference to governance issues, particularly noting any changes to the structure, management and/or practices of the registry;

▶ Activity statements, including changes to data collected and reporting mechanisms and timetable;

▶ Descriptions of links and involvement of the relevant professional organisations;

▶ Summary information about data lodged;

▶ Listings of requests for access and whether they were accepted or declined, with reasons;

▶ Data on major indicator trends without necessarily identifying individual organisations or providers. This should include commentary on interpretation of major findings, and any improvement efforts undertaken as a result of issues identified by the Australian Clinical Quality Registry;

▶ Commentary on the way in which Australian Clinical Quality Registry data are routinely used by local users.

In addition to the publicly released Annual Report, Australian Clinical Quality Registry custodians might consider providing register participants with information about how the register data is being used via public forums and/or distribution of written updates.

Addressing unexplained variance

Australian Clinical Quality Registries must have a formalised process to address quality of care issues. This has previously been described (refer to the *Organisation and governance* section) and needs to include a documented procedure for addressing outliers or occurrences of unexplained variance from noms. Such procedures need to involve the appropriate peak bodies and jurisdictions so as to ensure appropriate corrective actions can be taken in a timely manner.

One recent example is the Proposed Outlier Management Plan developed by the Australian and New Zealand Intensive Care Society (ANZICS) http://sas.anzics.com.au/Portal/backToMain.do

Summary
In reporting output from Australian Clinical Quality Registries, the following principles should be observed: - Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.   - Australian Clinical Quality Registries must report without delay on risk adjusted outcome analyses to institutions and clinicians;   - Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings;   - Local database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care;   - Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.   - Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance.

♦ Resourcing

Australian Clinical Quality Registries can be regarded as long-term data repositories. As such, they must be funded to ensure their sustainability. The Steering Committee should formally assess the resources required for the maintenance of the registry on a scheduled basis. Funding renewal for registries should incorporate a review of their continuing relevance, impact and performance

When considering the funding requirements for registries, consideration must be given to costs associated with:

1. Staffing

   ► Costs associated with training of data collectors, including data entry;

   ► Data processing and coding personnel;

   ► Personnel required to construct and maintain the purpose-built database, including database programmers;

   ► Administrative assistance e.g. to arrange meetings and investigator/ scientific forums and prepare Ethics Committee applications;

   ► Legal consultation to establish Contracts and Funding Agreements.

2. Information technology

   ► Hardware and software costs;

   ► Security provision and database infrastructure.

3. Ensuring data quality

   ► Cost associated with validation and quality checks of data, including case audits. For an Australian Clinical Quality Registry to be well-maintained it requires scheduled data cleaning and quality checks to be performed and for it to be interrogated to assess the usefulness and functionality of the dataset.

4. Disseminating Australian Clinical Quality Registry findings

   ► Costs associated with publishing reports, including the Annual Report;

   ► Data linkage costs;

   ► Provision of specialist skills such as those required to assist with analysing, interpreting data and publishing findings.

Additional funding is usually required to enable specific projects to be implemented using register data. As these projects seed from the Australian Clinical Quality Registry, it is the role of the Steering Committee to ensure that governance structures are maintained.

Summary

When considering the resourcing and funding of registries, the following principle should be observed:

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

Part B: Technical standards

The Technical Standards for Australian Clinical Quality Registries is composed of two sections:

▶ *Architecture Overview* – describes the architecture relevant to Australian Clinical Quality Registries. This includes a discussion of the ideal longer term national e-health environment and how Australian Clinical Quality Registries figure in such a landscape. There is also the shorter term view, also including suggested national infrastructure to enhance the sustainability and efficiency of registries.

▶ *Standards Map* – a listing or mapping of the various technical standards that may be relevant to an Australian Clinical Quality Registry. There is recognition that there may be varying levels of technical sophistication required depending on a given registry's scope and purpose and identifies the different standards that may be applicable for each level.

Part B: Technical standards – Architecture overview

This *Architecture Overview* describes:

▶ the short-term approaches which can realistically be implemented immediately to increase the consistency and value of information stored in clinical registries; and

▶ a longer term vision of a new approach to clinical registries.

The National E-Health Transition Authority (NEHTA) had defined the scope of its work in clinical registries as primarily focusing on high-quality, high-value registries that operate on a national level and have the potential to support the adoption and implementation of NEHTA specifications on a large scale. These national registries are considered likely to grow in number and purpose in the future, and hence steps taken to improve the consistency across registries, in terms of information collected and technologies deployed, are likely to reap future benefits in terms of usability and interoperability.

The proposed new approach would provide significant efficiencies in data collection, accuracy and analysis through elimination of duplication, collection of more complete and accurate data and in increased ability to utilise data for research and statistical analysis.

♦ Infrastructure

This section contains discussion of the following:

▶ NEHTA infrastructure

▶ Clinical registry infrastructure

▶ Application of this Architectural Overview.

NEHTA infrastructure

The National E-Health Transition Authority (NEHTA) was established in July 2005 to set the necessary foundations for the widespread and rapid adoption of e-health across the Australian health sector.

Although electronic exchange of clinical information is already occurring in some areas, significant issues can arise from a lack of standards and agreed ways of working. Accelerating the adoption of information technology within the health sector will require a common set of standards and policies that allow people, organisations and electronic systems to work together – that is, it will require 'interoperability'.

To address this lack of standards generally, NEHTA has developed an overarching e-health interoperability framework. To address the lack of standards for Australian Clinical Quality Registries, NEHTA has developed this Architectural Overview and associated Standards Map.

The interoperability framework provides guidance on identifying and defining key concepts which must be addressed at the organisational, information and technical levels before systems can effectively communicate and interoperate. It also provides the basis for an e-health architecture including identifying e-health requirements, specifying e-health technical approaches through products and technologies, testing conformance to interoperability requirements, value assessment; and change management.

Increased sharing of clinical information will only be acceptable to consumers and clinicians if it occurs within a trusted environment, and so privacy is critical to the success of e-health. NEHTA is committed to developing the national foundations for the electronic exchange of healthcare information in a way that ensures the privacy of individuals' information is appropriately protected. A Privacy Management Framework has been developed to ensure privacy is managed effectively across the entire NEHTA work program. A range of key stakeholders have received this framework positively, in particular privacy regulators and consumer advocates. The Privacy Management Framework will continue to inform, guide and support NEHTA's privacy work.

The following sections provide further details on key NEHTA building blocks and national infrastructure relevant to Australian Clinical Quality Registries.

Unique Healthcare Identifiers (UHI)

The ability to accurately identify healthcare providers, healthcare organisations and individuals who are interacting with the healthcare system, is critical to health IT interoperability. To achieve this end, NEHTA and Medicare Australia are developing both an individual healthcare identifier and a healthcare provider identifier.

(1)   Individual healthcare identifier (IHI)

The IHI service will provide the facility to uniquely identify an individual for healthcare purposes and will link them correctly to their health information.

ⓘ No clinical information will be stored on the IHI record.

The IHI is essential for the safe electronic exchange of patient information, as it ensures that it is accurately attributed to the correct patient. An IHI will be recognized across the entire healthcare sector.

The IHI service will make available both a number and a record of information. The record of information will be divided into three sections – a summary record, an identification record, and a demographic record.

The summary record will contain the minimum number of data fields to enable the matching of an individual to their IHI (e.g., name and date of birth).

The identification record also contains any additional data fields required for the positive identification and association of an individual with their IHI.

The demographic record includes data fields not essential to accurately identify an individual, but which could assist in the provision of quality health care (e.g., an individual's mobile phone number could be part of their demographic record).

Activation of an IHI will occur subject to individual consent. However, an individual's eligibility to receive health services is not affected if an IHI is not activated.

(2)   Healthcare provider identifier (HPI)

The purpose of the HPI is to uniquely identify both healthcare provider *individuals* (eg, general practitioners, pharmacists, pathologists) and healthcare provider *organisations* (eg, hospitals, pharmacies and pathology laboratories). The HPI service provides the ability to verify the provider is registered and authorised, and improve the reliability of manual and electronic communications between providers.

In addition to accurate identification of healthcare providers, there will also be a requirement to authenticate their identity, i.e. to confirm they are who they say they are, in order to support electronic processes such as prescribing which currently requires a paper-based form and signature. NEHTA is proposing a strong authentication system which will be achieved by applying digital identity management approaches.

Clinical information specifications and terminologies

Healthcare practitioners capture and record clinical information about their patients, to provide a history of care for ongoing clinical care and to share with other clinicians involved in the care of the patient. The ability to record the information in a standard and accurate format is critical to the process of its safe exchange. A standard clinical terminology, in conjunction with standard data specifications can provide clinical data with both consistent meaning and context, enabling entry, storage and communication of clinical information in ways that allow it to be safely and consistently reused, retrieved and processed by different software applications.

Through consultation NEHTA has developed a range of structured documents and re-useable data group specifications for use in care delivery. In contrast to the national minimum datasets currently used for statistical reporting, these specifications provide a comprehensive dataset and generic clinical information structure, that is sufficient to support clinical complexity, such as that encountered when reporting results of diagnostic investigations, and which can be specialised or further constrained where required.

In 2005 Australian Health Ministers endorsed NEHTA's recommendation that the Systematised Nomenclature of Medicine, Clinical Terms (SNOMED-CT) should be adopted nationally. SNOMED-CT is a clinical terminology which uniquely identifies clinical concepts and their associated synonyms and relationships. Its purpose is to assist in the care of the patient by providing a consistent language that is both human-readable and computer-processable.

NEHTA has established the national service required to centrally maintain, update and distribute the national clinical terminology and clinical information specifications, including customisation of the terminology to meet Australian needs. Local extensions will be developed in line with the SNOMED-CT standard. Where local variations in terms exist, these will be mapped or linked to the core reference terminology.

Work is in train in Australia and internationally to develop mappings between terminologies and the classifications (such as the International Classification of Diseases) that are used in health statistics.

NEHTA is also working to develop specifications for standard exchange formats (HL7 and/or CDA, as appropriate).

For more information about the clinical information specifications, refer to http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&gid=154&Itemid=139

Individual Electronic Healthcare Record services

The primary purpose of the Individual EHR will be to support the delivery of safer and higher quality health care. The Individual EHR will contribute to this by improving the availability, quality and sharing of selected healthcare information to support clinical decision making. Secondary uses of the Individual EHR include public health and policy planning, and supporting safety initiatives, disease detection, research and education.

Participation in the Individual EHR will be voluntary. The Individual EHR will maintain a longitudinal record of structured healthcare information for participating individuals. The Individual EHR will, with the patient's agreement, be accessible from multiple points of care and will maintain a high standard of privacy and security. The Individual EHR is designed to record key facts about participants (such as current medications, allergies and alerts, problems, etc.) and to make them accessible to all those involved in providing care to the individual. Copies of clinical documents (such as discharge summaries, pathology results, radiology reports and other event summaries) may also be stored and be accessible to authorised users via the Individual EHR services whenever and wherever required.

NEHTA is currently collaborating with Australian, State and Territory Governments to develop a business case for a national approach to Individual EHR, which will be submitted to the Council of Australian Governments (COAG) in 2008. Assuming the business case is adopted, the Individual EHR will be progressively implemented in a number of urban and regional areas over the next five to ten years.

For more information about the Individual EHR, refer to
http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&g
id=130&Itemid=139

Australian Clinical Quality Registry infrastructure

The number of clinical registries in Australia has grown markedly in recent years as has interest in the establishment of new clinical registries to ensure quality in the provision of health care. To date there is no single standard or shared methodology for the development, establishment and ongoing management of clinical registries. Clinical registries in Australia vary in their purpose, design, scale, and scope and as such there is little continuity in their design.

The *Architecture Overview* and *Technical Standards* recommended by NEHTA will have varying degrees of application at different stages of development, dependent on the maturity of each individual registry. For example, a small local registry with a paper-based data collection entered into a Microsoft Excel or Microsoft Access database in a non-networked computer will have very different needs to a large international registry that uses a browser-based user interface to collect information and electronically cross-checks information for validity in real time with external data collections.

To enable those individuals and agencies responsible for clinical registries to easily navigate the architecture and standards developed by NEHTA and determine their applicability registries have been divided into four registry types (Figure 9). These types have been determined by the level of technology utilised in the collection, storage, cleansing, quality checking, analysis and reporting of data. Australia currently has registries representative of all four types. These are as follows:

1. Level 1: Stand-alone registry.

▶ Paper-based submission of data to the registry; and

▶ Data entry into a stand-alone computer system for analysis and reporting.

2. Level 2: Web-based submission of data into the registry.

▶ Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting.

3. Level 3: Web-based submission of data into the registry and electronic cross-checking of data or linkage of data with an external system.

▶ Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting; and

▶ Cross-checks data with external sources for validity (either in real time or after data entry), or

▶ links with external systems to link data.

4. Level 4: All level 3 plus automatic data collection from local clinical systems.

▶ Local clinical system is the primary vehicle for data collection, relevant data is either automatically sent or prompted to be sent to the relevant registries.
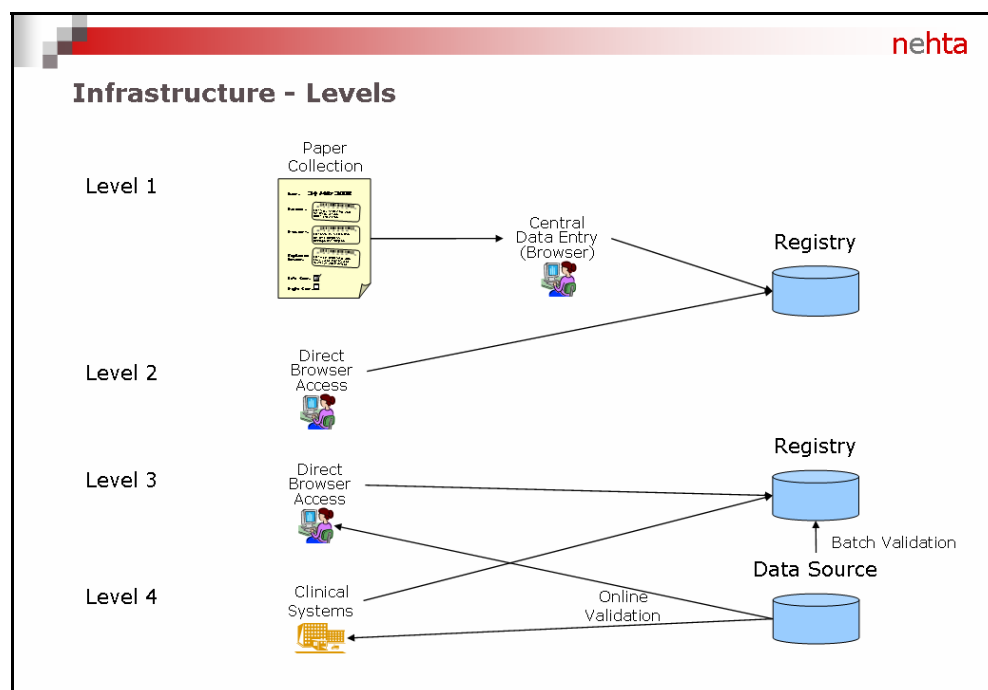

Figure 9. Registry categories

Application of *Architecture Overview*

Application of the architecture to clinical registries is expected to occur over time. NEHTA has developed both a short-term and a medium to long-term architecture to accommodate the Australian Clinical Quality Registries timelines and to account for the varying levels of technical maturity for Australian clinical registries.

The short-term architecture recommends the creation of a common registry portal and applying a more standards-based approach to the individual registries with technology choices and design that will migrate to a better interconnected e-Health system in the future. The level of technical maturity achieved by a clinical registry will determine the extent to which the standards will need to be applied. Although some registries in Australia are quite technically mature and may be classified as Level 4, the recommended short term architecture is independent of the individual registries and can be applied to all levels.

