TESTING AND VALIDATING DRAFT OPERATING PRINCIPLES AND TECHNICAL STANDARDS FOR AUSTRALIAN CLINICAL QUALITY REGISTRIES

"**BI-NATIONAL BURNS REGISTRY**"

FINAL REPORT

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PART A.   EXECUTIVE SUMMARY

Significant burn injury is a distinct and important component of the overall burden of injury in Australia. There are approximately 50,000 burns related hospital admissions per year in Australia. The management of burns requires immediate emergency and surgical management, followed by prolonged nursing and rehabilitation input. There is great potential for permanent disability involving expensive surgical/medical treatments and psychological rehabilitative measures that span decades. Good critical care and surgical management means that there are more survivors of serious burns with the potential for significant permanent disability, thus the impetus to measure variations in practice and outcomes resulting from those variations is high.

The opportunity to participate in the ACSQHC clinical quality registry project came at a critical time in the development of the Bi-NBR. The Bi-NBR had been developed with strong clinical support but without registry methodological expertise. The resultant product was a registry with the aims of a clinical quality registry but neither the minimum dataset nor the methodology to achieve the set aims. The Department of Epidemiology and Preventive Medicine, through a tender with the Australian and New Zealand Burns Association (ANZBA) and underpinned by funding from the Julian Burton Burns Trust, assumed the management and custodianship of the Bi-NBR in March 2009 and commenced the development of the registry towards a clinical quality registry. Overall, participation in the ACSQHC project has resulted in a functioning clinical quality registry with strong prospects for the future. The responsibility of undertaking the evaluation of the draft Operating Principles and Technical Standards for Clinical Quality Registries provided a framework to stimulate thinking, progress the changes beyond what was possible with existing resources, provide a better end-product for users and stakeholders, and cement a clear plan for the future of the registry.

Through participation in the ACSQHC project, the Bi-NBR was able to meet the planned measurable outcomes including revision and implementation of the minimum dataset and data dictionary, development of key quality indicators and outcomes, commencement of a pilot project to collect long term functional and quality of life outcomes, development of a revised centralised web-based information system and associated hospital linkages, improved governance processes, and establishment of a routine reporting schedule and content.   These outcomes were achievable through thorough consideration, evaluation and application of the draft Operating Principles and Technical Standards document. At the completion of the ACSQHC project, the Bi-NBR was compliant with 33 of the 42 operating principles and partially compliant with three. The Bi-NBR plans to comply with the remaining six operating principles but due to the phase of maturation of the Bi-NBR, application and full evaluation of these remaining operating principles was not possible in the ACSQHC project timeframes.

From the experiences of the Bi-NBR, the key barriers to implementing the operating principles were variable experiences with the institutional ethics committee (IEC) approval process, limitations to health documentation and the application of data standards, and the short project timeframe. These are discussed in detail in the body of this report and a brief summary of the issues are provided here.

Despite presenting consistent information to IECs, the response was highly varied and opt-off consent could not be obtained at one site. A co-ordinated approach to educating IECs from organisations, such

as national and state health departments and the ACSQHC, about clinical quality registries is necessary to ensure the integrity of clinical quality registries and to enable these registries to meet the necessary standards to achieve their aims.

Many of the operating principles relate to data quality, integrity, standardisation, validity and utility. There is a clear theme throughout the Operating Principles and Technical Standards document to utilise administrative and existing data sources.   While this is a sound principle, there are difficulties implementing this in practice due to the limited data items collected by administrative datasets and questions around the standardisation and validity of administrative data.

The 12-month project timeframe stimulated rapid development of the Bi-NBR but, to meet the registry's project aims, decisions were made early on that impacted on the capacity of the Bi-NBR to comply with some operating principles and fully evaluate others.   Therefore, there remains a concern that finalisation of the Operating Principles and Technical Standards document may result in the inclusion of principles and standards that are not fully evaluated.

The draft Technical Standards for clinical quality registries document was a placeholder to tens of lengthy standards documents, often embedded with links to further documents. In general the technical standards were assessed as being sound in principle, a useful roadmap and something to work towards in the short to medium term on an organisation-wide basis. Many barriers were encountered to fully implement the technical standards in the Bi-NBR. These included time to recruit staff with expertise, time to review and implement the volume of standards, existing organisational practices, characteristics of the registry, the burns clinical context and centralised storage of de-identified data. These are discussed in detail in Part E of this report and a brief summary of the issues are provided here.

Three to four months were needed to recruit staff with expertise and to review the standards. The 12-month project timeframe didn't allow sufficient time to test some standards such as data transmission. As the Interoperability Framework and TOGAF were not in operation within the organisation, considerable delay and cost would have been borne to implement this standard prior to software implementation. These standards were also assessed as being best suited to a new, large, organisation-wide software development project. The dimensions, level of progression and its place as one of many projects within the organisation did not constitute a 'good fit' for the Bi-NBR. As little burns clinical data is captured by local clinical systems, it had not been implemented in HL7 or NeHTA's data specifications. Some burns concepts have been identified in SNOMED, but it has taken time to understand and cumbersome to navigate for a small slice of data. It was hoped that the Bi-NBR could operate at Level 4 but without identifying data, data exchange with hospital administrative systems was difficult, requiring manual intervention by each burns unit.

Finally, the past 12-months have been an intense development and building period for the Bi-NBR with numerous key outcomes achieved. Using the Operating Principles and Technical Standards as a guide, and through our experiences over the past 12-18 months, there are numerous challenges ahead. The major goals for the Bi-NBR include:

    i.   Establishing secure ongoing funding for the Bi-NBR

ii.   Progression of the Bi-NBR towards collection and storage of identifiable data at the centralised registry

iii.   Evaluation and refinement of the selected clinical quality indicators and minimum dataset items

iv.   Validation of several dataset items and further development of standardised methods for capturing key clinical data including investigating the use of SNOMED

v.   Refinement of the processes for monitoring and reporting quality of care

vi.   Exploration of the potential for key data linkages.

vii.   Completion of the long term outcomes pilot project and development of a methodology for routine collection of this information by Bi-NBR participants

viii.   Refinement of data access policies and the development of a clinical research plan or strategy

ix.   Increased scientific output including presentation of the data at key clinical meetings and peer-review publication in scholarly journals.

x.   An organisation-wide adoption of TOGAF and the Interoperability Framework, incorporating the Bi-NBR

xi.   The adoption of Unique Healthcare Identifiers as they begin implementation in mid-2010

xii.   Progression of data linkages with sites to enable submission of ICD-10 diagnoses and procedures to the Bi-NBR in de-identified format

xiii.   Development of secure messaging methods for transmission of local burns database data to the Bi-NBR for relevant sites

xiv.   Review of Level 2 Registry data entry methods post first quarterly report

xv.   Additional functionality to be built into the web-based information system to provide standardised reports and data extraction functions

PART B.   ABOUT THIS REPORT

This document represents the final report for the Bi-National Burns Registry (Bi-NBR) participation in the pilot clinical quality registries project for the Australian Commission on Safety and Quality in Health Care (ACSQHC). The objectives of the project were to:

   i.   Inform the development of Australian Clinical Quality Registry Operating Principles and Technical Standards through the application of the draft standards against an existing national registry or to the development of a new registry.

   ii.   Identify any issues or barriers relating to the draft standards which would limit uptake by registries.

   iii. Provide recommendations which will maximise benefit and knowledge gained, thus promoting best practise and optimal information for Government and other key stakeholders to make decisions on the final principles and standards to be adopted.

Part A of the report includes an Executive Summary.

Part C of the report provides a clear statement of the results of the project and details the status of the defined measurable outcomes of the project for the Bi-NBR. Essentially, Part C describes the achievements of the Bi-NBR relative to the deliverables outlined in the tender document.

Part D of the report provides a detailed evaluation of the Operating Principles (OP) outlined in the draft document. This section describes the methodology of the Bi-NBR relative to the operating principles, the influence of the OPs on the development of the Bi-NBR, an assessment of the relevance of each OP, the ease and cost implications of complying with the OPs, barriers to implementation of these principles, learnings associated with the use of the OPs, future plans to address Ops not achieved by the Bi-NBR, and recommendations regarding revision of the OPs. Part D of the report also includes a summary table outlining the progress made by the Bi-NBR in complying with the draft OPs. The information provided in Part D details the Bi-NBR's experience in applying the OPs, highlighting issues experienced and potential solutions, where solutions were found.

Part E of the report provides a detailed evaluation of the draft Technical Standards (TS). Following review of each TS, an assessment was made of it's relevance to the Bi-NBR. Further assessment of the TS's quality and relevance to registries in general was also conducted. The extent to which each Technical Standard was implemented was then provided, based on the proposed level of usage outlined in the draft NeHTA Standards Map document. The level of implementation was based on whether the standard is currently met, could be implemented in the short (within 1 year) to medium (1-3 years) term, requires external changes, requires further development and/or funding, not considered able to be implemented in the short to medium term or not relevant to the Bi-NBR and therefore not evaluated. Part E of the report also includes methodological details of the Bi-NBR implementation of relevant technical standards.