The medium to long-term architectural vision would cater for clinical registries at all levels and is intended to prompt thinking and discussion about the way clinical registries operate and the long-term goals of registries in an ideal environment.

It would be unrealistic to attempt this scale of change for all registries in the short term. The proposed short-term architecture has been specifically designed to be realistic in the short term but allowing migration to the longer term vision. The short-term architecture acknowledges the fact that currently clinical registries often begin as a small stand-alone database and develop into large, highly sophisticated systems. Some of the more mature registries may be ready to adopt additional aspects of the longer term architecture sooner, and could look to leverage components of the national e-health infrastructure as they become available.

◆ Short-term architecture

This section proposes the first steps in changing the approach taken to clinical registries. It is designed to be achievable in the short term. The aim is to make improvements where possible in a way that allows subsequent progression in the direction of the vision.

The longer term vision is characterised as a national approach supported by national infrastructure that:

1. assembles the many different registries together under a consistent portal for the convenience of individual providers; and

2. applies a standards-based discipline to improve sustainability.

The short-term architecture recommends a National Portal providing a very basic, and therefore achievable, directory of registries. This national infrastructure is a place holder where the more sophisticated functions of the vision can be added over time.

The short-term architecture also recommends applying a more standards-based approach to the individual registries with technology choices and design that will migrate to a better interconnected e-Health system in the future.

Constraints

In Australia clinical registries have been established in a variety of health care settings for a range of purposes over time. This has resulted in a large number of registries that have differing organisational, informational and technical processes. These variations constrain what can be immediately achieved through implementation of the short-term architecture.

The following are the main constraints that determine what may be achievable in the short to medium term:

▶ National registries currently lack a shared national infrastructure and standards that would enable them to harness benefits emerging from the implementation of e-health. The main issue in temporarily filling the gaps is to ensure it is done in a way that can be migrated to the national infrastructure in the future. Note some of this national infrastructure will be provided through the NEHTA work program – of particular relevance is the NEHTA work on identifiers, data specifications and terminologies.

▶ The current approach to achieving direct system interfaces between the source, capture systems and the registry systems is costly and unlikely to be sustainable in the long term. Establishment of these interfaces is on a point by point basis and the stability of the systems and the quality of the data capture (mainly due to static, non-extensible software and unconstrained user interfaces) causes significant operational overhead. Again, NEHTA's current work on web services and secure connectivity is of relevance and may provide alternative mechanisms for connectivity.

▶ Web browser user interfaces generate double data entry environments.

Browser user interfaces are only better than paper-based systems as the quantity and complexity of data capture increases. For very simple data capture sticky printed labels (found in abundance in hospital settings) containing most of the relevant details and stuck on a paper form along with marking some checkboxes can literally take a few seconds to complete. This process leads to high quality data capture with minimal error. With barcode scanners this efficiency and quality can also be achieved at the point of central data entry into the system.

Browser user interfaces can improve data quality as the data capture is closer to the proximity and time of the event. It is, however, much harder for central data entry staff to clarify and/or correct data captured on paper forms (kilometres away and/or weeks ago).

Browser user interfaces generally require compensation to offset the overhead imposed in a clinical setting. This compensation could be business value, additional resources, monetary, etc.

National infrastructure

The national infrastructure envisioned by NEHTA includes:

► a national portal for Australian Clinical Quality Registries

► e-health infrastructure elements that NEHTA is developing that are relevant to Australian Clinical Quality Registries.

National registries portal

A directory of registries is a new element of infrastructure recommended by NEHTA. It will act as a single point of contact between the individual providers and the national registries. The directory (Figure 10) would be set up as a National Portal or website which provides basic details and links as a convenience for individual providers and would be a reliable mechanism to expose the existence of registries to the individual providers who perform the critical task of data capture.

Individual providers would go to the National Portal to:

1. Determine what registries may be appropriate for a particular care event.

2. Review provider participation and patient consent requirements.

3. Review the required data capture and download the latest printable forms.

4. Navigate to the individual portal of any registry.
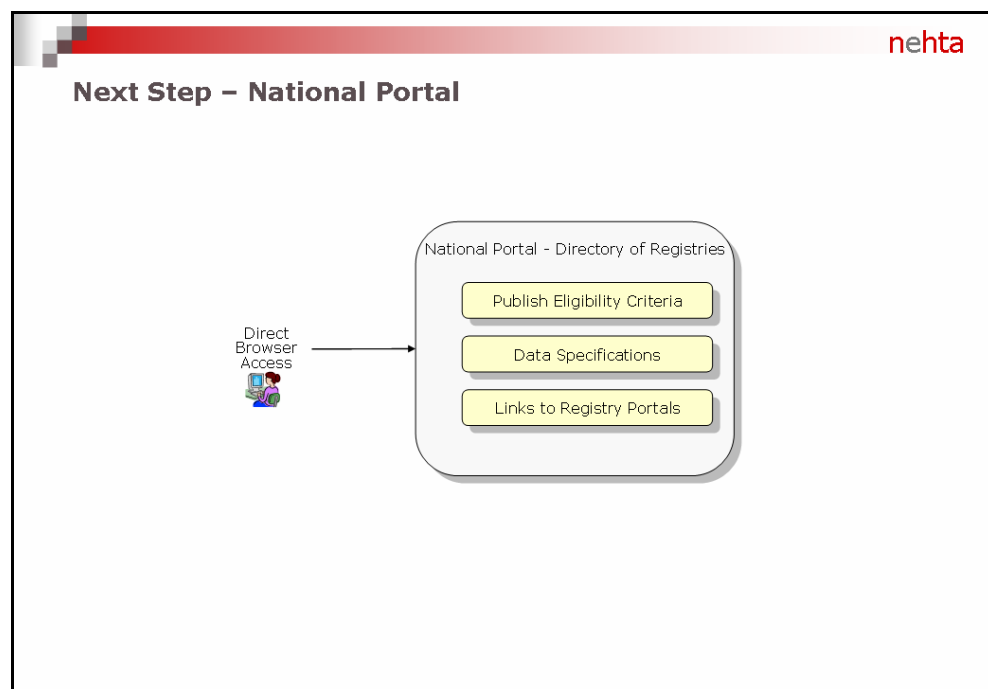

Figure 10. National registries portal

NEHTA suggest that this is a key element of the short-term architecture. However, it is not funded as part of NEHTA's work program, and a relevant body would need to seek funding for its establishment.

NEHTA infrastructure

Other elements of the short-term architecture are already planned as part of national infrastructure development through the existing NEHTA work program. In particular, the following national infrastructure services are scheduled to come on-line by the end of 2010, and should be leveraged to provide short to medium term value for registries:

► Individual Healthcare Identifier (IHI)

► Healthcare Professional Identifier – Individual (HPI-I)

► Healthcare Professional Identifier – Organisation (HPI-O)

► National Product Catalogue (NPC)

► Clinical Terminologies (SNOMED/AMT) and Data Specifications

► NEHTA Standards Catalogue.

Each of these areas has published recommended standards that can be used in system design and development to ensure compatibility with the national infrastructure and alignment to the NEHTA direction. *Part B: Technical standards – Standards Map* lists the applicable standards in each of these areas along with specific usage criteria for Australian Clinical Quality Registries.

Regardless of whether data capture is paper or electronic-based, the use of these data sources as soon as possible will increase the efficiency and effectiveness of registry data capture and analysis.

Data capture

There are three major options for data capture:

► Paper collection;

► Direct entry into a registry portal via electronic form; and

► Direct entry into CIS and integrated simultaneous (or near real-time) update of registry portal.

Some existing registries allow contributors to submit data using one of a number of methods. There is also an option for batch update from the local clinical system to the registry. However, this approach can lead to difficulties associated with lack of standardisation and delayed submission. Some registries have also developed data collection and submission software for local data providers to use. Such systems can be useful in incorporating data entry validation and quality checks while also ensuring standardised collection and submission of data. However, such an approach can be expensive and time-consuming and may only be effective in complex areas where large-scale *de novo* collection of data is necessary.

One of the key issues facing registries today is to ensure that data captured by any of these methods is consistent. Collection fields on paper and electronic forms need to be consistent. Data fields and specifications used for registry design should be consistent with the emerging standards for data entry into other clinical information systems and electronic health records systems. These standards are being developed by NEHTA and include the use of agreed data specifications and clinical terminologies (SNOMED CT). Although they will align with the existing data standards, minimum data sets (NMDS) and classifications (such as ICD10) recommended by the Australian Institute of Health and Welfare (AIHW) for statistical data sets wherever possible, there may be differences, because data used for clinical care is more extensive and granular than data used for 'secondary purposes'. NEHTA and AIHW are undertaking work in this area to explain the distinctions, and appropriate use of these standards.

For the short term, paper capture of registry data at the point of care may still be the preferred and/or optimal method for data collection in certain cases. NEHTA is not recommending that wholesale change to electronic capture is the best approach in the short term, and the short-term architecture for registries includes paper capture as well as browser capture for data. Integrated data capture through clinical systems at the point of care is unlikely to be achievable in many cases until the introduction of more sophisticated systems within hospitals and community practices is further advanced. Registries need to be vigilant for opportunities for direct capture, as opportunities need to be assessed and included early in the design or implementation phases of new IT system roll-outs.

The most appropriate method will depend on the quantity and type of data captured for the registry, but in any case there is expected to be local preferences and constraints that will lead to use of the sub-optimal method and so it is proposed that both paper capture and electronic capture are made available, at least in the short to medium term.

The architecture also allows for direct system to system connectivity. As more sophisticated clinical systems are implemented in the health sector in the coming years, these systems will be expected to communicate seamlessly, and the NEHTA work on the Individual EHR will pave the way for this improvement in interoperability. But in the short term, system to system connectivity is expected to be problematic due to the lack of standards and the (in)flexibility of the local clinical systems. There are a few existing examples of data capture applications with a high degree of context sensitive validation which are already providing a valuable direct data source for registries (such as the AORTIC application developed by ANZICS). However, in general, direct system to system connectivity is hampered by the lack of clear, agreed business processes for exchange of information, the lack of adherence to national information standards, and the delays imposed by batch submission of data to the registry which can lead to a number of practical difficulties for data quality and completeness.

System to system connectivity is more easily achieved at a micro level, where data is then aggregated up to a macro level. Unfortunately, in Australia clinical registries currently do not have consistent organisational governance structures to allow effective and efficient national aggregation of multiple repositories. It is hoped that national collaboration to establish an Individual EHR will need to address and answer many of these issues – including development and assessing compliance with required standards.

As shown in Figure 11, the optimal use of paper-based capture involves a smaller number of simple data fields that can be barcoded and scanned. This method is especially attractive where the content can be obtained from sticky labels (as commonly used in hospitals). The labels make capture at the point of care extremely efficient and accurate. The use of barcodes makes central data entry also efficient and accurate.
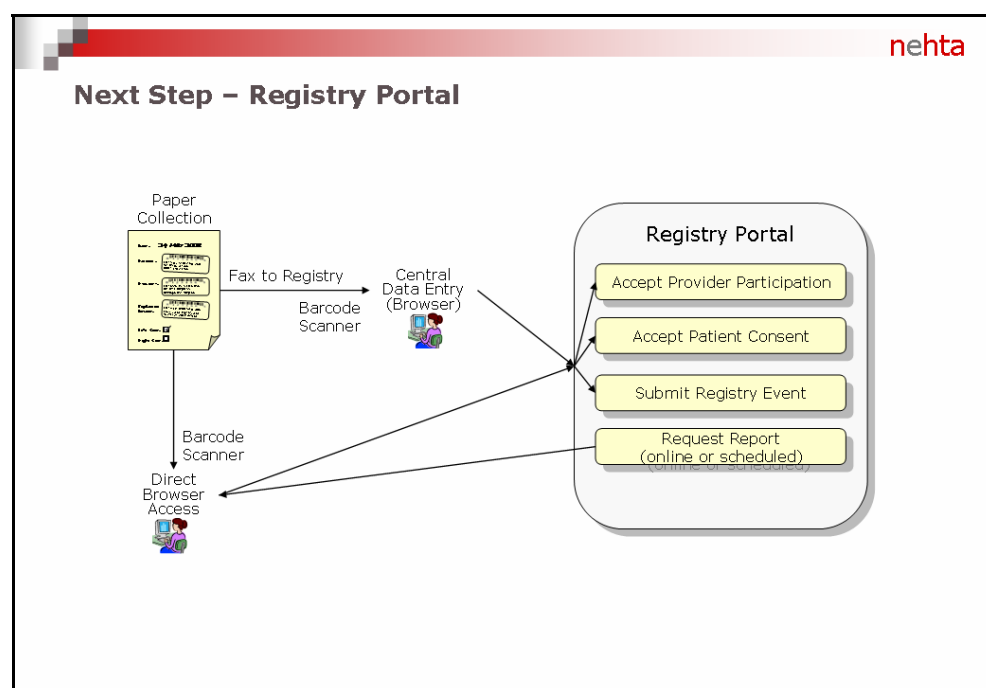
Figure 11. Paper-based data capture

Where the data set involves a larger number of complicated fields, direct browser entry via a web-form at the point of care is expected to be the preferred method unless level 4 integration with the local clinical system can be achieved. This is particularly preferred as identification and correction of errors can be performed within the context (timeframe, staff and location) of the care event. Correcting errors at this point (as opposed to a week later at a central facility in another city by data entry staff) is far more efficient and successful.

The major draw back of the direct data entry is the overhead imposed in the care setting. Use of barcode scanning will also provide benefit during direct browser entry.

National registries portal

A directory of registries is a new element of infrastructure recommended by NEHTA. It will act as a single point of contact between the individual providers and the national registries. The directory would be set up as a National Portal or website which provides basic details and links as a convenience for individual providers and would be a reliable mechanism to expose the existence of registries to the individual providers who perform the critical task of data capture. The following sections provide further details.

Provider participation

Individual providers will need to identify themselves and agree to the terms and conditions of participating in a registry. This function will accept provider credentials, record their agreement and enable access to the registry.

Longer term, it will be ideal if the HPI was used to identify the individual providers and the National Identity Management infrastructure was used to validate their credentials.

In the short term, a number of local identifiers will need to be supported and demographics collected. Medicare Australia certificates could be used to authenticate individual providers for the purposes of registration and also subsequent logins. Alternatively, there may need to be a manual step to authenticate the identity of individual providers during registration.

To enable transition from the short term to the use of the HPI, it is important that multiple identifiers (such as a hospital identification number and others numbers, such as Medicare or Veterans Affairs number) are supported for a single individual provider. Not only will this help manage the many disparate identifiers in use today, it will allow the addition of the HPI more readily when it becomes available. The demographics collected should also align to the minimum needed by the HPI service to perform a unique search. For further information on minimum standards for identifiers, refer to *Part B: Technical standards – Standards Map*.

To assist with maintaining unique identifiers, the local identifiers will support the addition of a namespace prefix. Once an identifier is associated with an individual provider, it can be used to identify the provider to any of the registry functions.

The individual provider will be supplied with login credentials to access the registry functions. Once the Identity Management infrastructure is in place, these registry specific credentials can be retired and the national credentials used to access all registries.

Patient consent

Individual providers will be responsible for gaining and recording patient consent. This process may also record the identity of the patient. This process would be supported either via paper or directly via the browser.

Longer term, it will be ideal if the IHI was used to identify the patient, thereby allowing confidence in the aggregation of longitudinal patient-centric data to maintain currency of the required data and/or to collect outcome data.

In the short term, each register will need to allocate a new patient identifier and support the searching functions to allow providers to find existing patient identifiers to reduce duplicates.

The registry will need to support the use of multiple identifiers, qualified with a namespace to allow linkage between other data sources and to simplify inclusion of unique identifier when it becomes available.

To support patient privacy, the identifiers kept in the registry may point to an independent external party that is custodian of linkages to other data sources. This may also apply for linkage to the IHI for certain de-identified registries.

Registry events

Individual providers will be responsible for collecting the required registry data. Assuming consent has been confirmed and/or gained, this will involve filling out the data as specified by the registry, either via paper or direct browser entry.

Over time, all captured data should be captured and coded in a standardised fashion according to national standards i.e. with agreed terminology (SNOMED/AMT) being used to populate standardised data sets (NEHTA data specifications, AIHW, etc.). For further details refer to *Part B: Technical standards – Standards Map*.

The data which relates to an entity should also be identified via a standardised unique identifier, including identifying the Individual Providers involved (HPI), the Patient (IHI), and the products used (NPC).

In the short term, each register will need to publish (via the National Registry Portal) a comprehensive guide to encourage individual providers to collect consistent and coded data. The guide will need to contain clear descriptions of each field, unambiguous definitions of the data values, and a list of the applicable codes.

The difficulty in transitioning to use national standards is that the transition will impact the historical integrity of the existing data captured. This is generally handled by conversion of historical data, generic real-time mapping from older versions to the current version, or a combination of both. All approaches can introduce errors and all approaches impact on the resource usage/profile of the system. Early adoption of these standards, specifically SNOMED, AMT, NPC, and the data specifications, while increasing short-term cost and requiring fine tuning, would reduce the potential disturbance at some point in the future.

Report requests

Individual providers will need convenient access to information derived from their data capture efforts. Registries should optimally support:

▶ Online requests for reports which are returned to the provider while they wait.

▶ Scheduled reports to be generated periodically and automatically sent to the provider.

The available reports will need to include two types of reports:

1. Reports that contain analysis of the data contributed by the individual provider (requester). These reports may contain identified data.

2. Reports that compare aggregated data (e.g., benchmarks) between the individual provider (requester), peer groups, regions (e.g., states) and nationally (or even internationally).

Reports will need to support some customisation, via the collection of pre-determined parameters that are used to generate the report. Typically these parameters will be report-specific and include, date ranges, filter criteria, and sort criteria.

For further details about reporting, refer to *Part A: Operating Principles*.

Design considerations

The following sections describe some of the design considerations that should be borne in mind when developing a registry.

Authentication

The short-term architecture does not address the issues around consistent login credentials for access to the registries. Each registry has the potential to issue the individual provider with a separate set of credentials. At a minimum each registry should allow individual providers to select their own passwords, PIN codes, etc so they can achieve some consistency between registries. In addition, assuming multiple identifiers are supported for all registries, the individual provider may be able to use one of their identifiers consistently across all of them, until they have a HPI.

It is also expected that individual providers will need to authenticate themselves multiple times throughout their day and from multiple locations. When multiplied across multiple registries and taking into account the many local systems they are required to access, this may create an unreasonable burden. A distributed approach to authentication could be considered which allows individual providers to gain a token that can be re-used until it expires. The OpenID framework is recommended for this purpose.

Secure messaging

Most interactions with a registry contain private information. These interactions need to be protected from intercept, access and modification. It is expected that the NEHTA Secure Messaging standards will be applied for all interactions between individual providers and the registries.

Application tiers

As shown in Figure 11, whether the individual provider is using paper or a browser, the data entry, and interaction with the system is likely to be via a browser. The user interface tier is likely to be via a web application user interface framework.

It is recommended that the user interface tier be built on top of a middle tier of web services. The web services would conform to the NEHTA Secure Messaging standard. The main advantage is that this middle tier supports the transition to direct connections with other systems, as shown in Figure 12.

It is expected that the database tier is based on a Relational Database Management System (RDBMS) product with access via Structured Query Language (SQL). However, irrespective of the product used, the key functionality is the ability to inter-connect.
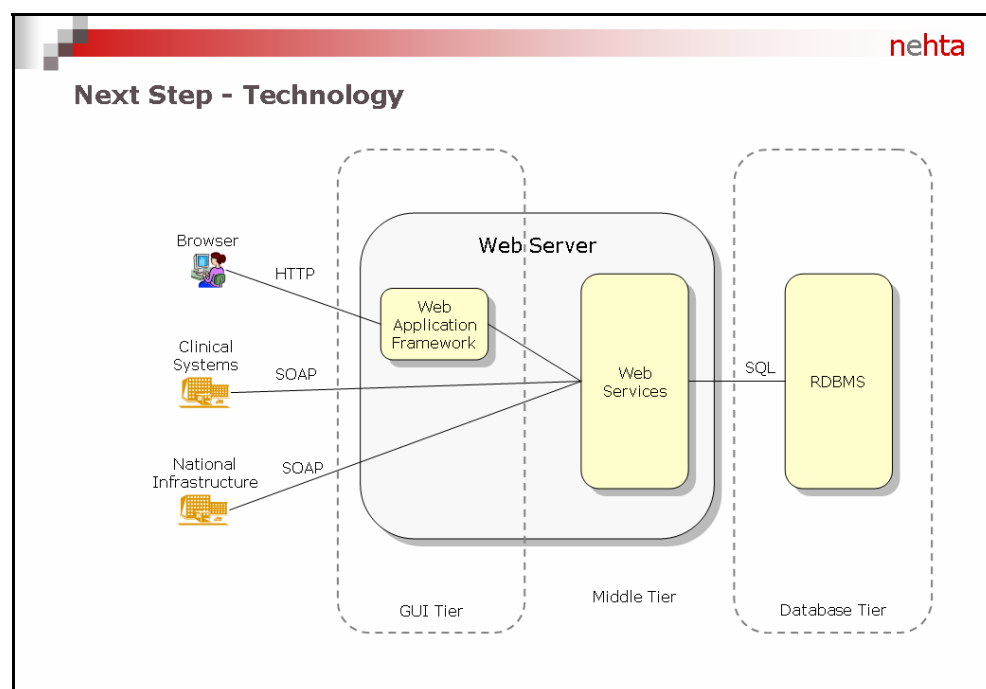

Figure 12. Application tiers

It is possible that other channels may also be used, such as mobile devices, thick client over web services, integration with third-party applications, etc. The architecture will need to be flexible enough to support evolution of interfaces.

♦ Long-term architectural vision

This section is intended to prompt thinking about the way clinical registries operate and the long-term goals of registries in an ideal environment. It is recognised that such a vision may not be achieved. It is unrealistic to attempt this scale of change in the short term. The proposed short-term architecture has been specifically designed to be realistic in the short term, but to also allow for migration to the longer term vision described in this section.

Business issues

NEHTA has identified that the two main business issues related to architecture currently facing clinical registries in Australia are:

1. Duplicate recording of clinical data (both for local use at point of care and separate capture repeated potentially across multiple registries) increases data captures errors and is resource intensive requiring skilled staff and their time.

2. The current system relies on the registry knowledge of each individual clinician that can lead to under-reporting or inappropriate reporting.

Vision overview

The long-term architecture vision (Figure 13) is specifically designed to tackle both of the identified business issues.
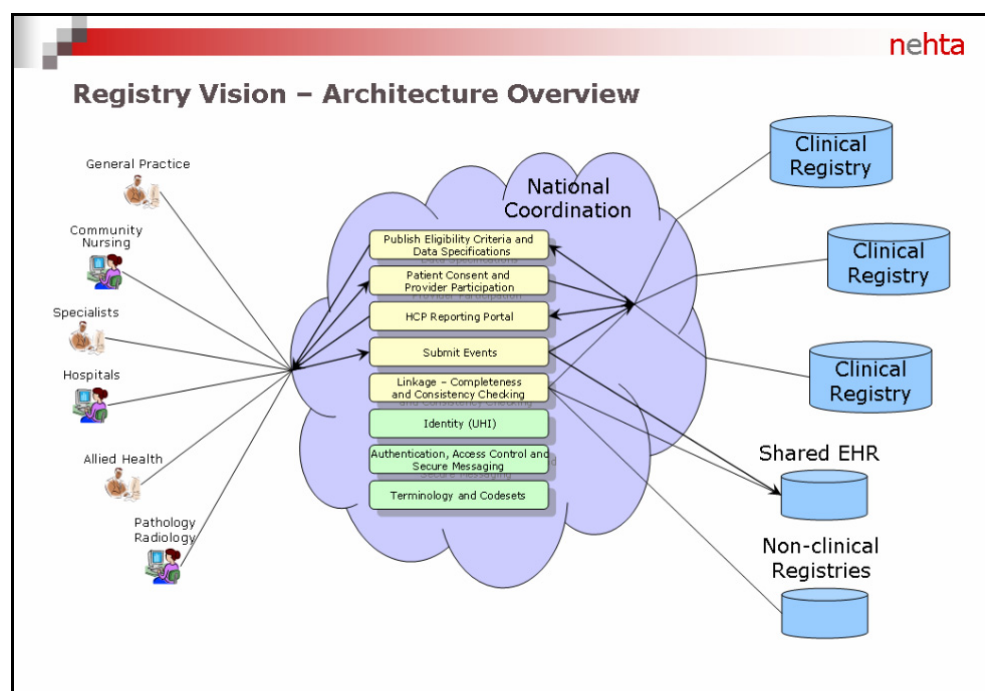

Figure 13. Long-term architecture overview

In Figure 13, the national infrastructure connects the individual providers, shown on the left, with the clinical registries, shown on the right. The national coordination components are logically central and represent central management of the functions. It is this central nature that addresses the first business issue of appropriately connecting the individual providers nationally with the many registries.

This, however, does not mean that the national coordination components all physically sit on a single national server. Ideally, selected components of the national infrastructure would be implemented in a distributed fashion.

The individual providers will use local clinical systems to perform the normal clinical data entry as required by the primary task of providing care to the patient. It will be the responsibility of these systems to prompt the individual providers when an event of patient care qualifies for entry into a registry (this may be the first defining registry event or follow-up to obtain outcome information). It will also be the responsibility of these systems to prompt the individual providers in an efficient manner to obtain any necessary consent and capture the necessary clinical data to be submitted into the registry. This addresses the guiding principle to minimise the impact on individual providers and automate tasks.

The clinical registries, shown on the right, would all interface with the national infrastructure, providing by default a consistent, single point of access. The national infrastructure will also support a standards-based approach to the implementation and management of the registries.

It is assumed here that registries will remain separate, purpose-built information stores. Registries may also gather data from many sources, including administrative datasets, the Individual EHR and non-clinical registries. There could be the capacity for a registry to notify the Individual EHR when the Individual EHR is missing data that may be uncovered during the consistency check processing. The submit processing may also copy registry events to the Individual EHR.

If analysis highlights that additional information is required, the registry can be augmented to store the additional information permanently or temporarily link to it from another source.

The following sections provide a more detailed description of the proposed national infrastructure components.

Eligibility criteria and data specifications

The primary responsibility of this component will be to publish and maintain the eligibility criteria and data specifications for each registry to the local clinical systems (Figure 14).

The eligibility criteria will be in a computer-processable form and will allow automated assessment of a patient event. Determination of whether any data needs to be captured for any of the registries will be based on:

▶ the individual provider and their role (for example either the treating provider or the pathologist reports the event – not both);

▶ the patient (for example demographics); and
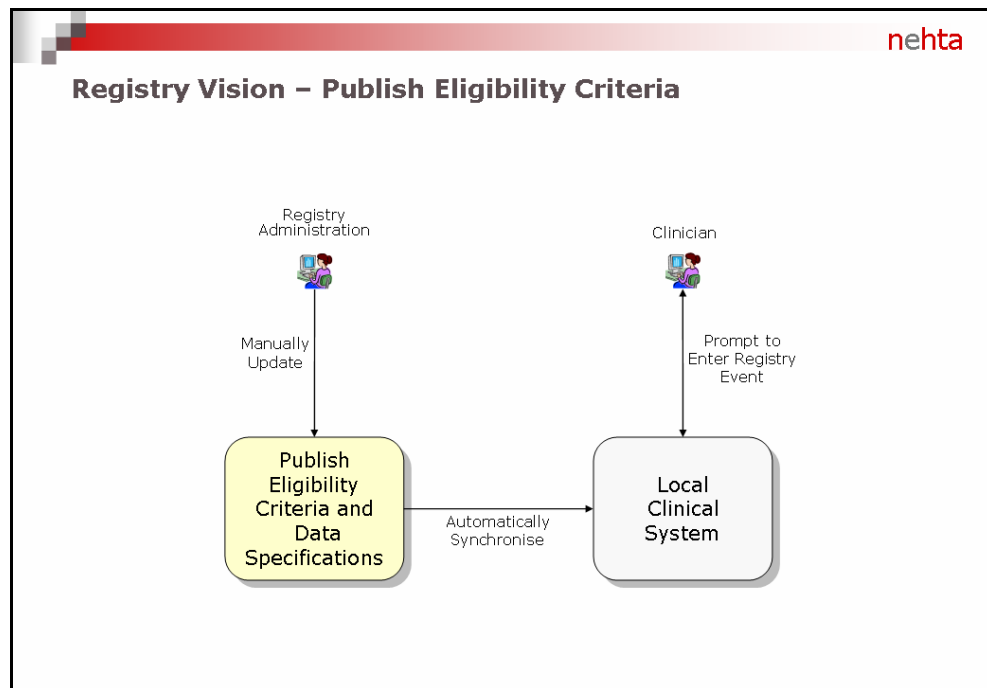
▶ the clinical event.

Figure 14. Long-term architecture – Publish eligibility criteria

Each registry entity will be responsible for maintaining the eligibility criteria and data specifications in this component. It is expected that this would be a manual task. Local clinical systems will automatically synchronise with this component to receive any updates.

The local clinical systems will automatically process each patient event (in real time) to determine if the event has registry implications. The local clinical system will notify the individual provider of the candidate registries that a patient event qualifies for. The local clinical system will then assist the individual provider to satisfy the registry requirements. This would include:

▶ Pre-filling the patient and individual provider demographic details required;

▶ Prompting the individual provider to collect the appropriate consent;

▶ Pre-filling any clinical data required from the data already captured;

▶ Prompting the individual provider to collect any clinical data gaps required by the data specifications for the registry; and

▶ If the registry was mandatory and the required data has already been captured, the local clinical system may be able to fulfil all the registry requirements without even interrupting the individual providers (workflow or attention).

Patient consent and provider participation

This component is responsible for ensuring the patient consent and participation of providers for each registry is recorded in a secure, consistent and appropriate way. This component will provide a centralised function that brokers the registration of patient consent and provider participation on behalf of each registry. The final acceptance of each request will be the sole responsibility of each individual registry (Figure 15).
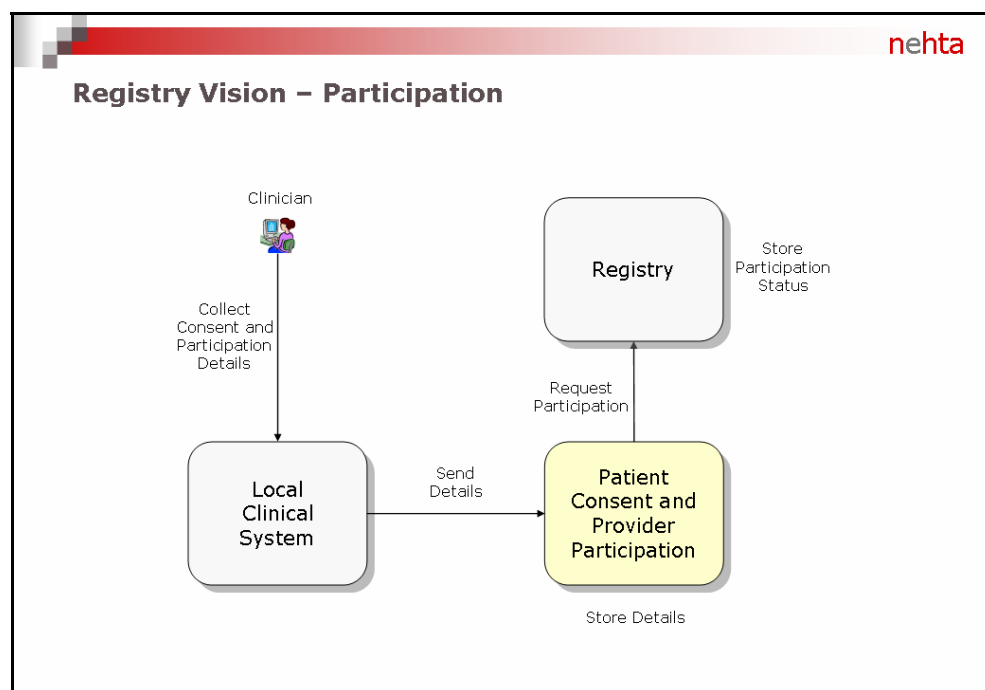
Figure 15. Long-term architecture – Participation

The persistent storage of the record of consent/participation will be the joint responsibility of this component and each registry. This component will be the master record of the patient wishes/provider agreements and the registries will be the master of what they have individually accepted.