Part F of the report provides a detailed summary of the project experience and future directions for the Bi-NBR with respect to its development as a clinical quality registry which complies with the ACSQHC's Operating Principles and Technical Standards.

The final sections of the report provide the supporting documentation for the registry and various documents relevant to the project.

PART C.   STATUS AGAINST MEASURABLE OUTCOMES

The status against measurable outcomes is reported, along with other key project tasks. The Bi-National Burns Registry (Bi-NBR) experiences with the Operating Principles (OP) and Technical Standards (TS) are detailed in Parts D and E. A summary of the measurable outcomes from the project plan and their status at the completion of the tender project is included at the end of Part C.

1. Reporting to the ACSQHC

All monthly status reports were completed and submitted to the ACSQHC, incorporating the period of December 2008 to September 2009 (inclusive).

2. Updated minimum dataset and data dictionary

The process of updating the minimum dataset was guided by the Operating Principles. The process for selection of the minimum dataset items were described in detail in the April 2009 progress report with further developments related to evaluation of the Operating Principles further discussed in Part D of this report. In summary, the minimum dataset consists of 30 data items provided as Appendix 1, many of them refined versions of the original data items. The minimum dataset also includes relevant burn-specific risk adjustment elements. Identifying data are held at the individual sites with de-identified data submitted to the central Bi-NBR using a unique case identifier. The revised minimum dataset and key clinical quality indicators were incorporated into a data dictionary using the METeOR system in June 2009 and a copy of the data dictionary is provided as Appendix 2. The completed METeOR data dictionary was not provided to end users, as it was considered too cumbersome and not user friendly. As a result an additional data dictionary was developed and provided to the data collection staff. This is provided as Appendix 3.

3. Development of key quality indicators

The ACSQHC provided the opportunity for the Bi-National Burns Registry (Bi-NBR) to evolve from an epidemiology-based clinical registry to a clinical quality registry. The development of key quality indicators and the collection of outcome data enable the Bi-NBR to better monitor and benchmark health care performance across contributing institutions.

The development of the key quality indicators involved a process of investigation, discussion and consensus decision making. A working party of expert clinicians in burns care was established to guide discussion and decision making, facilitated by the Bi-NBR Project Officer. Following extensive group, individual and email discussions between the working party members and the project officer, 20 core clinical quality indicators were agreed upon for inclusion into the Bi-NBR dataset. The draft Operating Principles and Technical Standards were used to drive the development of the quality indicators with the method of categorisation of quality indicators described by Donabedian (1988), and outlined in the principles adopted for the project. The planning, development and preliminary testing phase used to develop the indicators were taken from Mainz (2003) who outlines multiple broad phases to ensure that quality indicators are meaningful, scientifically sound and generalisable. A discussion document was

collated throughout this process to capture the journey of indicator development. The final document and the 20 quality indicators were ratified by the Steering Committee in June 2009 and incorporated into the data dictionary in Appendix 2.

The working party were guided by three key principles in the development of the quality indicators. These were: (i) they did not create significant data collection burden; (ii) were epidemiologically sound and; (iii) were valid in the burns setting. These basic principles created challenges for the group due to the variations in practice in burns care both in Australia and internationally, the ability to quantify outcomes in clinical care and resource commitment required from participating sites. These challenges and the relevance and ability to implement the Operating Principles will be discussed in further detail in Part D. The key quality indicators developed are therefore considered evolutionary, subject to review and modification as data provides information on their feasibility and usefulness.

The 20 key quality indicators were embedded into the dataset that went live on July 13th 2009. They will be reviewed in the same timeframes as the minimum dataset.

4.   Development of a revised centralised web-based information system

The existing Level 2 Bi-NBR database only partly met the key Operating Principles relating to data quality. In-built data management processes such as data range and validity checks (OP25) were minimal. Whilst security authentication was implemented using individual logins and passwords (OP19), data transmission between browser and web and database servers was not SSL encrypted. The risk to breach of privacy was minimal as data were de-identified, but the risk to data tampering and corruption was real.

Consideration was given to a short term update of the existing database to enable a rapid change to the revised minimum dataset, or to delay the implementation of the new database until the appropriate Technical Standards had been reviewed and considered for implementation. Given the delays in the revision of the minimum dataset and the development of the clinical quality indicators, the latter option was chosen by the Management Committee in consultation with the database personnel. The information system was developed to meet pre-defined project timelines so that there may be opportunity to test the data exchange and secure messaging standards with sites' local burns databases and hospital administrative systems.

User Acceptance Testing of the web-based information system was completed by the 30th June by four sites. Any identified bugs were fixed, and feedback incorporated into the revised version, prior to commencement of training on the 6th July. Three teleconference training sessions were completed by the 10th July, involving 20 representatives from 16 of the 17 burns units in Australia and New Zealand. Participants were equipped with a training manual (Appendix 4), to each enter a sample case during the session and provided with a feedback form on completion. The system went "live" on the 13th July as planned for participating sites with ethics approval. Data from the old system was mapped and migrated to the new system on the 23rd July. Paper data collection forms for primary admissions and readmissions were developed in the Teleform software and distributed for site use. These are provided as Appendices 5a and 5b. Ten sites have now entered 577 admissions via the new system.

5.   Establishing Data Linkages with sites

Extensive consultation with each Bi-NBR site commenced in February, to identify the existence of local burns databases and to better understand existing data collection processes. As individual sites identified different challenges with respect to submission of Bi-NBR data, a number of data process flowcharts were developed by the Project Officer and database personnel. These flowcharts (provided as Appendix 6) encapsulated four scenarios based on a combination of the existence and continued use of local burns databases, the submission of identifying data, the capacity and resources to link to hospital administrative systems and the need for an extended burns dataset, separate from the Bi-NBR Minimum Dataset. For example, a site with an established high quality local registry would benefit most through improved linkage with hospital information systems for data extraction, and electronic transfer of data to the Bi-NBR. Other sites, without a high quality local burns database, would benefit most through the addition of an extended burns dataset to the central Bi-NBR to expand its utility to an equivalent local burns database.

Site visits and consultations incorporated assessments of local burns databases' robustness, level of support and capacity for linkage with the Bi-NBR and, where necessary, advice was provided on their suitability to each scenario. Each site selected the most suitable option for their requirements for participation in the Bi-NBR. The selected scenarios have been implemented, or continue to be implemented, across the participating sites. The progress of each site is provided in Appendix 7. Data specifications provided to sites maintaining or developing local burns databases are provided in Appendix 8.

6.   Pilot collection of quality of life and functional instruments

The Operating Principles suggest that for clinical quality registries, outcome determination needs to occur when the clinical condition is stabilised. The increased survival of patients with severe burn injury has resulted in a focus on measuring long term outcomes for this group. Outcomes commonly referred to in the literature include quality of life and functional ability. Pain, itch, psychosocial functioning, return to work or school, and parent factors have also been highlighted as domains to measure. Due to the additional cost associated with collection of long term outcomes and the need for results to influence and drive monitoring of quality of care, it was decided to firstly determine the feasibility of collecting outcome measures as a routine component of the Bi-NBR.

A working party was established to develop the Long Term Outcome Pilot Project Methodology using the Operating Principles as a guideline. The group had varying experience in collection of outcomes for burns patients and were able to agree on most components of the methodology with ease. The time points to follow-up and the mode of administration required most discussion. Due to the length of time of rehabilitation and recovery involved with a burn injury, follow-up over an extended period of time was necessary. The time points chosen were 1, 6, 12 and 24 months after injury. Follow-up rates are critical to obtaining valid and reliable data. Working party members had varying experiences with follow-up rates from different modes of outcome administration and therefore consensus on a single mode could not be achieved. It was decided that multiple modes would be used in the pilot project and analysis of follow-up rates and resource usage would also be captured to inform future protocol

recommendations for outcome collection for the Bi-NBR.   An expression of interest to participate in the pilot project was sent to the Head of Unit of each adult burn centre.   Five sites volunteered to participate in the pilot.   Ethics has been submitted to the 5 sites with 2 approved and results of the other 3 pending.   Recruitment commenced at the 2 sites with ethics approval from Monday 19th October.   The aim is to recruit 400 participants for the pilot project.   The project will span 3 years and results will inform recommendations for the future collection of long term outcomes as a routine component of the Bi-NBR.   The relevance and ability to implement the Operating Principles in developing this pilot project methodology is discussed in detail in Part D.

7. Established Routine Reporting Schedule and content

The reporting schedule for the quarterly reports were agreed upon after circulation to the Reference Committee and endorsed by the Steering Committee. This is provided as Appendix 9. A draft of the quarterly report content was provided to the Steering Committee for feedback and endorsement. This is provided as Appendix 10. The first quarterly report based on the revised dataset and database will be completed in December 2009.

8. Summary Status against Measurable Outcomes

Task		Status
Reporting to the Commission	Detailed project plan & initial assessment	Complete
	January status report	Complete
	February status report	Complete
	March status report	Complete
	Progress report 1	Complete
	May status report	Complete
	June status report	Complete
	July status report	Complete
	August status report	Complete
	September status report	Complete
	October status report	Complete
	Final project report	Complete
Updated minimum dataset & data dictionary	Revised dataset approved by Steering Committee	Complete
	Revised data dictionary approved by Steering Committee	Complete
	Complete update of data dictionary	Complete
Development of key quality indicators	Establish working party	Complete
	Provide report to Steering Committee for feedback	Complete
	Revision of document	Complete
	Ratification of suite of indicators	Complete
Pilot collection of quality of life & functional outcomes	Establish working party	Complete
	Identification of outcome measures	Complete
	Development of collection protocols	Complete
	Approval of pilot project by Steering Committee	Complete
	Revision of database to accommodate measures	Complete
	Staff training at pilot sites	Complete
	Commence data collection	Complete

Task		Status
Development of revised centralised web-based information system	Incorporate revised Minimum dataset	Complete
	Incorporate Quality Indicators	Complete
	Staff Training	Complete
	Data Migration	Complete
Establishing Data Linkages between the Bi-NBR and sites' Local Burns Databases and Hospital Administrative Systems	Liaison with IT staff at each site to establish feasibility	Complete
	Report to Steering Committee	Complete
	Development of linkages at sites	In progress
	Trial and revision of linkages	In progress
	Finalisation of linkages	In progress
Established routine reporting schedule and content	Draft report of reporting schedule and content	Complete
	Presentation of report to Steering Committee for approval	Complete
	Finalisation of reporting policy	Complete

PART D.   OPERATING PRINCIPLES

A summary table outlining the progress made by the Bi-NBR in complying with the draft Operating Principles (OPs) is provided at the end of Part D. A detailed evaluation of each OP follows.

Attributes of Australian Clinical Quality Registries

OP1.   Clear and defined purpose

Should be developed with clear and precisely defined purpose

Methodology

The Bi-National Burns Registry captures information about adult and paediatric burn injuries admitted to Australian and New Zealand burns units. Prior to the ACSQHC project, ANZBA had clearly and precisely defined aims for the registry and these have been retained:

  i.   Describe the epidemiology of burn injuries and inform the development of burn injury prevention strategies in Australia and New Zealand

  ii.   Monitor the type and quality of burn care management

  iii. Establish the clinical outcomes of burn patients

  iv.   Improve service planning

  v.   Develop best practice clinical guidelines and initiatives

  vi.   Benchmark performance indicators on a state, national and international level.

While the original aims of the registry included aspects of clinical performance and benchmarking, historically the registry acted as an epidemiological registry only as the original minimum dataset was only capable of addressing aims i. and iii. The ACSQHC project provided the opportunity to evolve the clinical registry into a clinical quality registry capable of monitoring and improving healthcare performance, and benchmarking.

Recommendations

OP1 remains unchanged as it is fundamental to clinical registry development. OP1 should be a core operating principle and one of the first addressed by any registry, not just clinical quality registries.

OP2.   Collect a core minimum dataset

Should focus their core data collection on the essential elements required to serve their main purposes

Methodology

Prior to the Bi-NBR tender to Monash University, 24 data items were collected by the registry. These data items were largely descriptive of the admitted burn population, basic management and patient outcomes. Whilst the dataset would be described as minimal, clear definitions of many data items were absent and many of the data items were poorly populated in the database The pre-existing minimum dataset was not an adequate 'date spine' and was incapable of meeting the aims of the registry. Each minimum dataset item was evaluated through a process of working documents, meetings and teleconferences. The Operating Principles were used extensively to guide this consultative process.

The revised minimum dataset contains 126 data items. Many of these are refined versions of the original data items providing a 'data-spine', essential to understanding the demographics of the burns population and their injuries. The minimum dataset also includes relevant burn-specific risk adjustment elements (e.g. % TBSA and burn depth), discussed in further detail with OP18. The Bi-NBR minimum dataset does not currently include identifiable data items and the reason for this, and the implications for the future, is discussed with OP15.

The ACSQHC project provided the opportunity to move to a clinical quality registry with the inclusion of quality indicators and long term outcomes. An additional 12 quality indicators were developed using a similar process to the minimum dataset. These indicators are considered the core items necessary to better understand the care provided to burns patients based on anecdotal and documented evidence of best practice. OP2 recommends that "registries collect only the bare minimum of easily obtained data to supplement existing administrative systems." In order to collect valuable data on quality of care, however, data elements need to be specific to the clinical population studied. The variations in, and quality of, documentation, hospital administration systems, and hospital resources for data collection make it challenging to adhere to this principle. Competing interests within the burns community and participants in the registry committees also challenge this principle as there is often considerable pressure from clinicians to include data items of interest to their particular are of research or practice, increasing the importance of OP2 as a core principle for clinical quality registries.

Recommendations

This principle is clearly defined and would represent a core principle for all clinical quality registries.

OP3.   Collect epidemiologically sound data elements

Data collected should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible;

<u>Methodology</u>

The revision of the existing Bi-NBR minimum dataset involved developing definitions where none previously existed, refining definitions where they did, removing redundant items that were not being collected, and a thorough review of the utility of the data items relative to the aims of the registry. Where standard definitions were available from either METeOR, burns-specific sources, or other established classification systems (e.g. International Classification of External Cause of Injury (ICECI), these were considered and were adopted in preference. The collection of ICD-10 codes was included in the minimum dataset as a standardised way of collecting diagnosis and procedure data.

OP3 is a valuable principle and should be a primary consideration in the selection of items. However, it is difficult to ensure data provided is comparable and epidemiologically sound. Challenges exist due to individual hospitals not applying the same methodology to data collection and therefore using existing administration systems can be limiting. Feedback from participating sites suggests the METeOR definitions used in the dataset are not necessarily those used within the hospitals. For example, the METeOR definition and code set for ethnicity was adopted by the Bi-NBR but feedback suggests that hospitals do not use the same definition of ethnicity or collect this information uniformly. While METeOR is considered the authoritative repository for data standards, this does not translate to standardised data collection within the hospital setting. When existing data standards are not applied by hospitals, there are significant implications for clinical quality registries and the onus is shifted back to the registry to develop and evaluate the validity of data elements. The wider implications for this are increased costs in registry development and the potential for registries to use different methodologies for collecting similar data items. Where a data standard exists, this should not be necessary.

The lack of uniform burns specific definitions or practices also challenges the application of this principle. For example, there is currently no standardised practise across the burns community for collection of the definitive total body surface area (%TBSA) burnt. Assessment of %TBSA influences initial treatment and predictions for outcome, and is considered a core data element for assessment of burn severity and risk-adjustment.   The absence of a standardised methodology for the collection of %TBSA is a significant limitation for the Bi-NBR but exclusion of this important item would be untenable. The reliability of findings for this element will be questioned until an agreed standardised assessment and recording method is established.

The absence of standardised methodology and data standards is also true for the burns-specific quality indicators where data elements have been developed specifically for the registry and are not routinely collected in hospital administration systems. The quality indicators have been developed to measure variations in burns care practise, and the reliability and validity of these items will be necessary as a function of the registry development.

Manual retrieval also challenges OP3. Individual interpretation contributes to the inability to ensure data collected is epidemiologically sound. For example, initial feedback from the Bi-NBR suggests that data from event details are often subject to coders' interpretations. Additional work is required by the Bi-NBR to ensure data accuracy of these items.

Recommendations

OP3 is useful for the development of a clinical quality registry and clearly defined. The application of the principle is challenged by hospital administrative data not adhering to established data standards (e.g. METeOR) and the need to collect specialty clinical information to meet the aims of a clinical quality registry. This limits the use of existing administrative data and the validity and reliability of the data. The major implication for a developing clinical quality registry is the requirement to undertake specific data reliability and validity studies to justify and evaluate minimum dataset items, increasing the operating and development costs of the registry. While OP3 is well defined in principle, for many registries to meet their aims, development work will be needed to establish epidemiologically sound data elements and perhaps a recommendation or suggestion along these lines could be added to the discussion and qualification of OP3.

OP4.   Uniformly collect data

Methods used to collect data should be systematic, with identical approaches used at the different institutions contributing information

Methodology

The Bi-NBR data collection processes are reliant on the sources of information available at each site. All participating institutions use a combination of medical records and hospital administrative systems to collect data. Some hospital systems do not allow for easy access to primary source data while others do. One coder has not been able to access an electronic version of the ICD-10 codes and been manually entering data that should be easily accessible in an electronic version. Substantial discussion and negotiations have been required to resolve this issue and the outcome is pending.