The local clinical systems will forward the collected consent/participation details to this central component which will provide authentication, audit, pre-qualification of conditions and non-repudiation services for the request providing proof of the data's origin and integrity. Successful requests to participate are then forwarded to the relevant registries for acceptance.

Submitting events

This component is responsible for providing authentication, audit and non-repudiation services and accepting (from the local clinical system) the required data to submit into a registry. The submission is forwarded to the relevant registries for acceptance (Figure 16).

This component will not retain any data other than an audit trail. The registries are solely responsible for storing the clinical data.
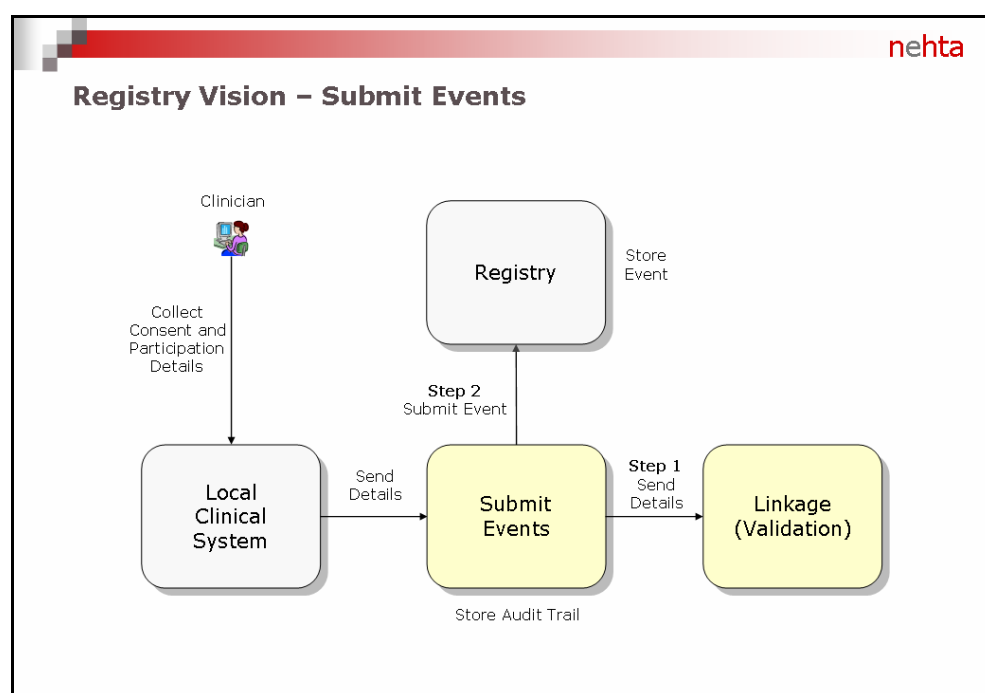
Figure 16. Long-term architecture – Event submission

This component will be distributed close to the data source end points. Submission will be directly to the registries and will not go through a central hub. The component may be implemented directly in local clinical systems or as part of the common infrastructure along side the local clinical systems.

Reporting

This component is responsible for providing a central point of access to the reporting capabilities of each registry. It will present a list of the applicable registries (that is those where the provider is registered) and provide authentication services. This provides convenient access to all the reports available to an individual provider (Figure 17).

Figure 17. Long-term architecture – Reporting

Users will be able to request a report online or schedule reports to be sent to them. Online reporting will allow selection from the available reports, parameters, and output format. Scheduled reporting will allow selection from the available reports, parameters, preset frequencies (for example, weekly) and destination email address where the report will be sent.

This component is not responsible for executing the reports, the request for a report is sent directly to the registry and the response is returned directly to the user from that registry.

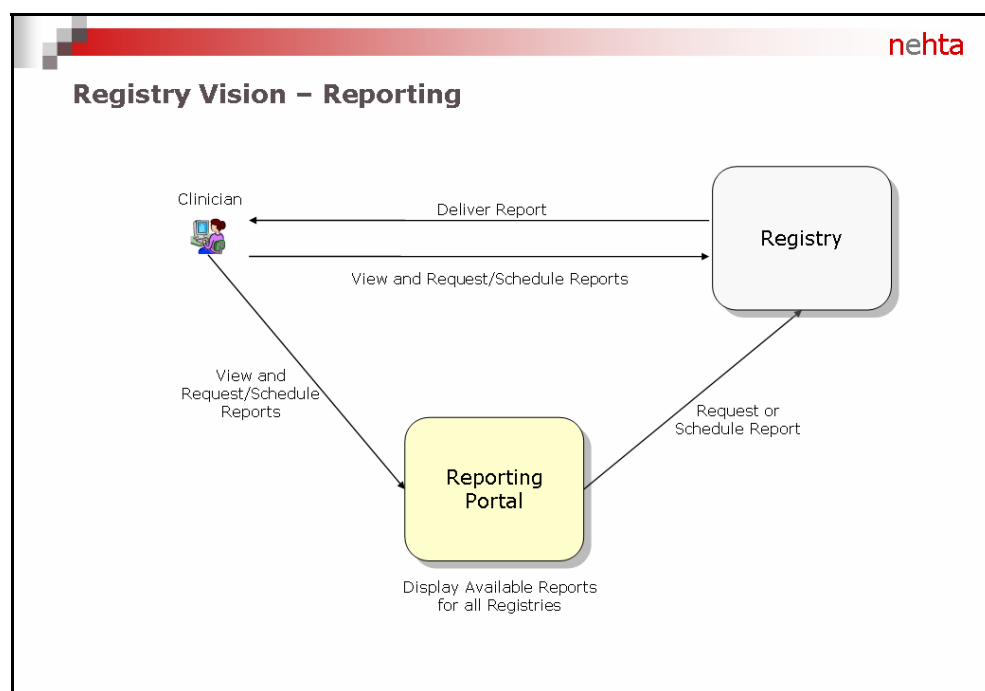Where a registry has its own reporting portal, the user may be referred directly to it. In this case the user would then interact directly with the registry's own reporting portal and this component would simply be a single access or referral point.

It is expected that only the results of the reports will be accessible to the users and that they will not be able to access raw data. It is also expected that they will not only be able to print the reports, but they will be able to receive the results in a number of different formats (CSV, XML, MS Access, etc.).

Linkage for checking consistency and completion

This component is responsible for improving the quality of the registry content. It will provide data consistency and quality checking by comparing data in the clinical registries with each other and the following external sources, as shown in Figure 18:

▶ other registries (i.e., Births, Deaths and Marriages, National Death Index);

▶ the Individual EHR; and

▶ other sources of clinical and administrative data.
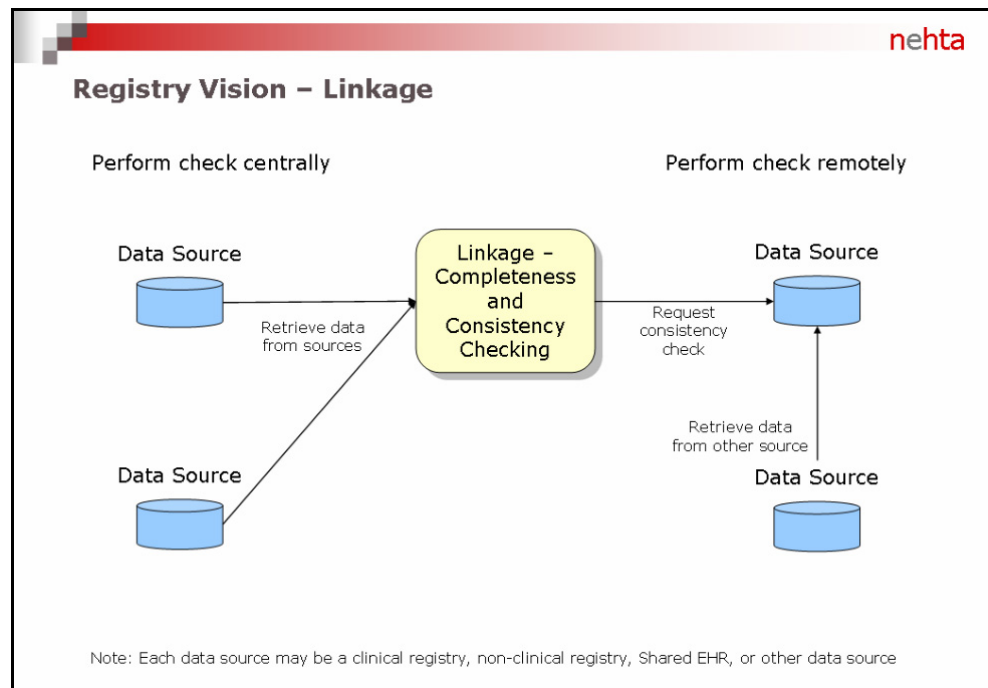
Figure 18. Long-term architecture – Checking linkages

This checking will be specific to each pair of compared data sources, for both the method of access to the data and the logic required to validate the consistency. Checking will occur both before and after submitting data to a registry.

Ideally, checking would be performed during data capture, or immediately before the event is actually submitted to a registry. This provides timely feedback to the provider while they are still able to efficiently correct any errors.

This component would be notified of the entered data and would then trigger a number of cross checks with other data sources. The logic may be executed centrally by this component or delegated to services provided by the registries themselves.

Any inconsistencies would ideally be sent back to the provider during data entry. For example, the identity of the patient is incorrectly entered and the provider is immediately notified that the identity specified is known to be deceased. The provider can correct the mistake before it even makes it to the registry.

It is important to ensure that data entry is not delayed if the consistency checks are not possible or can not be completed in time. This would normally imply that the checking is performed asynchronously.

Certain cross checking will need to be done in bulk/batch mode, where a large quantity of records is checked one-by-one against another set of records. In some cases full database scans may be required that would need the local registry infrastructure to execute the query and checking logic.

This type of cross checking would be scheduled in off-peak times and would not form part of the data entry process. For example, checking all the procedures performed in the last six months from a clinical registry against a payment database.

Linkage can also be used to check completeness of data held in the registry or to upload identified information into a registry. For example, an outcome registry that records information from multiple providers may benefit from uploading of certain identified data fields from a single point of collection such as the Individual EHR, as opposed to uploading duplicate data provided by multiple clinicians via a web upload or other type of submission.

Unique Healthcare Identifier

This component will be nationally provided infrastructure (independent of the registry infrastructure) to support the allocation of a unique identification number for all patients, individual health care providers and healthcare organisations.

The other components would use the Unique Healthcare Identifier (UHI) services to find the unique identifier for patients and health care providers and then use these identifiers internally to register providers and capture data against the correct patient.

For further information on UHI Services please refer to the NEHTA website: http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&gid=153&Itemid=139

Authentication, access control and secure messaging

This component will be nationally provided infrastructure (independent of the registry infrastructure) to protect the security of the systems and exchanges of information. Services provided will allow authentication of users, assignment of privileges, and support to communicate clinical data between organisations and systems so that it cannot be tampered with or viewed along the way. The latter relates to Secure Messaging which will include a number of standards that are applied to the development of the interfaces.

An important part of electronic communications is that, in order to communicate with others you require knowledge of which parties and services are available for communication. All the services provided by the national infrastructure and each registry would be published in a Service Instance Directory (SID). This will be provided by this component.

The other components would use these services and apply the required standards to make sure only authorised Providers can contribute protected data about their identified Patients. In addition, Providers will only be able access data they have been authorised to access.

For further information on Identity Management please refer to the NEHTA website: http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&gid=152&Itemid=139

For further information on Secure Messaging please refer to the NEHTA website:
http://www.nehta.gov.au/index.php?option=com_docman&task=doc_view&gid=104&Itemid=139

Clinical communication

This component will be nationally provided infrastructure (independent of the registry infrastructure) to support the capture of clinical and product data in an unambiguous way.

In order to achieve interoperability, the use of structured data specifications, standardised terminology and codesets will ensure that clinical content from any of the data sources can be understood accurately by any of the providers and enable computer systems to understand and compare the content. This will require application and integration of data standards from numerous sources such as NEHTA (SNOMED CT, Clinical Information Data Standards), AIHW (National Health Data Dictionary).

Using a standardised National Product Catalogue (NPC) for medical product identification will ensure that the identification of products used in health care is associated with clinical context and individuals. This supports detection of faulty designs and batches due to outcome analysis and the identification of affected Individuals.

The other components would use these services to make sure the clinical and product data is captured and stored in a standardised way that can be later analysed as required without error.

For further information on Clinical Communication please refer to the NEHTA website:
http://www.nehta.gov.au/index.php?option=com_docman&task=cat_view&gid=154&Itemid=139

Part B: Technical standards – Standards Map

The Standards Map lists standards that those developing and implementing an Australian Clinical Quality Registry should be cognizant of. It is not intended as a proscriptive list of standards that every registry must comply with. Given the scope and purpose of a given Australian Clinical Quality Registry a varying subset of these standards may be relevant.

ⓘ The standards listed here are current at the time of writing. It is recommended that you check the current status, and version where applicable, for any given standard.

♦ Overview

The number of clinical registries in Australia has grown markedly in recent years as has interest in the establishment of new clinical registries to ensure quality in the provision of health care. To date there is no single standard or shared methodology for the development, establishment and ongoing management of clinical registries. Clinical registries in Australia vary in their purpose, design, scale, and scope and as such there is little continuity in their design.

The *Architecture Overview* and *Technical Standards* recommended by NEHTA will have varying degrees of application at different stages of development, dependent on the maturity of each individual registry. For example, a small local registry with a paper-based data collection entered into a Microsoft Excel or Microsoft Access database in a non-networked computer will have very different needs to a large international registry that uses a browser-based user interface to collect information and electronically cross-checks information for validity in real time with external data collections.

To enable those individuals and agencies responsible for clinical registries to easily navigate the architecture and standards developed by NEHTA and determine their applicability registries have been divided into four registry types (Figure 9). These types have been determined by the level of technology utilised in the collection, storage, cleansing, quality checking, analysis and reporting of data. Australia currently has registries representative of all four types. These are as follows:

1. Level 1: Stand-alone registry.

▶ Paper-based submission of data to the registry; and

▶ Data entry into a stand-alone computer system for analysis and reporting.

2. Level 2: Web-based submission of data into the registry.

▶ Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting.

3. Level 3: Web-based submission of data into the registry and electronic cross-checking of data or linkage of data with an external system.

▶ Allows some or all contributors to submit data to the registry electronically via web browser user interface, this may be combined with paper-based reporting; and

▶ Cross-checks data with external sources for validity (either in real time or after data entry), or

▶ links with external systems to link data.

4. Level 4: All level 3 plus automatic data collection from local clinical systems.

▶ Local clinical system is the primary vehicle for data collection, relevant data is either automatically sent or prompted to be sent to the relevant registries.