The detailed clinically-specific information required for collection of quality indicators is not captured by routine hospital administrative data, increasing reliance on data collection from other data sources such as medical records. Abstraction of information from medical records and non-electronic data sources provides an environment for greater error in data collection and methodological variation. Clear and standardised definitions for data elements are necessary and have been defined by the Bi-NBR but where the capture of information relies on non-standardised data sources (e.g. clinician notes in the medical record), the ability to apply the registry's established method and definitions is challenged.

Recommendations

The very nature of clinical quality registries which involve collection of information necessary to assess the quality of clinical care and performance in key clinical specialties is the major

challenge to OP4. Because the detailed clinical information is not routinely captured by administrative data sources, a major challenge for registries is to establish standardised methods for data collection from sources where standardisation is difficult. OP4 is important and as a base principle, is critically important. In practice, the reliance on clinical data and medical records makes it difficult to ensure complete standardisation of methodology across sites, as each has a different amalgam of local clinical systems, some have existing local burns databases and the quality of record keeping will always vary. This will be true for most clinical specialties.

OP5.   Time to Outcome Assessment

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

<u>Methodology</u>

OP5 refers to stabilisation of the clinical condition and that stabilisation does occur. OP5 is non-specific and allows for clinical specialities to determine the length of outcome determination appropriate to the specific condition. The pattern of recovery and rehabilitation from burn injury has not been studied well in the past, particularly in Australia and New Zealand.   In order to gain valuable outcome data for the burns population, consideration of the prolonged process of healing and rehabilitation was required. The time points of 1, 6, 12, and 24 months were identified as key milestones for burn recovery and rehabilitation.   A pilot project was developed to establish the pattern of recovery of burns patients using key patient outcome measures such as health-related quality of life, burn-specific function, return to work, itch and others. The pilot project will provide the opportunity to determine if the current time points are feasible and reasonable for the burns population and inform the long term outcome assessments for the Bi-NBR. Establishing the pilot project was a key outcome measure for the Bi-NBR tender but completion of this project will take approximately 3 years. Clearly this pilot project of longer term outcomes will extend beyond the completion of the ACSQHC project period.

<u>Recommendations</u>

OP5 should remain unchanged at present. The experiences of the Bi-NBR to date do not support recommendations for change at this stage. The discussion underpinning OP5 related to cost, burden, loss to follow-up and clinical stability, were all considered when developing the pilot project and were a valuable prompt for discussion and decision making. Outcome assessment and the measures used is a registry-specific. However, given that OP5 considers the potential for long term follow-up, and a number of registers are moving towards this, there could be an additional OP developed related to long term outcomes.   For example, it is generally recommended that a "generic" instrument is paired with a "condition-specific" instrument. Consideration should be given to ensuring that Australian clinical quality registries consider using the same "generic" instrument (e.g. EQ-5D or SF-12 or SF-36) to maximise the potential for linkage and comparison. Understandably, this extends beyond the current operating principles

but as more registries move towards collecting long term patient-reported outcome measures, there will a greater need for guidance and more specific principles put in place.

OP6.   Outcome Assessment considerations

In determining the time to outcome assessment, must consider the burden and cost of data collection together with the likelihood of loss to follow-up

<u>Methodology</u>

OP6 suggests consideration is required of the burden of data collection and the likelihood of loss to follow-up. It is acknowledged in the Bi-NBR pilot project that collecting long term outcome data is costly and requires additional resources. One of the pilot project aims is to determine the feasibility of collecting this data as a routine component of the registry. Variations and success in mode of administration, loss to follow-up and the quality of received data (e.g. completeness) will all be reviewed in the pilot project to provide recommendations for future long term outcome protocols. If the data are deemed valuable in monitoring quality of care provided, ongoing funding would be required in order to sustain this date collection. The utility information and outcomes of this project, and of other registries pursuing long term outcomes follow-up, will be critical in guiding registries with respect to appropriate costs and budget planning.

<u>Recommendations</u>

OP6 suggests consideration of these factors but does not extend towards standards or guidelines for these elements. OP6 therefore is useful for directing registries to consider these factors, but provides no further insight into how a registry would measure the benefit (e.g. cost-benefit) or identify acceptable follow-up rates. It is the latter that registries would find the most useful and could be given consideration in any future updates of the operating principles or supporting documentation for clinical quality registries. Nevertheless, the Bi-NBR is not in a position to further evaluate this OP as the pilot project is not due for completion for some time.

OP7.   Selection bias

Must ensure that complete registry data are collected from the eligible population

<u>Methodology</u>

OP7 suggests that 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 on the registry. There are two concepts embedded in this principle that have been separated for the purposes of evaluation:

Selection bias

'All eligible patients within a defined clinical population are included on the registry'

The primary strategy employed by the Bi-NBR, and recommended in the supporting documentation, was to minimise the potential for selection bias by obtaining opt-off consent.

Opt-off consent ensures all eligible patients are included in the registry unless they specifically request not to be and has been shown to improve case capture (Tu et al, 2004). At the time of this report, all but one of the Bi-NBR sites with ethics approval has obtained opt–off consent. One paediatric site has refused opt-off consent and a formal written informed consent process is required. This creates the potential for selection bias and will need to be considered in any institutional comparisons. The refusal of opt-off consent also has implications for the costs of operating the Bi-NBR at this site as gaining individual written informed consent requires considerable resources beyond the collection of data. This site is collecting information about their recruitment rate which will prove useful in feeding back to the Bi-NBR and the relevant ethics committee.

Our experiences to date, particularly with paediatric and Queensland sites, suggest there is limited understanding within Ethics Committees about the purpose of clinical quality registries and the need for opt-off consent, or an inability to accept the risk associated with approving a registry using opt-off consent. One Bi-NBR participant reported that their ethics committee "would not approve any form of *passive* consent".   It is anticipated that as the ethics committees' exposure and experiences with clinical quality registries increases, consistency in the approach to consent will be achieved. However, the development of specific documentation for ethics committees by the NHMRC and organisations such as ACSQHC would be enormously beneficial. Through the duration of this project, there have been varying reports of the pilot registries' experiences with obtaining opt-off consent and the issue of capture of identifiable data. It should be noted that every IEC's approach to applications is individual. Our experiences at putting different registries to the same IEC have resulted in different outcomes despite using the same documentation and wording. Assuming that because one registry was approved, another would be is an over-simplification of the ethics process as each registry studies a different population (of varying sizes) and collects different information.

The methodology for audits on the number of admissions to a burns unit versus the number entered into Bi-NBR will be developed to measure the level of ascertainment. This is explored further in OP22.

Data Completeness

'Meticulous attention must be afforded to ensuring that complete data are collected on all patients'

Registries have the capacity to ensure a degree of data completeness by building measures into the data entry system. The following have been included in the Bi-NBR:

i.   All data fields have been made mandatory. Where a site does not collect certain data items, they are still required to populate the field with the most appropriate response (e.g. inadequate documentation to code, not stated, etc.)

ii.   Conditional data fields are disabled until a response to the mandatory field is recorded.

iii.   Validation checks to ensure fields have a pre-prescribed set of values and that responses outside the prescribed set of values cannot be entered.

iv.   Data completeness reports provided to sites when requested and progress has been made on building these reports into the web-based system for sites' adhoc use

Registries have limited control over the level of data completeness within the hospital setting. Here, the level of data completeness is largely dependent on local processes and systems. As a registry is developed separate from these processes, it is unknown across all jurisdictions as to whether all data items can be collected. Changing processes to collect data items not routinely collected can be slow and may require organisational change at the clinician level.

Recommendations

It is recommended that OP7 should be separated into two operating principles; the first, complete case capture; the second, complete data collection for each case. It is also recommended that complete data collection be included in the data quality section (OP23-25.) OP7 (either as stated or split into two operating principles as recommended) is fundamental to the aims of all clinical quality registries. Further education and training of Ethics Committees with respect to the purpose and needs of registries would assist clinical quality registries in approving their operations and adhering to this OP.

Data collection

OP8.   Minimise Data Collection Burden

Does not impact on the provision of health care and should not be a burden or incur a cost to consumers

Methodology

Piloting and Training

Prior to implementation of the web-based information system, user acceptance testing was completed by 4 sites with feedback incorporated into the final version. Three teleconference training sessions were conducted involving 20 representatives from 16 of the 17 burns units in Australia and New Zealand. Participants were equipped with a training manual to each enter a sample case during the session and provided with a feedback form on completion. Training was an important strategy to reduce the burden of data collection, and to ensure data collectors become proficient in the data collection and entry process.

Data collection in the hospital

Documentation and record keeping remains the biggest obstacle in the data collection process. Data retrieval is time consuming as documentation is not standardised within or across institutions. Current data collection feedback from the Bi-NBR has indicated that data retrieval and entry into the database is time consuming. There are inconsistencies in resources available to retrieve and code the data as some Bi-NBR facilities have designated positions to do this while others do not.

The inclusion of data items that are not routinely collected in administrative systems creates additional burden for data collections. The burns-specific elements such as burn size and depth and many of the quality indicators rely on manual retrieval. With the current standard of documentation and record keeping within facilities, OP8 is at odds with the purpose of clinical quality registries in the current data environment. The information required to monitor quality of burns care is time consuming to collect and at times considered burdensome but without improved administrative data and data systems, there are few alternatives if the aims of the registry are to be met.

Data Capture Tools

A revised web-based information system was developed for the Bi-NBR to incorporate the revised minimum dataset and quality indicators, and to migrate any existing data into one system. The data entry process was streamlined to minimise manual effort, the look and feel changed to improve the user experience, and the means of searching for and tracking the completeness of cases entered incorporated. OP8 could be considered at odds with OP25 which requires assurance of data quality thru built-in validation, requiring a balancing of needs and priorities. Of the cases that had data entered from admission to discharge on the same day, the median time for entry was 10 minutes (excluding ICD-10 data) which would be considered acceptable. However, the retrieval time (i.e. abstracting the information for entry) was not included in the data entry time, and is considerably longer.

Existing data sources were also evaluated in order to minimise the data collection burden (see OP13)

Recommendations

Strategies such as training, the data elements selected and the database developed can minimise data collection burden. However, without additional resources to validate data items and improve hospital data systems, it is difficult to apply OP8 without compromising the quality of data collected and, in turn, the aims of the registry. With the development of electronic health records in the future, many of the burdensome data collection processes have the potential to be eliminated. However, current data availability limitations and the need to capture detailed clinical information from non-electronic data sources challenge the implementation of OP8. Nevertheless, OP8 provides a guide that can be useful in discussion and prioritisation of data items when dataset items are selected and data collection processes developed.

OP9.   Timeliness

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

Methodology

Registry procedures, including timeframes for capture of specific data items, were specified. However, each site has its own local procedure for data capture with many of the Bi-NBR sites

having longstanding local registries and procedures. A data collection form was developed and data collectors are encouraged to retrieve the data as close to the episode of care as possible and the quarterly reporting schedule specifies deadlines for completion and submission of cases, a strategy implemented to improve the timeliness of data capture and submission. All sites have the same data submission timeframes to ensure analysis and reporting can be completed in a timely manner. With the inclusion of the ICD-10 codes these reporting timeframes have allowed for local health information coding timeframes to ensure all data are available for reporting. Nevertheless, it is unclear at this stage if the reporting timeframes developed are feasible and meet the needs of the Bi-NBR sites. This will be further evaluated following the completion of the first Bi-NBR quarterly report.

The major challenge to implementing OP9 is resourcing at individual sites. As burns admissions are less prevalent than, for example, cardiac surgical procedures, justification for dedicated staffing for data collection becomes difficult. The solution to this problem would be specific allocation of funds to individual sites to support a data collector. Currently, there are no ongoing funds allocated for this purpose and is reliant on the individual site budget and staff availability. Future requests for funding will attempt to address this. Potentially, submission of complete data to the Bi-NBR could form a component of unit accreditation, which would assist in establishing dedicated Bi-NBR staff.

Recommendations

In principle, OP9 is appropriate and has assisted in developing Bi-NBR protocols. However, the principle has not been adequately tested for the Bi-NBR to make clear recommendations.

OP10. Accessible from the Primary data source

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

Methodology

The issues with data abstraction and access, and the implications for data quality and validity have been discussed in detail with OP4 and OP8. Data accessibility is site dependent and is not uniformly done. The individuality of hospital administration systems provide varying levels of ease of accessibility. For example, the collection of information related to mechanical ventilation of patients is straightforward in some hospital administrative systems, complex at others requiring access to hospital databases that are not routine (e.g. ICU register) or requires collection and calculation directly from the medical record.

Recommendations

It is unclear whether this OP adds additional information that is not already covered by OP4 and OP8. Further justification and clarification of this OP above and beyond the other operating principles warrants consideration. Any redundancy should be addressed.

OP11. Standardised Data Elements

Standard definitions, terminology and specifications should be used 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.)

<u>Methodology</u>

Applying this principle was possible for standard data elements. Where standard definitions were available from either METeOR, burns-specific sources, or other established classification systems (e.g. International Classification of External Cause of Injury (ICECI), these were considered and were adopted in preference. The collection of ICD-10 codes was included in the minimum dataset as a standardised way of collecting diagnosis and procedure data. However, as discussed in detail in OP3, the existence of data standards does not ensure that these are used by hospitals, creating considerable difficulties in applying OP11 to the Bi-NBR.

For burns-specific elements, many new definitions were required. Most data elements included in the Bi-NBR minimum dataset were not addressed by systems such as METeOR or versions listed by METeOR were not suitable. While every effort was made to identify existing data standards, and to incorporate these in the revised Bi-NBR dataset, the tight timeframes of the project and limited expertise and understanding of particular standards e.g. SNOMED), restricted the opportunity to explore how these systems could be useful for the Bi-NBR and the application of OP11. Following recent training, it is anticipated that more standardised data elements will be incorporated into revisions of the Bi-NBR. Given that the minimum dataset will be reviewed in detail following the first completed quarterly report, the recent training and discussions will be timely in that revision process.

In practice, some of the standardised data definitions have been too inflexible or ambiguous for use in the Bi-NBR population. Additions and modifications to some of these definitions have been required in order to obtain the information appropriate to the burns population. For example, additional funding sources were required than those contained in METeOR, particularly to address key compensable bodies in the burns population and the inclusion of New Zealand in the Bi-NBR. Nevertheless, where modifications were made to any standardised item, it was ensured that the Bi-NBR could be mapped back to the standard for comparison with other registries or data sources. See Technical Standards 2.1

<u>Recommendations</u>

Time constraints and pre-existing Bi-NBR project deliverables limited the opportunity to explore all potential data standard sources fully. There were existing project deliverables for the Australian and New Zealand Burns Association (ANZBA) that required implementation of project aspects before consideration of all existing data standards could be exhausted. Through improved availability of registry data dictionaries, sharing of information and experiences, the potential to maximise consistency in definitions, terminology and specifications will be realised. OP11 is critical for underpinning this aim.

OP12. Data Dictionaries

Used to ensure that a systematic and identical approach is taken to data collection and data entry. Eligibility criteria, metadata, data dictionaries, etc. should be published.

Methodology

Through the ACSQHC project, the Project Officers and database personnel underwent METeOR training in February 2009 in preparation for the data dictionary development. The revised minimum dataset and key clinical quality indicators (126 data items) were documented in the METeOR data dictionary in June 2009. This took longer than expected as the METeOR system was slow, the training was not comprehensive, and little post-training user support was available. The completed METeOR data dictionary was not provided to the end users as it was considered too cumbersome and not user friendly. As a result an additional data dictionary was developed and provided to the data collection staff. This is provided as Appendix 4.

Recommendations

The Bi-NBR, under advisement, pursued the use of METeOR to develop a working data dictionary for the registry. The end product was unsuitable as a working data dictionary. This reflects the issues identified earlier in the methodology aspect of this OP evaluation. There is no question that OP12 is a necessity and that all clinical quality registries should have a data dictionary. OP12 should be extended to include direction about the data dictionary being up to date. During the project, access to existing and mature registry data dictionaries was requested and it was clear that many were outdated. OP12 should specify the presence and the accuracy of the data dictionary. While the Bi-NBR had a negative experience with the METeOR system for developing a working data dictionary, there are plans to further explore other areas.

OP13. Existing Data Sources

To avoid duplicating data capture, Australian Clinical Quality Registries should use existing data sources including administrative data, where they are of a satisfactory quality

Prior to the ACSQHC project, the Bi-NBR Steering Committee had agreed that existing administrative data were not adequate to meet the needs of the registry, but every effort would be made to use existing administrative data where possible. The revised dataset therefore includes data elements not routinely collected as discussed in OP3, OP4 and OP8.

OP13 provides a clear directive to avoid duplication of data capture which is important overall for registries, but also assists in meeting OP3, OP4, OP6, OP7, OP8, OP10, and OP11. Discussion of previous operating principles has detailed the challenges we faced with accessing quality routinely collected data. Nevertheless, to apply OP13 and minimise data capture duplication, a number of data process were developed encapsulating four data retrieval and submission processes. The scenarios were based on a combination of the existence and continued use of local burns databases, the submission of identifying data, the capacity and resources to link to hospital administrative systems and the need for an extended burns dataset, separate from the Bi-NBR Minimum Dataset.

For example, a site with an established high quality local registry would benefit most through improved linkage with hospital information systems for data extraction, and electronic transfer of data to the Bi-NBR. Other sites, without a high quality local registry, would benefit most through the addition of an extended burns dataset to the central Bi-NBR to expand its utility to an equivalent local clinical system. The addition of the Quality Indicators served to encapsulate much of the extended burns dataset.