The following matrix (Table 6) provides an overview of the standards map noting the NEHTA-relevant standards and their applicability to each type of registry (levels 1–4). Whilst this may identify some standards as optional in some settings, this will always be a value-judgement which needs to be considered in the context of future capacity or plans to expand the scope, nature or purpose of the registry.

This standards map has been organised based on the NEHTA domains. For each domain a list of the recommended standards is provided. Each standard (or group of standards) is documented with the following sections containing content applicable to the proposed architecture:

▶ Overview

▶ Motivation

▶ Usage criteria

▶ Comments (where applicable).

The majority of the content for the Overview, Motivation and Comment sections has been taken from the Standards Catalogue on the NEHTA web site (http://www.nehta.gov.au).

The Usage Criteria has been tailored to be applicable to clinical registries and describes how the document relates to Australian Clinical Quality Registries. Only those standards with some relevance to Australian Clinical Quality Registries have been included from the NEHTA Standards Catalogue.

The standards documents can be downloaded from the Standards Catalogue on the NEHTA web site which is available at: http://www.nehta.gov.au/index.php?option=com_content&task=view&id=139&Itemid=383.

Relevant standards	NEHTA recommended standard	Level 4 Automatic data collection	Level 3 Two-way linkage	Level 2 One-way submission	Level 1 Stand-alone
Interoperability Framework (eg. Architecture)	Interoperability Framework	Recommended	Recommended	Optional	Optional
	Unified Modelling Language v2.0	Recommended	Recommended	Not required	Not required
	TOGAF	Recommended	Recommended	Optional	Optional
	Information Technology – Open Distributed Processing	Recommended	Recommended	Optional	Optional
Clinical Communications	Terminology	Required	Required	Required	Recommended
	Data Specifications	Required	Required	Required	Required
	HL7 Messages	Required	Required	Not required	Not required
	Datatypes	Required	Required	Required	Required
Unique Healthcare Identification	Health Care Provider Identification	Required	Required	Required	Required
	Health Care Client Identification	Required	Required	Optional	Optional
Identity Management	Authentication Assessment Methodology	Recommended	Recommended	Optional	Optional
	Framework for Analysing, Planning and Implementing Identity Management	Recommended	Recommended	Optional	Optional
	Identity Management resource Set	Recommended	Recommended	Optional	Optional
	AGAF	Recommended	Recommended	Optional	Optional
	ACSI 33	Recommended	Recommended	Optional	Optional
	Security Techniques	Optional	Optional	Optional	Optional
	OASIS eXtensible Access Control Markup Language (XACML) TC	Optional	Optional	Optional	Optional
	OASIS Security Services (SAML)	Optional	Optional	Optional	Optional
Secure Messaging	Web Services	Recommended	Recommended	Not required	Not required
	XML	Recommended	Recommended	Recommended	Not required
Supply Chain	Supply Chain	Required	Required	Required	Recommended
Engagement & Adoption	Understanding Standards	Optional	Optional	Optional	Optional
	CGOI and Communication Technology	Recommended	Recommended	Optional	Optional

Table 6. Technical standards overview

♦ E-health interoperability

NEHTA has identified a number of standards pertinent to ensuring the interoperability of Australian Clinical Quality Registries. These include:

- ▶ Interoperability Framework v2.0
- ▶ Unified Modelling Language v2.0
- ▶ TOGAF "Enterprise Edition" v8.1
- ▶ Information technology – Open Distributed Processing.

Interoperability Framework v2.0

Overview

This document describes the Interoperability Framework, version 2.0. The Interoperability Framework (IF) is a common reference point that provides guidance to business and IT experts in delivering interoperable e-health systems in Australia – while allowing for the evolutionary and emergent aspects of business, policy and technology.

Version 2.0 provides a number of extensions, refinements and guidelines for applying the interoperability approaches and concepts to e-health systems, including enterprise architecture, certification principles and interoperability maturity model.

Motivation

The Interoperability Framework is developed to promote a shared understanding about different aspects of e-health system and for various e-health stakeholders involved. This understanding is enabled through interoperability concepts and patterns, addressing separate, but related aspects of e-health systems i.e., organisational, informational and technical aspects.

The IF includes a methodology, which emphasizes a disciplined approach in delivering fit-for-purpose systems, where specifications play an important role, providing a bridge between requirements and conformant systems.

Usage criteria

The IF concepts and patterns can be used within various e-health projects and jurisdictions to deliver specifications for e-health systems based on clearly stated organisational, informational and technical requirements. These specifications will need to include definition of conformance points to facilitate certification of implementations against specifications. The IF concepts and patterns are valuable tools in delivering downstream enterprise architectures at national, State, Territory or domain levels.

Unified Modelling Language v2.0

Overview

constructing, and documenting the artefacts of distributed object systems. UML is a set of specifications published by the Object Management Group (OMG). UML can be used to describe requirements for building a system, model structural and behavioural relationships between components in a software system and support the expression of business process models.

Motivation

UML has become a de facto modelling notation used for describing business requirements, structural and behavioural models constituting architecture of software systems. UML plays a central role in many software development methodologies.

Usage criteria

UML can be used as a modelling notation to represent different architecture modelling concepts proposed by the NEHTA Interoperability Framework, as well as Enterprise Architecture and Solution Architectures.

UML 2.0 is based on better semantic foundation allowing more precise expression of modelling concepts such as UML activity diagrams. Therefore, NEHTA recommends UML 2.0 (in preference to UML 1.4.2) for use as a modelling notation.

TOGAF "Enterprise Edition" v8.1

Overview

The Open Group Architecture Framework (TOGAF), Enterprise Edition is an architecture framework – a set of methods and tools for developing a broad range of different IT architectures. It enables IT users to design, evaluate, and build the right architecture for their organisation, and reduces the costs of planning, designing, and implementing architectures based on open systems solutions. There are four main parts to the TOGAF document:

▶ *PART I – Introduction*: This part provides a high-level introduction to some of the key concepts behind enterprise architecture and in particular the TOGAF approach.

▶ *PART II – Architecture Development Method*: This is the core of TOGAF. It describes the TOGAF Architecture Development Method (ADM) – a step-by-step approach to developing an enterprise architecture.

▶ *PART III – Enterprise Continuum*: This part describes the TOGAF Enterprise Continuum, a virtual repository of architecture assets, which includes the TOGAF Foundation Architecture, and the Integrated Information Infrastructure Reference Model (III-RM).

▶ *PART IV – Resources*: This part comprises the TOGAF Resource Base – a set of tools and techniques available for use in applying TOGAF and the TOGAF ADM.

Motivation

The Open Group Architecture Framework (TOGAF) is an open standard that provides a technology neutral framework for developing enterprise architectures, covering the constituent business, information systems and technical architectures, while providing guidance for the architecture deployment and governance.

TOGAF can be tailored for the needs of specific industries or sectors such as e-health. NEHTA's tailoring of TOGAF includes the use of the NEHTA Interoperability Framework concepts as an architecture description language for building interoperable systems. This combination provides a powerful basis for long-term evolution of enterprise architectures in the Australian e-health environment in spite of technological, business, regulatory or legislative changes.

Usage criteria

TOGAF can be used to develop Enterprise and Solution Architectures for various e-health segments, within or across organisational or jurisdictional boundaries. NEHTA has chosen TOGAF as a vehicle for facilitating a disciplined and consistent approach to architecture development for national e-health infrastructure with which NEHTA is tasked. The NEHTA Interoperability Framework provides a set of modelling concepts essentially forming an architecture description language for national e-health infrastructure developments.

Comments

In order to achieve the highest degree of e-health alignment and effective engagement among stakeholders within the Australian e-health environment, NEHTA recommends the adoption of TOGAF for respective enterprise architecture developments.

Information technology – Open Distributed Processing

Overview

The following documents provide detail on understanding and applying Open Distributed Processing (ODP) as specified in the ISO/IEC 10746 group of standards:

- ▶ ISO/IEC 15414:2006 Information Technology - Open Distributed Processing - Reference Model - Enterprise Language

- ▶ ISO/IEC 10746-1:1998 Information Technology - Open Distributed Processing - Reference Model: Overview - Part 1

- ▶ ISO/IEC 10746-2:1996 Information Technology - Open Distributed Processing - Reference Model: Foundations - Part 2

- ▶ ISO/IEC 10746-3:1996 Information Technology - Open Distributed Processing - Reference Model: Architecture - Part 3

- ▶ ISO/IEC 10746-4:1998 Information Technology - Open Distributed Processing - Reference Model: Architectural Semantics - Part 4

Motivation

There is currently a lack of an existing precise framework for modelling enterprise aspects of open distributed systems, which is of great relevance for cross-organisational and cross-jurisdictional nature of e-health systems in Australia. The ODP-EL (enterprise language) provides a generic framework, yet with a sufficient precision, needed for the organizational perspective of the Interoperability Framework.

These standards provide a technology-independent architecture framework, supporting the 'separation of concern' principle, which allows for the specification of complex systems from different viewpoints. It has a high level of precision commensurate with the formalism adopted (and which exploits constructs from different standardized formal description techniques). Over the years, ISO/IEC 17046, as a standardization framework, has influenced development of a number of specific industry standards such as OMG and OASIS.

Usage criteria

NEHTA recommends compliance with these specific standards when describing the organizational roles, processes, policies and communities as a context for positioning computing systems and other technology solutions in support of delivery of healthcare services.

The modelling concepts, structuring rules and architecture principles from these standards can be used to provide architecture specifications of complex systems, from different viewpoints and in a technology-neutral manner. The standards also provide a clear conformance and compliance framework that can be used for various certification purposes, which has been leveraged within the NEHTA Interoperability Framework.

♦ Clinical communications

NEHTA has identified a number of standards pertinent to clinical communications for Australian Clinical Quality Registries. These cover:

- ▶ Data specifications
- ▶ Terminology
- ▶ Data exchange
- ▶ Datatypes.

Data specifications

Overview

NEHTA has developed a suite of data specifications to standardise various clinical concepts to form structured clinical documents. These data specifications are intended for use at point of care. NEHTA is working with the Australian Institute of Health and Welfare (AIHW) to ensure data specifications are consistent with the National Minimum Data Set (NDMS) and metadata in MeTEOR (the Metadata Online Registry). For further information about the AIHW and MeTEOR, refer to the AIHW website at http://ww.aihw.gov.au.

The library contains both:

- ▶ *Data Specifications* for particular health topics i.e., foundation 'data groups' such as problem/diagnosis, clinical intervention, adverse reactions; and
- ▶ *Content Specifications* for structured clinical documents such as discharge summary and referral, which make use of the foundation data groups.

As of mid-2008, the list of data specifications includes:

- ▶ NEHTA 0013:2006 Medication Data Specifications v1.0
- ▶ NEHTA 0032:2006 National Discharge Summary Data Content Specification v1.0
- ▶ NEHTA 0058:2007 General Practitioner and Specialist/Critical Care Referral Data Content Specifications v1.0
- ▶ NEHTA 0082:2007 Pathology Data Specification v1.0
- ▶ NEHTA 0093:2007 Diagnostic Imaging Data Specification v1.0
- ▶ NEHTA 0133:2007 Adverse Reaction Data Specification v1.0
- ▶ NEHTA 0134:2007 Alert Data Specification v1.0
- ▶ NEHTA 0135:2007 Clinical Intervention Data Specification v1.0
- ▶ NEHTA 0136:2007 Clinical Synopsis Data Specification v1.0
- ▶ NEHTA 0137:2007 Immunisation Data Specification v1.0
- ▶ NEHTA 0138:2007 Observation Data Specification v1.0

▶ NEHTA 0139:2007 Problems and Diagnosis Data Specification v1.0

▶ NEHTA 0140:2007 Reason for Encounter Data Specification v1.0.

ⓘ It is recommended that readers confirm the currency of the above recommended data specifications when applying them to clinical registries to ensure they are up to date by checking the Standards catalogue on the NEHTA website:
http://www.nehta.gov.au/index.php?option=com_standardscatalogue&cid=8&Itemid=424

Motivation

These data specifications can be used by system designers to implement level 4 (semantic) interoperability in the Australian health care setting. Semantic interoperability means that the information exchanged by different computer systems can be interpreted by both computer applications and human users.

Usage criteria

NEHTA data specifications are aimed at standardising the information structure and language used to name and describe clinical concepts, and to provide the necessary contextual constraints to remove potential ambiguity in clinical statements. They are not intended to be software or messaging design specifications. Instead, they represent the clinical information requirements for data collection and information exchange required for facilitating safe and effective continuity of care across health care i.e., General Practice and Acute Care.

It is expected that these specifications will be used in conjunction with other NEHTA-provided specifications such as the Australian Medicines Terminology (AMT) and other SNOMED CT-based clinical terminologies.

These specifications should be applied when data is captured for storage in a registry that overlaps with any of the topics in the data groups or documents. It is expected that the data groups will be more applicable in the Registry setting than the clinical documents.

Terminology

Overview

SNOMED CT (Systematised Nomenclature of Medicine, Clinical Terms) is a comprehensive and precise clinical reference terminology. Terminology is used to populate data specifications. It provides an extensive list of clinical terms and identifiers that allows complex clinical concepts to be described in a way that computers can interpret. SNOMED CT operates at many levels including history, examination, provisional diagnosis, test results, and treatment.

The Australian Medicines Terminology (AMT) release is a national extension of SNOMED CT for use within information systems within Australia to define and describe medicines and related concepts. This release contains the products listed on the Schedule of Pharmaceutical Benefits.

The AMT delivers standard identification of branded and generically equivalent medicines and their components. It also provides standard naming conventions and terminology to accurately describe medications. The terminology is for use by medication management computer systems, in both primary and secondary health care.

As of mid-2008, the relevant terminology specifications are:

▶ IHTSDO 0109_07:2007 SNOMED CT® International Release (UK Language Edition) – July 2007

▶ NEHTA 0143:2007 Australian Medicines Terminology v1.0 – Data

▶ NEHTA 0144:2007 Australian Medicines Terminology v1.0 - UML Class Diagram v7.0

▶ NEHTA 0145:2007 Australian Medicines Terminology v1.0 - Editorial Rules v2.0

It is recommended that readers confirm the currency of the above relevant terminology specifications when applying them to clinical registries to ensure they are up to date by checking the Standards catalogue on the NEHTA website:

http://www.nehta.gov.au/index.php?option=com_standardscatalogue&cid=8&Itemid=424

Motivation

NEHTA is responsible for defining a national approach to clinical terminology, to support the efficient and accurate electronic recording and exchange of clinical information across the health sector. Essential to this work is access to SNOMED CT and the AMT extension. These specifications will assist technical stakeholders in adopting standard terminologies in software applications used to store clinical information.

Usage criteria

These terminology specifications should be applied to all clinical data captured for storage in a registry.

Access to this material is limited to those holding license agreements managed by NEHTA:

▶ The SNOMED CT Affiliate License Agreement for access to SNOMED CT Core; and

▶ The Australian National Terminology Release License Agreement to provide access to extensions and derivatives supplied by NEHTA.

Data exchange

Overview

Defines how Australian healthcare organisations implement the global Health Level Seven standard (for the various selected 2.x versions) for communication of patient administration and clinical information. Australia currently uses HL7 version 2 for data exchange. However, NEHTA has recommended and supports the move to HL7 Clinical Document Architecture (CDA). These specifications are suitable for use within Australian public and private healthcare organisations.

The clinical specifications provide consistent use of data definitions as well as commentary and references to the International Organization for Standardization (ISO) and the National Health Data Dictionary.