Applying this principle has been challenging and time consuming, and has required extensive consultation and ongoing review of data elements and existing data systems. The absence of identifiable data has proved to be an impediment to the electronic submission of some data elements such as the ICD-10 codes as retrieval of these data must be done at the site-level and forwarded to the centralised Bi-NBR for upload. Collection of identifiable data would improve access to existing administrative systems and remains a priority for further development of the Bi-NBR. A summary of each site's status is provided as Appendix 7.

Recommendations

OP13 is clearly defined and useful however application of the principle remains a challenge due to the limited data routinely collected by hospitals, the non-adherence to data standards at hospitals, and the lack of information about the validity and reliability of routinely collected data. Again, many of these issues should be overcome with the progression to electronic health care records, another reason to pursue the inclusion of identifiable data on the centralised Bi-NBR.

OP14. Data linkage

Capacity for data linkage to other disease and procedure registers or other databases

Methodology

The Bi-NBR would anticipate needing to link with the National Death Index to supplement long term outcomes data collected directly by the registry. Throughout the development of the Bi-NBR and this ACSQHC project, the potential for the Bi-NBR to link with other data sources and registries (as approved by ethics) has remained at the forefront of discussions. The capacity to link with other routinely collected data would have enormous benefits in minimising the duplication of data capture, assessing data quality and case capture, and enabling comparison across other disease and clinical populations.

The major challenge to applying OP14 and ensuring that the Bi-NBR is "linkage ready" has been the exclusion of identifiable data storage centrally. Identifying information are retained at the individual participating site level and cases can be re-identified at hospital sites using the unique registry identifier where needed. While the capacity for linkage remains, with linkage performed at site-level, the potential for linkage is far from maximised and creates an extremely cumbersome process for any linkage activities.

The decision to capture de-identified data centrally by the Bi-NBR was the product of the existing structure of the registry, time pressures, and early poor experiences with the ethics

approval process. The Bi-NBR existed previously, operating without ethics approval, but with good momentum and support from participating sites. The need to establish ethics approval (including retrospective approval for data already submitted) was paramount to maintain the momentum of the project and the continuity of the data. The decision was made to seek ethics approval to continue the data collection using de-identified data. However, participation in the ACSQHC project, experience with evaluating the technical standards, and a general increased in the aims and activities of the registry have established that progression to central collection of identified data is a priority. Until ethics approval is secured for storing identifiable data by the registry, data linkage is unlikely to be attempted. Previous experience with the Victorian State Trauma Registry shows that even with identifying data, probabilistic linkage is problematic and costly. The implementation of unique health identifiers should streamline this process and the existence of a working UHI would be the ideal time point to approach ethics for a change in the registry processes.

<u>Recommendations</u>

OP14 is a valuable operating principle for clinical registries but the current ethics, privacy and health environment are challenges towards achieving this. Collecting de-identified data makes application of this principle extremely difficult but progressions in these areas would greatly enhance the capacity for linkage and will be a priority for future development of the Bi-NBR.

Data elements

OP15. Identifying Information

Should collect individually identifiable patient or subject information

<u>Methodology</u>

The Bi-NBR does not currently store identifiable data centrally and the implications of this are well described in the discussion relating to OP14 and OP7. This decision was made prior to the commencement of the ACSQHC project for expeditious ethics approval for a registry that had been previously operating without any ethics approval. The aim is to rectify this for the future.

Through liaison with the database personnel regarding the technical standards, the issue of the collection and storage of identifiable data has arisen. One Bi-NBR site has elected to use the centralised web-based registry as their local registry with the addition of site-specific modules, while a number of other sites have expressed in this arrangement but are yet to pursue this. These sites have requested, or will request, the collection and storage of identifiable data which can be used to exclude duplicates, improve the potential for linkage and enable follow-up of patients as this element of the registry exists. For other sites, where a local registry exists and the sites have opted to continue with data collection via the local registry and electronic upload of data to the Bi-NBR, the issue of identifying information is being raised. One site has now submitted an application for ethics approval to provide this additional information and has been successful. Over time, it is anticipated that all Bi-NBR sites will apply for similar approval however, it is clear that this may not be possible for New Zealand sites.

The absence of identifiable data made the system build more complex to register and validate duplicate patients and to add multiple admissions to the same burn injury patient, therefore taking longer than anticipated. The absence of identifiable data will make data linkages more challenging as discussed in OP14. In order to collect the long term outcome data, separate ethics applications have been submitted for the pilot project to enable capture of identifiable information for consenting participants. It is likely that in the future ethics applications will be submitted for identifiable data collection for the Bi-NBR. The introduction of unique health identifiers would be the ideal trigger to request a change in processes through the ethics committees.

<u>Recommendations</u>

OP15 is a valuable principle for clinical quality registries but is challenging to implement in the current ethics/privacy climate. Nevertheless, OP15 should be an aim for all registries. The Bi-NBR does not currently comply with this OP for the reasons outlined but the limitations of not doing so are well recognised and the addition of this information will be the focus of future work of the Bi-NBR.

OP16. Process of Care Measures

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

<u>Methodology</u>

The quality indicators were developed by consultation with an expert working party. OP16 guided their development and only process quality indicators that were linked to outcomes of care were included. There were challenges in ensuring that these process definitions were simple enough to allow data to be easily collected. This meant that some process indicators were broken down into a series of questions that started with a leading question about whether the process occurred and additional questions about the process.   While fragmentation of the indicators was done to simplify data collection, the end result is a higher number of data items.

For example, 'Did the patient go to theatre for burn wound excision?' is a primary question and an additional question is 'For full thickness and deep partial thickness wounds, was a complete burn wound excision completed within 5 days?'

As in OP5 the challenge with OP16 is defining the processes to ensure the outcomes are quantifiable and therefore easily understood and collected. There are a lot of processes in health care that are not easily quantified but have a direct link to an outcome. For this principle to be achieved, clear process definitions are required to enable data to be collected.

An underlying challenge of applying this principle is the relatively evidence-base that the registry development group had to identify process of care measures for inclusion in the Bi-NBR. Process of care measures are highly dependent on detailed clinical data and many process of care measures were excluded from the minimum dataset due to an inability to collect the necessary data reliably. This problem is unlikely to be solely confined the burns setting. For

many registries which are leaders in their field (e.g. the Bi-NBR), the information collected by the registry will be needed to establish whether there is an association between process of care and outcome in the first instance. Many process of care measures were identified by clinicians as having an impact on outcome but only through anecdotal evidence. OP16 does not further define "established link" and the level of evidence required to lead to inclusion is not specified. The Bi-NBR has therefore included process of care measures in the key clinical indicators where high level evidence is unavailable, but only where the data collection is feasible. Data from the Bi-NBR will determine whether these process measures do have a relationship with outcome and will provide valuable evidence for the future development of the Bi-NBR and registries elsewhere.

Recommendations

OP16 is valuable for providing guidance regarding the selection of process of care measures and providing standards of to aspire to. For many clinical areas, the science underpinning their selection is absent and in the case of the Bi-NBR, the evidence behind "established link" was taken very broadly to enable inclusion of process measures that could be validated within the operations of the registry and provide evidence for establishing whether they are valuable process measures.

OP17. Outcome Measures

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.

Methodology

The Bi-NBR was able to comply with OP 17 and compliance with this OP was given high priority. The outcome quality indicators are all assessed using objective measures and are often collected via administrative or pathology databases (e.g. ventilator hours or length of stay). The challenge is in creating clear definitions for the outcomes for even outcomes as superficially simple as mortality could be complex. Standardised and validated instruments were selected for the pilot study of long term outcomes and include the 36-item Short Form health survey (SF-36), the Burn Specific Health Scale Brief (BSHS-B) and the Brief Fatigue Inventory (BFI). Standards tools were also modified and abbreviated to answer questions where an existing standardised measure was not appropriate to the population or project. The Sickness Impact Profile work related questions have been adopted for inclusion in the project and questions specific to itch have been developed.

Recommendations

OP17 is clearly defined, useful and easily applied. No changes are recommended to this OP.

Risk adjustment

OP18. Risk Adjustment

Collection of 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

Methodology

Whilst defining the minimum dataset for the Bi-NBR, relevant burn-specific risk adjustment elements were identified and incorporated into the dataset. The risk-adjustment items are broadly separated into administrative and burn-specific. The Administrative risk-adjustment items include age, sex, ethnicity, and pre-morbid health. The burn-specific items include the %TBSA, cause of burn and the presence of inhalation injury.

Additional variables for risk adjustment will be considered if specific data is required such as cooling techniques and correlation with LOS or mortality.

Recommendations

Risk adjustment is fundamental to any registry and variables adjusted for are often those that are routinely collected in clinical registries. OP18 should remain unchanged. The Bi-NBR has included risk adjustment variables which are consistent with the broader health setting but also burn-specific measures necessary to enable valid benchmarking of burns units and care provided.