The list of recommended messages can be found on the NEHTA website on the following URL:
http://www.nehta.gov.au/index.php?option=com_standardscatalogue&cid=8&Itemid=424

Motivation

Standardised messages support independent system vendors developing interoperable interfaces. NEHTA has selected these standards because they are currently in use in a number of different sites in the Australian health care environment and are consistent with the direction recommended in the *Standards for E-Health Interoperability v1.0, 08/05/2007*.
NEHTA's recommendation for the use of these standards is on an interim basis. As discussed above, the future direction recommended by NEHTA in the *Standards for E-Health Interoperability v1.0* is based on CDA.

Usage criteria

These standards should be used when transferring messages containing the relevant content from the capture systems to the registry storage systems. In general, the more recent versions of the standards are preferred. Older versions are used when interfacing with existing ICT systems that do not support the more recent versions of HL7 interfaces.

Datatypes

Overview

The ISO/IEC 11404 international standard specifies the nomenclature and shared semantics for a collection of datatypes commonly occurring in programming languages and software interfaces, referred to as the Language-Independent (LI) Datatypes. It specified both primitive datatypes, in the sense of being defined without reference to other datatypes, and non-primitive datatypes, in the sense of being wholly or partly defined in terms of other datatypes.

Motivation

These datatypes are foundational components that are used in many industries, not just health care. Standardising across industries will facilitate software developers and language-specific implementations to more readily interoperate without a requirement to introduce error-prone mappings.

Patient safety and the quality of data for decision support and secondary use depends on standardised and known representations of fundamental datatypes. The volume of systems potentially exchanging and processing information dictate such a requirement. Furthermore, e-health requires standardised additional compound datatypes such as quantities and special timing datatypes that need to be built from the standardised primitive datatypes described in ISO/IEC 11404.

Usage criteria

The data definitions used in the design of all the registry components, including data capture interfaces, databases and reporting, should be based on the datatypes in this standard.

Comments

ISO is currently considering a proposal for additional datatypes to meet the specific requirements of health care.

♦ Unique healthcare identifiers

A number of unique health identifiers (UHIs) have been under development and should be available and useful for Australian Clinical Quality Registries. These refer to both:

- ▶ Provider identification and
- ▶ Client identification.

For further information, also refer to Unique Healthcare Identifiers (UHI) on page 69.

Provider identification

Overview

The AS 4846-2006 standard provides a framework for improving the positive identification of health care providers. The standard applies in respect of all providers of health care services to the Australian health care system. It defines demographic and other identifying data elements suited to capture and use for identification in health care settings and provides guidance on their application. It also makes recommendations about the nature and form of health care provider identifiers. It includes only the minimum dataset required for unambiguous identification. It is a generic set of identifying information which is application-independent.

The objective of this standard is to promote uniform good practice in:

- ▶ Identifying both individual and organisational health care providers;
- ▶ The recording of health care provider identifying data; and
- ▶ Ensuring that data being associated with any given health care provider, and upon which clinical communication and data aggregation are based, are appropriately associated with that individual or organisation and no other.

Motivation

This standard was used as a foundation standard for Healthcare Provider Identifier (HPI) data elements, process of information collection (recording) and data management (data matching and linking).

This standard is currently being used as the basis for capturing provider identity information in some jurisdictional systems.

Usage criteria

This standard should be used when recording identification and demographic details for a healthcare provider. This is relevant for both participation in Australian Clinical Quality Registries and to identify authorship of clinical data.

Comments

NEHTA has contracted Medicare Australia to design, build and test the Unique Healthcare Identification (UHI) service which includes the HPI and Individual Healthcare Identifier (IHI). To obtain an HPI, participants will need to be currently registered and have signed a participation agreement. Further details will be provided on the NEHTA website as the service is developed (http://www.nehta.gov.au).

Client identification

Overview

The AS 5017-2006 standard provides a framework for improving the positive identification of clients in health care organisations. This standard applies in respect of all potential or actual clients of the Australian health care system. It defines demographic and other identifying data elements suited to capture and use for client identification in health care settings, provides guidance on their application, and provides an overview of data matching strategies. It also makes recommendations about the nature and form of health care identifiers.

Accordingly, this standard includes only the minimum dataset required for unambiguous identification. It is recognised that specific applications may require additional data to fulfil their purposes. The standard provides a generic set of identifying information, which is application independent.

Motivation

This standard is used by NEHTA as a foundation standard for the IHI system, particularly in the area of the implementation of client master indices and the use of appropriate and thorough searching techniques for the IHI system in ensuring that any existing client data will be linked to the relevant health care client.

This standard is currently being used as the basis for capturing client identity information in some jurisdictional systems.

Usage criteria

This standard should be used when recording identification and demographic details for a healthcare client. This is relevant for both participation in Australian Clinical Quality Registries and to identify the subject of clinical data.

Comments

NEHTA has contracted Medicare Australia to design, build and test the Unique Healthcare Identification (UHI) service which includes the HPI and IHI. Further details will be provided on the NEHTA website as the service is developed (http://www.nehta.gov.au).

♦ Identity management

NEHTA has identified a number of standards pertinent to identity management for Australian Clinical Quality Registries. These include:

- ▶ Authentication Assessment Methodology v1.0
- ▶ Framework for Analysing, Planning and Implementing Identity Management v1.0
- ▶ Identity Management Resource Set
- ▶ Australian Government Authentication Framework
- ▶ ACSI 33
- ▶ Security techniques
- ▶ OASIS eXtensible Access Control Markup Language (XACML) TC
- ▶ OASIS Security Services (SAML) TC v2.0.

Authentication Assessment Methodology v1.0

Overview

The Authentication Assessment Methodology describes a business process to be followed when attempting to establish authentication requirements for online healthcare transactions. It presents a risk-based approach which closely follows the structure of the Australian Government Authentication Framework (AGAF). For further information about AGAF, refer to Australian Government Authentication Framework on page 109.

Motivation

The purpose of this document is to provide healthcare organisations a single point of reference to use when analysing their user authentication requirements. The risk-based analysis helps identify the level of authentication required and assist with the selection of authentication mechanisms and implementation planning.

Usage criteria

The process outlined in this methodology should be applied when assessing authentication requirements for access to Australian Clinical Quality Registries.

Framework for Analysing, Planning and Implementing Identity Management v1.0

Overview

This document provides a framework to assist in the analysis, planning and implementation of Identity Management within healthcare systems. It identifies the issues that all healthcare providers and all E-Health infrastructural services will have to 'agree upon' in order to ensure security and trust across the E-Health Community, as well as technical and process robustness, and interoperability of identity and access elements across all stakeholders.

Motivation

The purpose of this document is to assist with the identification of the issues that healthcare providers and infrastructural service providers will need to address in order to specify, implement and maintain a secure and trusted e-health environment. As such this document provides the background to and overview of NEHTA's Identity Management (IdM) initiative. It introduces and positions a range of detailed IdM resources that will guide organisations and communities within the sector towards secure, efficient and seamless E-Health transacting across the sector.

Usage criteria

Although this document is broader than the architecture and design of the registry software systems, this document is essential background reading for users who have an interest or responsibility in the area of securing online healthcare environments. Having a common and shared understanding of the issues involved with the identification and authentication of individuals and organizations as they transact electronically is essential in order to ensure the successful implementation of national E-Health systems.

Identity Management Resource Set

Overview

The Identity Management Resource Set describes at various levels all the components needed to design and implement identity management solutions for healthcare systems. The set contains the following standards:

- ▶ NEHTA 0100:2007 Identity Management Resource Set Building Blocks Layer v1.0
- ▶ NEHTA 0101:2007 Identity Management Resource Set Guidelines Layer
- ▶ NEHTA 0102:2007 Identity Management Resource Set Standards Layer v1.0
- ▶ NEHTA 0103:2007 Identity Management Resource Set Templates Layer v1.0

The Building Blocks layer of the Resource Set is comprised of the Identity Management components, technologies and techniques that an organisation may utilise to assess and develop their identity management requirements.

The Guidelines Layer contains positions and guidelines to key issues identified as being on the critical path for health organisations wanting to join the e-health environment or improve their own identity management systems.

The Standards Layer provides details on standards that organisations and e-health initiatives can utilise to determine the best fit for their identity management needs in line with the National E-Health Identity Management Framework.

The Template Layer presents a collection of useful models and checklists that organisations can use to progress various aspects of the design, development and deployment of intra-organisational and cross-sectoral identity management.

Motivation

The purpose of this document is to provide a 'toolbox' from which identity management solutions in health can be constructed.

The components, technologies and techniques presented provide details that can be utilised by health organisations to determine the best fit for their identity management needs in line with the National E-Health Identity Management Framework.

The selection of existing standards where possible upon which to build identity management solutions for health is seen as desirable to both capitalise on existing expertise in identity management and promote interoperability between systems.

In particular, for NEHTA 0101:2007, the identification of and response to key identity management issues for e-health is intended to help focus attention where it is most needed.

Usage criteria

These documents should be used when the registry systems are being analysed, designed, and implemented to help guide the identity management aspects of the solution and ensure conformity with the NEHTA-prescribed Identity Management Framework.

The standards included cover multiple aspects of identity management system components development ranging from the risk based assessment of authentication needs to the specific implementation of a selected authentication mechanism.

The guidelines are particularly relevant during the analysis phase, but are still useful to keep in mind during the whole development process.

Australian Government Authentication Framework

Overview

The Australian Government e-Authentication Framework (AGAF) for Business standard (AGIMO AGAF:2005) provides a set of guidelines and practices for establishing the authentication requirements for an organisation, including a systematic approach to the evaluation of all online transactions for that organisation.

AGAF utilises a risk-based system of assessing the level of assurance of identity required for each transaction and provides a means of mapping the level of assurance to a suitable authentication mechanism. Once this assessment is completed AGAF then assesses the feasibility of the authentication approach.

Motivation

AGAF provides a good contextual basis for working with the Australian government and its agencies. It contains a thorough approach and detailed documentation to aid the provision of seamless national online services. Its generic approach also provides an effective and accessible process for analysing requirements. It has a high degree of compatibility with existing Commonwealth identity management programs, and close alignment with state-based programs also using AGAF as their basis.

Usage criteria

AGAF should be used as a basis for determining the authentication requirements of the registry organisations.

ACSI 33

Overview

The Australian Government Information and Communications Technology Security Manual (also known as ACSI 33) has been developed by the Defence Signals Directorate (DSD) (http://www.dsd.gov.au) to provide policies and guidance to Australian Government agencies on how to protect their ICT systems.

Motivation

The ACSI 33 guidelines are a solid and thorough set of principles developed to scope computer systems which must work in an environment which has data security implications.

Usage criteria

Registry architecture and design should follow the recommendations made in this standard in conjunction with recommendations made by the NEHTA User Authentication Initiative.

Security techniques

Overview

The following standards apply to Information Security Management Systems:

▶ AS/NZS ISO/IEC 27001:2006 Information technology - Security techniques - Information security management systems

▶ AS/NZS ISO/IEC 17799:2006 Information technology - Security techniques - Code of practice for information security management

The AS/NZS ISO/IEC 27001:2006 standard establishes guidelines and general principles for initiating, implementing, maintaining, and improving information security management in an organization. The objectives outlined provide general guidance on the commonly accepted goals of information security management.

AS/NZS ISO/IEC 17799:2006 specifies the requirements for establishing, implementing operating, monitoring, reviewing, maintaining and improving documented ISMS (Information Security Management System) within the context of the organization's overall business risks. It specifies requirements for the implementation of security controls customized to the needs of individual organizations or parts thereof.

Motivation

Healthcare organisations are moving towards higher adoption levels for information technology systems as part of a connected e-health sector. The data stored within these systems as part of patient care delivers significantly improved health outcomes compared to older paper-based systems, but it also brings the requirement to carefully protect this sensitive information, especially as the transition to a more connected e-health environment continues to progress.

These standards address the issues associated with information security management. While this is essentially outside the scope of Identity Management in particular, it does form part of the landscape into which Identity Management fits. It is expected that health organisations will have an information security management system in place prior to or as part of addressing their Identity Management requirements.

By following these standards healthcare organisations can be confident that they are following accepted and proven methodologies to protect the sensitive information they hold.

Usage criteria

Although these standards are much wider than the architecture and design of registry software systems, following these standards will have implications for the software which will need to be accounted for.

Application of this standard should initially be driven from a security risk assessment, as described in HB 231:2004.

OASIS eXtensible Access Control Markup Language (XACML) TC

Overview

The OASIS XACML (Extensible Access Control Markup Language) v2.0 open standard is an XML-based language designed to express security policies and access rights to information for Web services, digital rights management, and enterprise security applications. XACML was developed to standardise access control through XML so that, for example, a worker can access several affiliated Web sites with a single logon. XACML is sometimes referred to as Extensible Access Control Language (XACL).

XACML was designed to work in conjunction with Security Assertion Markup Language (SAML), another OASIS standard.

Motivation

The area of standardised access control in Web services is still relatively new and there is no mature solution currently available. As a maturing access control standard XACML promises the desired mix of a standard way of defining access rights along with compatibility with other OASIS standards such as SAML.

Usage criteria

Registries should use XACML to define their access policies for user and system access to registry functions and data.

OASIS Security Services (SAML) TC v2.0

Overview

The OASIS SAML (Security Assertion Markup Language) v2.0, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application.

Motivation

SAML is an XML-based framework for communicating user authentication, entitlement, and attribute information from a trusted source to a relying party. As such it can be used to distribute identity information to multiple services allowing for the construction of flexible and scalable identity regimes.

Usage criteria

SAML should be used to minimise the number of times users will need to authenticate while interacting with the many different registries and infrastructure components. Each separate component and registry should be designed to accept and trust previously established authentication, entitlement, and attribute information.

♦ Secure messaging

NEHTA has identified a number of standards pertinent to secure messaging for Australian Clinical Quality Registries. These include:

▶ Web services and

▶ XML.

Web services

Overview

The following documents describe the standards, guidelines and approaches recommended for application to application exchange:

▶ NEHTA 0009_2.0:2006 Web Services Standards Profile v2.0

▶ NEHTA 0033:2006 Technical Architecture for Implementing Services v1.0

▶ NEHTA 0067:2007 Guidelines for Implementing Interoperable Web Services v1.0

▶ OASIS WS-Security 1.1:2006 Web Services Security: SOAP Message Security 1.1 (WS-Security 2004).

Web Services Standards Profile recommends the use of HTTP 1.1, SOAP 1.2, MTOM and XOP, WS-Addressing, WSDL 1.1, and WS-Security as the standards that NEHTA supports.

The Technical Architecture for Implementing Services defines a service-oriented approach to the national e-health environment.

The Guidelines for Implementing Interoperable Web Services describes how to implement Web services in an interoperable manner.

The Web Services Security standards contain many options, which can result in incompatible implementations. These guidelines suggest ways to avoid those problems. These guidelines cover how to use WSDL, SOAP, WS-Addressing, and WS-Security.

The Web Services Security specification describes enhancements to SOAP messaging that provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies.

Motivation

The purpose of these publications is to provide guidance on the standards and approaches to use when implementing secure Web services. The Web services standards are designed to be composed together in different combinations. There are many Web services standards to choose from.

Usage criteria

Web service interfaces are required between capture systems, the national infrastructure, and with and between registry systems. These specifications are recommended for use when designing the services presented by these systems and the interfaces between them.

XML

Overview

The following are XML standards that are applicable to exchanging secure messages between systems:

▶ IETF RFC 3076:2001 Canonical XML Version 1.0

▶ IETF RFC 3275:2002 (Extensible Markup Language) XML-Signature Syntax and Processing

A logical XML (Extensible Markup Language) document can be represented in a number of different physical XML documents. They contain equivalent information, but the serialised representation is different. The Canonical XML standard defines a method to create a single canonical representation which can be used for signing and comparing documents.

The XML-Signature Syntax and Processing specifies how to digitally sign XML data. It defines the rules and process of how to create a signature, and additionally how it is to be validated. It also defines the syntax for representing digital signatures in XML.

Motivation

The purpose of these publications is to define the approach to use when digitally signing XML.

Usage criteria

Digitally signing XML is needed when XML content needs to be signed to ensure its integrity, authenticate the message, or authenticate the signing party.

The XML content must be canonicalised before it is digitally signed, as well as canonicalised before a digital signature is validated. These standards must be used when using WS-Security to sign SOAP messages.

Most messages transmitted to and from the national infrastructure and Australian Clinical Quality Registries will contain personal data and will often include clinical data. This data needs to be protected by applying these standards.

♦ Supply chain

Overview

These documents provide the architecture for the e-procurement solution at the business and technical levels:

- ▶ NEHTA 0090:2007 E-Procurement Business Architecture v1.0
- ▶ NEHTA 0088:2007 E-Procurement Technical Architecture v1.0
- ▶ NEHTA 0131:2007 Addendum to NEHTA's E-Procurement Technical Architecture v1.0
- ▶ NEHTA 0091:2007 E-Procurement WSDL v1.0

The E-Procurement Business Architecture document specifies the organisational roles and processes in the e-procurement community. It also explains how the e-procurement solution's technical and informational perspectives are related to the organisational roles and processes.

The E-Procurement Technical Architecture document provides the technical architecture detailing the paradigm of interactions between the three roles in e-procurement: buyers, hubs and suppliers. It also explains the technical requirements in the implementation of Web Services for e-procurement.

The E-Procurement WSDL is a zip archive that provides WSDL and XSD files for use with the E-Procurement Technical Architecture v1.0. These Web services interfaces can be implemented by buyers, suppliers and e-procurement hub service providers when implementing the exchange of e-procurement business documents i.e., an e-procurement solution.

Motivation

NEHTA recommends the use of these standards to understand the e-procurement solution. This document can be used by e-procurement hub service providers, buyers and suppliers in implementing an e-procurement solution.

Usage criteria

Registries that record products (for example, device or implant registries) will ideally interact with the National Product Catalogue (NPC) to ensure effective unique product identification. These standards will guide the use of the NPC and the design of the interfaces with the NPC.

♦ Engagement and adoption

NEHTA has identified a number of issues or standards pertinent to engagement and adoption for Australian Clinical Quality Registries. These include:

- ▶ Understanding standards and
- ▶ Corporate governance of ICT.

Understanding standards

Overview

HB 107-1998 explains the concept of standardization and assists readers of Australian Standards and other similar documents in their use and understanding of these documents.

Motivation

Standards must be properly understood to ensure effect use. Therefore, this handbook assists in the selection and use of standards.

Usage criteria

NEHTA recommends this handbook to assist with all standards implementation activities such as adoption, uptake and implementation.

Corporate governance of ICT

Overview

AS 8015-2005 provides guiding principles for Directors of organizations (including owners, board members, Directors, partners, senior executives, or similar) on the effective, efficient, and acceptable use of Information and Communication Technology (ICT) within their organisation.

The standard applies to the governance of resources, computer-based or otherwise, used to provide information and communication services to an organisation. These resources could be provided by ICT specialists, within the organisation or external service providers, or by business units within the organisation.

Motivation

The guiding principles this standard provides for effective, efficient, and acceptable use of ICT within an organization can be applied to all organisations regardless of size and extent of ICT use.

Usage criteria

NEHTA encourages suppliers, developers, purchasers and implementers to assess their own governance structures and planning activities and identify the best way to implement the standards endorsed by NEHTA. NEHTA recommends the use of this particular standard to guide organisations with their reviews.

Comments

This standard was recommended for use in Supporting National E-Health Standards Implementation – Adoption, Uptake and Implementation published by NEHTA on the 02/02/2007.

♦ References

1. Last J, (ed). *A Dictionary of Epidemiology*. 4th edition. New York, NY: Oxford University Press, 2001.

2. Steinbrook R. Guidance for guidelines. *N Engl J Med* 2007; 356(4):331–3.

3. Australian Institute for Health and Welfare. *Australia's Health 2006*. Canberra: AIHW, 2006; AIHW Cat No. Aus 73.

4. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. *Med J Aust* 1995; 163(9):458–71.

5. Hayward R, Hofer T. Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer. *JAMA* 2001; 286(4):415–20.

6. Nolte E, McKee C. Measuring the Health of Nations: Updating an Earlier Analysis. *Health Aff* (Millwood) January/February 2008, 27(1):58–71.

7. Health Care Complaints Commission. *Investigation Report: Cambelltown and Camden Hospitals Macarthur Health Service* [Web Page]. December 2003; Available at http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf . (Accessed 4 April 2008).

8. Australian Council for Safety and Quality in Health Care. Lessons from *the Inquiry into Obstetrics and Gynaecological Services at the King Edward Memorial 1999–2000*. Canberra: Commonwealth of Australia, 2002.

9. Queensland Health. *Queensland Health Systems Review: Final Report.* Brisbane: Queensland Government, 2005.

10. Forster P. *Queensland Health Systems Review – Final Report*. Qld Health, 2005.

11. Community and Health Services Complaints Commissioner of the ACT. *A final report of the investigation into adverse patient outcomes of neurosurgical services provided by the Canberra Hospital*. Canberra: ACT Government, 2003.

12. Health Services Commissioner. *Royal Melbourne Hospital Inquiry Report*. Melbourne: Government of Victoria, 2002.

13. Scott I, Ward M. Public reporting of hospital outcomes based on administrative data: risks and opportunities. *Med J Aust* 2006; 184(11):571–5.

14. Stevens I, Thomas S, Eckerman E, Browning E, Dickens E. The provision of preventive care by General Practitioners measured by patient completed questionnaires. *J Qual Clin Pract* 1999; 19(4):195–201.

15. Queensland Government. Chapter 7: Safety and Quality. *Queensland Public Hospitals Performance Report 2006–07*. Brisbane: Queensland Health, 2008.

16. Wolff A. A review of methods used for medical quality assurance in hospitals: advantages and disadvantages. *J Qual Clin Practice* 1994; 14:85–97.

17. Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Health Care* 2003; 12 (6):458–64.

18. Kohn LT, Corrigan JM, Donaldson MS. *To Err is Human: Building a safer health system*. Washington, DC: National Academy Press, 2000: 1–16.

19. Donabedian A. The quality of care– how can it be assessed? *JAMA* 1998; 260:1743–8.

20. American Heart Association. *Get With The Guidelines* [Web Page]. Available at http://www.americanheart.org/presenter.jhtml?identifier=1165. (Accessed 4 April 2008).

21. Donabedian A . Evaluating the quality of medical care. *Millbank Quarterly* 2005; 83(4):691–729.

22. Willis CD, Evans SM, Stoelwinder JU, Cameron PA. Measuring quality. *Aust Health Rev* 2007; 31(2):276–81.

23. Eyenet Sweden. *Handbook for Establishing Quality Registries*. Sweden: Eyenet Sweden, 2005.

24. Graves S. *Benefits and limitations of Registries*. Nordic Orthopaedic Federation Conference.

25. Solomon DJ, Henry RC, Hogan JG, Van Amburg GH, Taylor J. Evaluation and implementation of public health registries. *Public Health Rep* 1991; 106(2):142–50.

26. Agency for Healthcare Research and Quality. *Guide to Patient Safety Indicators*. Department of Health and Human Services, 2003; Version 3.0a.

27. Australian Institute of Health and Welfare. *METeOR Metadata Online Registry* [Web Page]. 2006; Available at http://meteor.aihw.gov.au/content/index.phtml/itemId/181414. (Accessed 5 March 2008).

28. National Cancer Institute. *Cancer Data Standards Repository* [Web Page]. Available at http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr.

29. US Environmental Protection Agency. *Environmental Data Repository* [Web Page]. Available at http://www.epa.gov/edr/. (Accessed 5 March 2008).

30. National e-Health Transition Authority. *Standards for E-Health Interoperability: an E-Health Transition Strategy*. Sydney: NEHTA, 2007.

31. Health Level 7 Inc. *HL7* [Web Page]. Available at http://www.hl7.org/. (Accessed 8 March 2008).

32. Cystic Fibrosis Australia. *Australian Cystic Fibrosis Data Registry: Information management policy and practices* [Web Page]. 2005; Available at http://www.cysticfibrosis.org.au/pdf/ACFDR_policy_and_practices_2005 L.pdf. (Accessed 18 August 2008).

33. Dorman P, Dennis M, Sandercock P. Are the modified "simple questions" a valid and reliable measure of health related quality of life after stroke? United Kingdom collaborators in the international stroke trial. *Journal of Neurology, Neurosurgery & Psychiatry* 2000; 69(4):487–93.

34. Tu J, Willison D, Silver F *et al*. Impracticality of informed consent in the registry of the Canadian Stroke Network. *New Eng J Med* 2004; 350(14):1414–21.

35. Pilcher D, Ernest D, George C, Hart G, Mullany D. *CUSUM analysis may have detected deteriorating hospital mortality among intensive care patients at the Bundaberg Base Hospital*. Presented at the ANZICS Scientific Meeting on Intensive Care Medicine, 25–28 October 2007, Rotorua, NZ.

36. See *Part B: Technical standards – Standards Map*.

37. World Health Organization. *International Classification of Diseases–Australian Modification* (ICD-10-AM) 10th revision. Geneva: WHO, 2006.

38. National E-Health Transition Authority (NeHTA). *National Product Catalogue FAQ v1.1* [Web Page]. April 2008; Available at http://www.nehta.gov.au/index.php?option=com_docman&task=doc_det ails&gid=465&Itemid=139&catid=-2. (Accessed August 2008).

39. International Health Terminology Standards Development Organisation. *Systematized Nomenclature of Medicine – Clinical Terms* (SNOMED CT) [Web Page]. Available at http://www.ihtsdo.org/our-standards/snomed-ct/.

40. Coory M, Duckett S, Sketcher-Baker K. Using control charts to monitor quality of hospital care with administrative data. *Int J Qual Health Care* 2008; 20(1):31–9.

41. Johnston TC, Coory MD, Scott I, Duckett S. Should we add clinical variables to administrative data?: The case of risk-adjusted case fatality rates after admission for acute myocardial infarction. *Med Care* 2007; 45(12):1180–5.

42. Iezzoni LI. Assessing quality using administrative data. *Ann Intern Med* 1997; 127(8 Part 2):666–74.

43. Shahian D, Silverstein T, Lovett A, Wolf R, Normand S-L. Comparison of clinical and administrative data sources for hospital Coronary Artery Bypass Graft Surgery Report Cards. *Circulation* 2007; 115(12):1518–27.

44. Tirschwell DL, Longstreth WT Jr. Validating administrative data in stroke research. *Stroke* 2002; 33:2465–70.

45. Beck CA, Richard H, Tu JV, Pilote L. Administrative data feedback for effective cardiac treatment: affect, a cluster randomized trial. *JAMA* 2005; 294(3):309–17.

46. Tuttle D, Panzer RJ, Baird T. Using administrative data to improve compliance with mandatory state event reporting. *Jt Comm J Qual Improv* 2002; 28(6):349–58.

47. Aylin P, Bottle A, Majeed A. Use of administrative data or clinical databases as predictors of risk of death in hospital: comparison of models. *BMJ* 2007; doi:10.1136/bmj.39168.496366.55.

48. Madsen M, Davidsen M, Rasmussen S, Abildstrom S, Osler M. The validity of the diagnosis of acute myocardial infarction in routine statistics: a comparison of mortality and hospital discharge data with the Danish MONICA registry. *J Clin Epidemiology* 2003; 56:124–30.

49. Christen P. *Probabilistic data generation for deduplication and data linkage*. Proceedings of the ARC Health Data Mining workshop. University of South Australia.

50. Westaby S, Archer N, Manning N *et al*. Comparison of hospital episode statistics and central cardiac audit database in public reporting of congenital heart surgery mortality. *BMJ* 2007; 335:759–63.

51. Gibbs J. Paediatric cardiac surgery mortality after Bristol: paediatric cardiac hospital episode statistics are unreliable [letter]. *BMJ* 2005; 330:43–4.

52. Li S, Cass A, Cunningham J. Cause of death in patients with end-stage renal disease: assessing concordance of death certificates with registry reports. *Aust NZ J Public Health* 2000; 27(4):419–24.

53. Gomatam S, Carter R, Ariet M, Mitchell G. An empiral comparison of record linkage procedures. *Stats in Med* 2002; 21(10):1485–96.

54. Holman C, Bass A, Rouse I, Hobbs M. Population-based linkage of health records in Western Australia: development of a health services research linked database. *Aust NZ J Pub Health* 1999; 23(5):453–9.

55. Centre for Health Record Linkage (CHeReL). *Centre for Health Record Linkage* [Web Page]. 20 September 2007; Available at http://www.cherel.org.au.

56. Bass C. *Overview of the WA Data Linkage System*. Future Directions of the Linkage of Data in South Australia Seminar. Flinders University, Adelaide.

57. Robinson P, Billah B, Leder K, Reid C on behalf of the ASCTS Database Committee. Factors associated with Deep Sternal Wound Infection and Haemorrhage following cardiothoracic surgery in Australia. *Interactive Cardiovascular & Thoracic Surgery* 2007; 6:167–71.

58. Friedman D, Bull A, Russo P *et al*. An alternative scoring system to predict risk for surgical site infection complicating coronary artery bypass graft surgery. *Infect Control Hosp Epidemiol* 2007; 28(10):1162–68.

59. Parker J, Li Z, Damberg C, Danielson B, Carlisle D. Administrative versus clinical data for coronary artery bypass graft surgery report cards. *Med Care* 2006; 44(7):687–94.

60. Evans S, Cameron P, McNeil J. *Register of registries*. (Available at http://www.crepatientsafety.org.au/resources/final_regsitriesdoc_april07 .pdf): Department of Epidemiology and Preventive Medicine, Monash University, 2007.

61. Attorney-General's Department. *Privacy Act 1988*. Canberra: Office of Legislative Drafting and Publishing, Australian Government, 2007; Act No. 119 of 1988 as amended.

62. Rob P, Coronel C. Chapter 2: *The relational database model. Database Systems: Design, Implementation and Management*. Belmont, Ca: Wadsworth Publishing Company, 1993.

63. Asplund K, Hulter Asberg K, Norrving B *et al*. Riks-stroke - a Swedish national quality register for stroke care. *Cerebrovascular Diseases*. 15 Suppl 1:5–7, 2003.

64. Ware J, Kosinski M, Keller S. SF-12: an even shorter health survey. *Med Outcomes Trust Bull* 1996; 4(2).

65. Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: construction of scales and preliminary test of reliability and validity. *Med Care*. 1996; 34:220–6.

66. Ware J, Kosinski M, Dewey J, Gandek B. *How to Score and Interpret Single-Item Health Status Measures: A Manual for Users of the SF-8 Health Survey*. Lincoln, RI: Quality Metric Incorporated, 2001.

67. National Health and Medical Research Council (NHMRC). *Guidelines approved under Section 95A of the Privacy Act 1988*. Canberra: Commonwealth of Australia, 2001.

68. National Health and Medical Research Council (NHMRC). *Guidelines approved under Section 95 of the Privacy Act 1988*. Canberra: Commonwealth of Australia, 2000.

69. National Health and Medical Research Council. *Guidelines for Genetic Registers and Associated Genetic Material*. Canberra: Australian Government, 1999.

70. National Health and Medical Research Council, Australian Research Council, Universities Australia. *Australian Code for Responsible Conduct of Research*. Canberra: Australian Government, 2007.

71. National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. *National Statement on Ethical Conduct in Human Research*. Canberra: Australian Government, 2007.

72. Black N, Payne M. Directory of Clinical Databases: improving and promoting their use. *Qual Saf Health Care* 2003; 12:348–52.