Data security

OP19. Secure data mechanisms

To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems

Methodology

Prior to the Bi-NBR tender to Monash University, security authentication was implemented in a Level 2 registry using individual logins and passwords. Passwords were not stored in an encrypted format within the database however. The revised web-based information system implemented password policies to further prevent unauthorised access, including database password encryption, mandatory password strength and locking account access after three unsuccessful attempts.

Data transmission between browser and web and database servers was not SSL-encrypted prior to the Bi-NBR tender to Monash University The risk to breach of privacy was minimal as data were de-identified, but there remained a risk to data tampering and corruption. As recommended in Technical Standard 4.3, Secure Sockets Layer (SSL) encryption was implemented without difficulty or significant cost.

Audit Logging was also implemented with minimal cost and difficulty to record successful and unsuccessful attempts at user access. System Logging was similarly able to be implemented to record the creation and modification of data records.

Recommendations

Whilst it is important to flag the importance of security in the Operating Principles so that they are given due recognition, security methodologies and techniques are defined at great length in the Technical Standards Section 4. It is not considered necessary to explicitly state the methodology for ensuring data security in the Operating Principles document, only to define that there is the requirement that this occurs.

OP20.   Compliance with privacy legislation

The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines

Methodology

The NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research were reviewed. Storage of paper forms at sites. Data is currently de-identified on submission to the registry, so there is no risk to inadvertent release of identifying details.

Registry electronic data are stored on a MS SQL Server 2000 database server. Data is mirrored using RAID so that data access is maintained when a single disk failure occurs. Data is backed up to an off-site facility on a nightly basis.

Submission of the Bi-NBR for Institutional Ethics Committee approval ensured that the privacy legislation in each state was adhered to. There is no site contributing data without IEC approval.

Recommendations

OP20 is important to ensure that relevant legislative requirements are addressed through appropriate data management practices. A National Privacy Legislation, instead of the current state-based legislation, would be beneficial as registry personnel would not need to be familiar with differing legislation and guidelines across multiple jurisdictions.

OP21.   Adherence to relevant Technical Standards

Institutional policy principles set out in Part B: Technical standards should be met

Methodology

Technical Standards were reviewed for relevance to the Bi-NBR. A detailed review and evaluation is provided in Part E of this document.

Recommendations

As for OP19, it is important to flag technical standards in the Operating Principles so that they are given due recognition, but there is no detail of this OP in the Operating Principles document

and no specific reference to the Technical Standards. It is recommended that OP21 remains but with a summary of its specific intent and a reference to particular Technical Standards.

Ensuring data quality

OP22. Ascertainment

Report as a quality measure the percentage of eligible patients recruited to the registry

Methodology

The process for ascertainment has not been tested for the Bi-NBR at this stage. Requests for ICD-10 data of burns cases to each Bi-NBR hospital are planned for comparison to those captured by the Bi-NBR. Admitted Episode Datasets in each jurisdiction may also be approached to gain a complete picture of all burns patients in each jurisdiction, not only the burns unit admissions. This would provide the percentage of eligible patients recruited to the registry.

Recommendations

The usefulness and validity of OP22 are clear. Whether this is achievable within all jurisdictions could not be ascertained within the project time frames.

OP23. Quality Control Plan

To allow ongoing monitoring of the completeness and accuracy of the data collected. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible

Methodology

Applying this principle is dependent on data management processes implemented for each site. Use of hospital administrative data ensures a high degree of ascertainment if used to recruit patients. Funding data is also likely to be very accurate. To ensure data integrity, data transferred from local burns databases needs to be tightly managed. This is particularly true in the absence of standardised definitions, terminology and data specifications. The same quality checks and business rules used in web-based data entry systems need to be applied to data received from existing electronic sources.

The use of web-based data entry systems have been used to ensure that the first quality checks have been completed at the point of entry. OP25 addresses reducing data entry errors by narrowing valid values entered manually. Building data completeness reports into these systems increases the timeliness of data collectors resolving incomplete data items and reduces study centre operating costs.

The first quarterly report will present the completeness of each data item in order to evaluate the "collectability" of each, particularly the Quality Indicators.

Recommendations

This OP overlaps with OP7 in its current format. It is recommended that data completeness is removed from OP7 and included in this section.

OP24. Regular Audit against source records

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.

Methodology

This principle has not been adequately tested at this stage. A data accuracy audit is in process to test for systematic (type 1) errors. This will identify ambiguous definitions and data capture methods and inform a data review scheduled after the first quarterly report. Additional audits will be conducted routinely to test for random (type 1) errors.

Recommendations

This principle is clear and essential. Whilst OP24 could not be performed within the project time frames for the Bi-NBR to provide recommendations, previous experience has found this to be resource-intensive and costly, but worthwhile.

OP25. Inbuilt data range and validity checks

Should incorporate in-built data management processes such as data range and validity checks

Methodology

The revised Bi-NBR system was developed with significant enhancements to meeting OP25 including required field, range and consistency validation, the facility to add multiple admissions (including readmissions) to a single case in the absence of identifying data, and minimisation of entry of duplicate cases. This was a moderately easy operating principle to administer, but was made more difficult by the absence of identifying data.

Recommendations

OP25 is an important tool for ensuring data quality. It is recommended that OP25 is expanded to include greater detail on the need to define mandatory versus optional fields, to ensure consistency checks or business rules are implemented, and to use coded values and minimise free text fields where possible. A section in the Technical Standards is also recommended to ensure best practice in achieving data quality.

OP26. Reporting Timeframes defined

Reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur

Methodology

This principle was easily applied. The reporting schedule for quarterly reports, were agreed upon after circulating to the Reference Committee. A draft of the quarterly report content has

been provided to the Steering Committee for feedback and finalisation prior to the first official quarterly report based on the revised dataset and database in December 2009.

Recommendations

Reporting is firstly identified in OP9.   OP26 appears to be a duplicate of this, though the intention may be quite different. One OP should cover Reporting and this should include;

- A strict timeframe
- Timeliness
- Funding

It is recommended that OP9 should focus only on data retrieval.

Organisation and Governance

OP27. Formal Governance Structures

Must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise outcome from the registry.

Methodology

The Bi-NBR governance structure was in place prior to the commencement of the ACSQHC project. Terms of reference for these committees were developed at that time based on the deliverables of the review and re-development of the Bi-NBR which broadly adhere to OP27. As the Bi-NBR shifts from the development phase to be more established with routine reporting commenced, the focus of the Steering Committee will change which will require revision of the Terms of Reference and membership.

The membership of the Steering Committee is consistent with OP27 except it does not yet include a consumer representative, a representative from funding bodies or policy developers. Potential representatives have been identified and invitations will be distributed in early 2010. Given the Bi-NBR is a Bi-National registry, gaining a representative from an appropriate jurisdiction is challenging. There is currently no single jurisdiction governing the registry or the Burns Units. This influences not only the ability to comply to OP27 but also to OP28 and OP36.

The membership committee structure and terms of reference are consistent with OP27. The Reference Committee was developed to complete the review of the minimum dataset and is responsible to the Steering Committee. The role of the Reference Committee has now shifted to ongoing monitoring and development work around the methodology of the Bi-NBR, its data collection and general operation. These functions are included in the terms of reference of the Reference Committee and will become the dominant activities.   Working parties were developed for the quality indicators and long term outcomes pilot and remain responsible to the Steering Committee as these projects are ongoing and their function will extend beyond the ACSQHC project.

Recommendations

OP27 is essential and the supporting information extremely valuable in assisting the formation of the governance structures. Minimal difficulty was experienced in complying with OP27 and no recommendations for change to this OP are made. However, further emphasis should be made regarding revision of terms of reference and committee membership to meet the changing needs of the registry.

OP28. Outlier Policy

Must establish policies to manage a range of contingencies arising from the analysis of data from the registry, include 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.

Methodology

OP 28 created significant discussion within the Steering Committee. Some clinicians voiced considerable concern regarding potential escalation protocols following past experiences with the misuse of such a protocol in the US. This highlighted the need for a true understanding of the aims and characteristics of a clinical quality registry and its purpose in monitoring quality of care. While the clinicians concerns were valid, the need for an appropriate process was highlighted. It was agreed that institutions that have outliers, whether resulting in poor or improved performance, would be notified. Consistent poor performance would be escalated to the level of a senior executive within that institution. As indicated in OP27, there is no single jurisdiction governing the Bi-NBR. Escalation polices at this level would need to be developed within the local jurisdiction.

Agreed Reporting and Escalation Process

- Generic epidemiological information will be used for annual reports. This will be publicly available and individual hospitals will not be named.
- If particular burns units had significantly worse outcomes the clinical processes will be reviewed in consultation with the hospital's Quality Assurance Committee.
- If particular burns units had significantly better outcomes, this information would be shared with other units and the hospital could be named if they give consent.