73. Barrie JL, Marsh DR. Quality of data in the Manchester orthopaedic database. *BMJ* 1992; 304(6820):159–62.

74. Sorenson H, Sabroe S, Olsen A. A framework for evaluation of secondary data sources for epidemiological research. *Int J Epidem* 1996; 25(2):435–42.

75. Arts D, De Keizer N, Scheffer G. Defining and improving data quality in medical registries: a literature review, case study and generic framework. *J Am Med Informatics Association* 2002; 9(6):600–10.

76. Williamson OD, Cameron PA, McNeil JJ. Medical registry governance and patient privacy. *Med J Aust* 2004; 181(3):125–6.

77. Royal Australasian Collage of Surgeons. *Professional standards: approved audits* [Web Page]. Available at http://www.surgeons.org/Content/NavigationMenu/FellowshipandStandards/ProfessionalStandards/ApprovedAudits/default.htm. (Accessed 13 May 2008).

78. Department of Health, UK. *Learning from Bristol: The DH Response to the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*.

79. Department of Health, UK. *The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: Final Report*. London: Bristol Royal Infirmary Inquiry, 2001.

80. National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. *National Ethics Application Form* (NEAF) [Web Page]. 2007; Available at https://www.neaf.gov.au. (Accessed 1 August 2008).

81. National Health and Medical Research Council (NHMRC). *National Statement on Ethical Conduct in Research Involving Humans*. Part 1 - Principles of Ethical Conduct [Web Page]. Available at http://www.nhmrc.gov.au/publications/humans/part1.htm. (Accessed 5 June 2008).

82. Junghans C, Jones M. Consent bias in research: how to avoid it. *Heart* 2007; 93(9):1024–5.

83. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. *Heart* 2007; 93(9):1116–20.

84. Al-Shahi R, Vousden C, Warlow C, Scottish Intracranial Vascular Malformation Study (SIVMS) Steering Committee. Bias from requiring explicit consent from all participants in observational research: prospective, population based study. *BMJ* 2005; 331(7522):942.

85. Adamis D, Martin FC, Treloar A, Macdonald AJ. Capacity, consent, and selection bias in a study of delirium. *J Med Ethics* 2005; 31(3):137–43.

86. Bjarnason NH , Kampmann JP. Selection bias introduced by the informed consent process. *Lancet* 2003; 361(9373):1990.

87. National Health and Medical Research Council. *When does quality assurance in health care require independent ethical review?* Canberra: Australian Government, 2003.

88. NSW Health. *Information package for quality assurance Committees seeking qualified privilege*. Available at http://www.health.nsw.gov.au/pubs/quality_assurance/pdf/qualified_brochure.pdf (accessed 8 May 2008): NSW Health, 2003; SHPN (QCP) 030046.

89. Society of Cardiothoracic Surgeons of Great Britain and Ireland. *Fifth National Adult Cardiac Surgical Database Report 2003*. Oxfordshire, UK: Dendrite Clinical Systems Ltd and the Society of Cardiothoracic Surgeons of Great Britain and Ireland, 2004.

90. Duckett SJ, Coory M, Sketcher-Baker K. Identifying variations in quality of care in Queensland hospitals. *Med J Aust* 2007; 187(10):571–5.

91. Kreder HJ, Deyo RA, Koepsell T, Swiontkowski MF, Kreuter W. Relationship between the volume of total hip replacements performed by providers and the rates of postoperative complications in the state of Washington. *Journal of Bone & Joint Surgery* - American Volume 1997; 79(4):485–94.

92. Jollis JG, Peterson ED, Nelson CL *et al*. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. *Circulation* 1997; 95(11):2485–91.

93. Ellis SG, Weintraub W, Holmes D, Shaw R, Block P, King S. Relation of operator volume and experience to procedural outcome of percutaneous coronary revascularization at hospitals with high interventional volumes. *Circulation* 1997; 95(11):2479–84.

94. Irving MJ, Craig JC, Gallagher M *et al*. Implementing iron management clinical practice guidelines in patients with chronic kidney disease having dialysis. *Med J Aust* 2006; 185(6):310–9.

95. Reid C, Birrell S, Skillington P, Shardey on behalf of the ASCTS Database Committee. *Cardiac Surgery Database Project Annual Report 2002–2003*. Australasian Society of Cardiothoracic Surgeons (ASCTS), 2004.

96. Gabbe BJ, Cameron PA, Wolfe R, Simpson P, Smith KL, McNeil JJ. Prehospital prediction of Intensive Care Unit stay and mortality in blunt trauma patients. *J Trauma* 2004; 59(2):458–65.

97. Cass A, Cunningham J, Snelling P, Wang Z, Hoy W. Urban disadvantage and delayed nephrology referral in Australia. *Health & Place* 2003; 9(3):175–82.

98. Chapman J, Russ G. Geographic variance in access to renal transplantation in Australia. *Transplantation* 2003; 76(9):1403–6.

99. Upadhya B, Sane DC, Applegate RJ, Kutcher MA, Gandhi SK, Deliargyris EN. Differences in baseline characteristics and in-hospital outcomes in patients with or without prior stroke undergoing percutaneous coronary intervention. *J Invasive Cardiol* 2005; 17(5):243–7.

100. Persoon A, Heinen MM, van der Vleuten CJ, de Rooij MJ, van de Kerkhof PC, van Achterberg T. Leg ulcers: a review of their impact on daily life. *J Clin Nurs* 2004; 13(3):341–54.

101. Kim MD, Hong SC, Lee SY *et al*. Suicide risk in relation to social class: a national register-based study of adult suicides in Korea, 1999–2001. I*nt J Soc Psychiatry* 2006; 52(2):138–51.

102. Qin P, Nordentoft M. Suicide risk in relation to psychiatric hospitalization: evidence based on longitudinal registers. *Arch Gen Psychiatry* 2005; 62(4):427–32.

103. Launois R, Giroud M, Megnigbeto AC *et al*. Estimating the cost-effectiveness of stroke units in France compared with conventional care. *Stroke* 2004; 35(3):770–5.

104. Ramsey SD, Berry K, Etzioni R. Lifetime cancer-attributable cost of care for long term survivors of colorectal cancer. *Am J Gastroenterol* 2002; 97(2):440–5.

105. Soanes C, Waite M, Hawker Se. *The Oxford Dictionary, Thesaurus and Wordpower Guide*. Oxford, UK: Oxford University Press, 2001.

106. Scally G, Donaldson LJ. Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ* 1998; 317:61–5.

107. World Health Organization. *International Clinical Trials Registry Platform* (ICTRP) [Web Page]. Available at http://www.who.int/ictrp/en/.

108. Harris P, Nagy S, Vardaxis Ne. Mosbys *Dictionary of Medicine, Nursing and Health Professions*. Marrickville, NSW: Elsevier Australia, 2006.

Checklist

Australian Clinical Quality Registry checklist

Different Australian Clinical Quality Registries have different characteristics and requirements. This checklist summarises the operating principles for Australian Clinical Quality Registries. You need to determine which principles are applicable in your circumstances/

Attributes

1	Clear and precisely defined purpose	☐
2	Core data collection of essential elements	☐
3	Systematic data collection at all contributing sites	☐
4	Epidemiologically sound data	☐
5	Outcomes properly ascertained	☐
6	Burden and cost of collection considered	☐
7	Complete collection from entire eligible population	☐

Data collection

8	No impact on provision of care and not a burden or cost to consumers	☐
9	Data collection as close as possible to point of care	☐
10	Uniformly and easily accessible from data source	☐
11	Standard definitions, terminologies and specifications used	☐
12	Data dictionaries used	☐
13	Use existing data sources where possible	☐
14	Use record linkage where possible	☐

Data elements

15	Collect individually identifiable patient or subject information	☐
16	Collect process of care information	☐
17	Collect objective outcome information	☐

Risk adjustment

18	Collect objective, reliable co-variates for risk adjustment	☐

Data security

19	Secure access controls and securing messaging	☐
20	Data collection, storage and transmission complies with all relevant legislation and guidelines	☐
21	Policies comply *with Part B: Technical standards – Standards Map*	☐

Data quality		
22	Reports percentage of eligible patients recruited	☐
23	Data quality control plan used	☐
24	Data checks/audits routinely performed	☐
25	Data management processes used	☐
26	Reports produced to specific timetable	☐
Governance		
27	Formal governance structures	☐
28	Quality of care policies developed	☐
Custodianship		
29	Custodianship explicitly declared	☐
30	Data access and reporting policies available	☐
31	Third party access only via Steering Committee and IEC approval	☐
Ethics and privacy		
32	IEC approval gained	☐
33	Personnel familiar with and abide by 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 made aware of the collection of register data and given the option to not participate.	☐
35	IEC approval sought for projects using register data	☐
Outputs		
36	Quality of care assessed	☐
37	No delay in reporting risk-adjusted outcome measures	☐
38	Formal peer review process prior to publication	☐
39	Local database managers can perform ad hoc analyses	☐
40	Annual report publicly available	☐
41	Documented procedures for reporting on quality of care, including addressing outliers or unexplained variance.	☐
Resources		
42	Appropriate and sustainable funding for collection, quality control and reporting	☐

Glossary

ACSQHC	Australian Commission on Safety and Quality in Health Care
AGAF	Australian Government Authentication Framework
AIHW	Australian Institute of Health and Welfare
AMT	Australian Medicines Terminology (AMT) – a national extension of SNOMED CT for use within information systems within Australia.
ANZICS	Australian and New Zealand Intensive Care Society
audit	An examination or review that established the extent to which a condition, process or performance conforms to predetermined standards or criteria.[1] Audits may be carried out on the provision of care, compliance, community response and completeness of records.
benchmark	A slang or jargon term, usually meaning a measurement taken at the outset of a series of measurements of the same variable, sometimes meaning the best or most desirable value of the variable.[1] A standard or point of reference.[105]
bias	Deviation of results or inferences from the truth, or processes leading to such deviation. Any trend in the collection, analysis interpretation, publication or review of data that can lead to conclusions that are systematically different from the truth.[1]
CDA	Clinical Document Architecture – an XML-based markup standard for specifying the encoding, structure and semantics of clinical documents for exchange. Part of the HL7 standard. Also see HL7.
clinical governance	A system through which…organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.[106]
clinical trial	Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.[107] In distinguishing a clinical register from a clinical trial: – A clinical register has broad inclusion criteria. It aims to recruit *all* patients with the disease or condition, or undergoing the procedure. A clinical trial is usually highly selective in its approach to patient recruitment. Therefore the findings from clinical trials are usually not as generaliseable as those from registers. – A clinical register is observational in nature. It observes practice in the real world without dictating the care to be given. In contrast, a clinical trial is interventional; patients are assigned to treatment or control groups.
clinician	A health professional whose practice is based on direct observation and treatment of a patient, as distinguished for other types of health workers, such as laboratory technicians and those employed for research.[108]

CRE PS	NHMRC Centre of Research Excellence in Patient Safety, Monash University
Guideline	A formal statement about a defined task or function. In the terminology developed by the European Community, directives are stronger than recommendations, which are in turn stronger than guidelines.[1]
HL7	Health Level Seven (HL7), is an all-volunteer, not-for-profit organisation involved in development of international healthcare standards. HL7 is also used to refer to some of the specific standards created by the organisation.
HPI	Healthcare Provider Identifier – for both individual providers (HPI-I) and for provider organisations (HPI-O). Also see UHI.
HTTP 1.1	HyperText Transfer Protocol 1.1 – a communications protocol for the transfer of information on the Internet.
HTTPS	Hypertext Transfer Protocol over Secure Socket Layer – indicates a secure HTTP connection; a communications protocol for the transfer of information on the Internet with enhanced security compared with HTTP.
ICD10	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
ICD10-AM	International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
IdM	Identity Management
IEC	Institutional Ethics Committee
iEHR	Individual Electronic Health Record
IHI	Individual Healthcare Identifier – a unique identifier for users of health care. Also see UHI.
ISO	International Organization for Standardization
MeTEOR	Metadata Online Registry – Australia's repository for national data standards for health, housing and community services statistics and information.
Minimum data set	A widely agreed upon and generally accepted set of terms and definitions constituting as core data acquired for medical records and employed for developing statistics suitable for diverse types of analyses and users.[1]
MTOM	Message Transmission Optimization Mechanism – a method of sending binary data to and from web services.
National Health Data Dictionary	The national metadata standards for the health sector are published in the National Health Data Dictionary by the Australian Institute of Health and Welfare.
NCRIS	National Collaborative Research Infrastructure Strategy
NEHTA	National E-Health Transition Authority
NHMRC	National Health and Medical Research Council
NMDS	National Minimum Data Set
NPC	National Product Catalogue
OASIS	Organization for the Advancement of Structured Information Standards (http://www.oasis-open.org/home/index.php)

ODP	Open Distributed Processing
OMG	Object Management Group – a consortium, originally aimed at setting standards for distributed object-oriented systems, focused on modelling (programs, systems and business processes) and model-based standards.
PBS	Pharmaceutical Benefits Scheme
quality of care	A level of performance or accomplishment that characterises the health care provided. Ultimately, measures of the quality of care always depend upon value judgements, but there are ingredients and determinants of quality that can be measured objectively. These ingredients and determinants have been classified by Donabedian into measures of structure (staff, facilities), process (diagnostic and therapeutic procedures) and outcome (fatality rates, disability rates, level of patient satisfaction).[1]
record linkage	A method of bringing together the information contained in two or more records – e.g. in different sets of medical charts, and in vital records such as death certificates – and a procedure to ensure that each individual is identified and counted only once. Record linkage makes it possible to relate significant health events that are remote from one another in time and place or to bring together records of different individuals, e.g. members of a family.[1]
register	The file of data concerning all cases of a particular disease or other health-relevant condition in a defined population such that the cases can be related to a population base. With this information, incidence rates can be calculated. If the cases are followed up, information on remission, exacerbation, prevalence and survival can also be obtained.[1]
registry	The system of ongoing registration for individuals entered into a register.[1]
SAML	Security Assertion Markup Language – an XML-based standard for exchanging authentication and authorization data between security domains, i.e., between an identity provider (a producer of assertions) and a service provider (a consumer of assertions)
SNOMED-CT	Systematised Nomenclature of Medicine, Clinical Terms
SOAP 1.2	A protocol for exchanging XML-based messages over computer networks, normally using HTTP/HTTPS.
standard	Something that serves as a basis for comparison; a technical specification or written report drawn up by experts based on the consolidated results of scientific study, technology and experience aimed at optimum benefits and approved by a recognised and representative body.[1]
TOGAF	The Open Group Architecture Framework – a framework for Enterprise Architecture providing a comprehensive approach to the design, planning, implementation, and governance of an enterprise information architecture.
TOGAF ADM	The Open Group Architecture Framework Architecture Development Method
UHI	Unique Healthcare Identifier, see IHI and HPI

UML	Unified Modelling Language – a standardised general-purpose software engineering modelling language. UML includes a set of graphical notation techniques to create abstract models of specific systems, referred to as UML model.
validity (study)	The degree to which the inference drawn from a study, warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn. Two varieties of study validity are distinguished: internal validity and external validity (generalisability).[1]
validity measurement)	An expression of the degree to which a measurement measures what it purports to measure. Several varieties are distinguished, including construct validity, content validity, and criterion validity (concurrent or predictive validity).[1]
WSDL 1.1	Web Services Description Language – an XML-based language that provides a model for describing Web services.
XACL	Extensible Access Control Language. See also XACML
XACML	Extensible Access Control Markup Language – a declarative access control policy language implemented in XML and a processing model, describing how to interpret the policies.
XML	Extensible Markup Language – a general-purpose specification for creating custom markup languages. It is classified as an extensible language as it allows its users to define their own elements. Its primary purpose is to help information systems share structured data, particularly via the Internet.
XOP	XML-binary Optimized Packaging – a convention for serialisation of XML Infosets that have a mix of binary and textual data, and, more generally for storing binary data in XML tags.