Recommendations

OP28 is clearly defined and extremely important in underpinning the purpose of clinical quality registries. For the Bi-NBR application has been limited by the lack of one single governing jurisdiction and concerns from the clinicians about the misuse of the data. As the Bi-NBR commences routine reporting and quality data outputs, further discussion will be necessary to refine the outlier reporting policy.

Data custodianship

OP29. Explicit Data Custodianship

Custodianship needs to be made explicit in Contracts and / or Funding Applications

Methodology

Prior to the involvement of Monash University, there was no clear custodianship of the Bi-NBR data and therefore the data were used minimally, and a formalised data access or reporting policy was not operational. Currently, the participating sites and ANZBA remain owners of the Bi-NBR with Monash University the custodians of the data. This was established in March 2008 and is consistent with OP29. Whether the current arrangement is appropriate for the future functions of the Bi-NBR as a clinical quality registry with the capacity to benchmark quality of care is still to be determined.

Recommendations

The Bi-NBR is compliant with OP29, however ongoing review is required and therefore there are no recommendations regarding change of this OP at this time.

OP30. Availability of data access and reporting policies

Data access and reporting policies should be made available to persons wishing to use register data.

Methodology

Reporting and data access policies have been newly developed but the first quarterly report of the Bi-NBR has not been completed. A detailed evaluation of these Operating Principles will occur as requests for data access are received following initial reporting of the data. These will be available to persons wishing to use register data.

Recommendations

The Bi-NBR complies with OP30 but there has been insufficient experience to date to fully evaluate the application of this OP and therefore it is not possible to make definitive recommendations.

OP31. Third Party Data Access and Publishing Policy

Third party wishes to access data and publish findings must seek approval from the Steering Committee and obtain relevant ethics

Methodology

The processes for third parties wishing to access data and publish findings have been developed but not yet trialled. The evaluation of this OP will occur as requests for data access are received following initial reporting of the data. The Steering Committee will oversee all third party data access and publication requests as outlined in OP31.

Recommendations

The Bi-NBR complies with OP31 but there has been insufficient experience to date to fully evaluate the application of this OP and therefore it is not possible to make definitive recommendations.

Ethics and Privacy

OP32. Ethics Approval

Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry.

Methodology

Seeking site IEC approval to contribute data to the Bi-NBR has been pivotal in sites being able to participate. At its inception, the Bi-NBR was developed and implemented without due consideration of ethics and privacy. In all cases, participating sites did not meet OP32. A key aim of the transfer of custodianship to Monash University has been establishment of the necessary IEC approval. To date, this has been one of the major challenges and barriers for the Bi-NBR. The approach of the IECs has been disparate, particularly with respect to the issues of consent and identifiable data.

The primary IEC approval was obtained from Monash University with the stipulation of individual site approval. Sites individually applied for local ethics approval, with support from the Bi-NBR staff members. Central support has included development of an information pack to provide consistent and standardised information for preparation of ethics applications. They were later further developed to strengthen the argument for opt-off consent following responses from the IECs. Also, ongoing support has been provided to help to clarify and answer queries from the IECs.

The Operating Principles do not address the issues of international participation which is understandable given the scope of the document. While the inclusion of New Zealand in the Bi-NBR does create an additional complexity with respect to ethics approval and privacy, this has not been the major challenge faced in arranging IEC approval across all participating sites.

Opt-off vs. Opt-in consent

The issues of consent are complex. Each site has requested opt-off consent approval to facilitate complete case capture (OP7) and reduce the resources required to operate a registry of the magnitude of the Bi-NBR. To date, 11 of the 17 Bi-NBR sites have received final institutional approval. Nine of the 11 have an opt-off consent process approved. Both sites in SA did not require submission to the full ethics committee and was approved as a quality assurance/audit project. One site could not achieve approval for an opt-off consent process and requires written informed consent from participants. The final site does not have an ethics committee and required sign-off from the Chief Executive Officer of the hospital and this was

received.   In particular, an opt-off consent process has been very difficult to achieve for paediatric sites.

One paediatric site continues to have ethics approval pending despite submission of the application in early 2009. The IEC queries largely relate to the opt-off consent process. The ethics committee of one of these sites has previously approved an opt-off consent process for a clinical registry but has requested an opt-in consent process for the Bi-NBR. Correspondence between the Bi-NBR site representative and the ethics committee continues.

Submission of Identifiable vs de-identified data

From its inception, the Bi-NBR had not collected identifiable data but data that are re-identifiable at the relevant participating site. Most sites have sought ethics approval to continue to submit data that are re-identifiable at the site level. Ethics committees have been largely amenable to this process and all but one of the sites that were submitting data without ethics approvals have been successful in securing retrospective approval, allowing data existing on the registry to remain and be used for the purposes of the Bi-NBR. The ongoing Technical Standards work has highlighted the importance of identifiable data for the registry and it is acknowledged that the submission of identifiable data would be beneficial for data quality, particularly OP23 (robust quality control plan) and OP24 (audit against source records), and for potential data linkages (OP14).   One site has acted as a test for seeking approval for the submission of identifiable data to the Bi-NBR while maintaining an opt-off consent process and the results of this ethics application was successful.   As outlined earlier in the report, the limitations associated with only collecting de-identified data are numerous and the plan would be to progressively re-apply to each IEC to seek similar approval across all sites.   However, New Zealand sites have already flagged that their regional ethics committees are unlikely to approve the submission of identifiable health data to a registry with an Australian-based custodianship. Widespread approval for the submission of identifiable data to the Bi-NBR was unlikely in the tight timeframes of the ACSQHC project and many of the sites had commenced the IEC approval process prior to commencement of the ACSQHC project.   A decision was made by the Steering and Management Committees to continue to pursue approval for de-identified data submission by the sites and enable greater time and resource focus on the development of the minimum dataset, quality indicators, piloting the long term outcome measures and commencement of data collection.   As discussed, seeking IEC approval for identifiable data collection will be addressed in the short to medium term.

Recommendations

OP 32 is very broad but the detail in the document does provide the guidance required to attempt to apply it. The variable IEC understanding of registries create challenges to gaining opt-off consent and collecting identifiable data, however the recent documents drafted by ACSQHC and Monash will assist in this establishing better understanding. Additional support and education on ethical issues for registries that could be provided to Human Research Ethics Committee (HREC) would assist in implementing this principle. Gaining ethics approval across multiple jurisdictions is also challenging. At present the use of the National Ethics Application

Form (NEAF) is not accepted by all HREC. Widespread acceptance of the NEAF would assist in making application of OP32 more streamlined and time efficient. Currently the inability to secure consistent consent processes across the Bi-NBR sites will likely impact on the registry's capacity to meet OP4 (systematic data collection with identical approaches) and OP7 (complete registry data collected from the eligible population) and will potentially reduce the percentage of eligible patients recruited to the registry. Without a standardised approach of ethics committees towards clinical quality registries, these issues will continue to arise and make it difficult for registries to comply with the Operating Principles.

OP33. Legislative Familiarity and Compliance

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

Methodology

Monash University has extensive experience in managing clinical registries and adheres to requirements set out in the above mentioned code and statement. Familiarity with the relevant guidelines and legislation enables personnel to understand whether clinical quality registries comply with these requirements and to help put forward a strong argument for IEC approval.

Recommendations

This principle is clearly defined and is easily applied when ethics applications are submitted to the appropriate IEC. As outlined in the discussion of OP32, applying OP33 would be made easier with greater understanding of clinical registries by IECs in terms of consent and identifiable information, and the compliance with privacy legislation. A National Privacy Legislation, instead of the current state-based legislation, would also assist in OP33 application as registry personnel would not have to be familiar with different legislation and guidelines across the multiple jurisdictions.

OP34. Participant Notification

Participants or their NOK should be made aware of the collection of registry data. They should be provided with information about ACQR, 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.

Methodology

OP34 has been applied across the Bi-NBR and is a requirement of IEC approval at each site. As a number of sites collect information beyond the minimum dataset of the Bi-NBR, the participant notification is not standardised across sites but standardised information about the registry was provided to sites for inclusion on the patient information forms. The challenge with this principle is ensuring that all patients actually receive the information. There is currently no process in place to determine whether patients are in fact receiving the forms distributed at the

site-level, however a checking system could be built into the audit process and will be considered for the future.

The five participating sites in the long term outcomes pilot project have been provided with standardised information about the project prior to consent being obtained but have been customised to meet local ethics requirements.

Recommendations

OP34 is an essential operating principle that is clear and easily defined. The challenges in applying the principle relate more to the requirements of local IEC approvals.

OP35. IEC approval sought for projects using register data

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

Methodology

Prior to the custodianship of Monash, there was no established governance for the registry and OP35 was never challenged as the data were not used for projects. A data access policy, publications policy and data request form have now been developed and therefore the Bi-NBR is compliant with OP35. Given the maturity of the data base these policies will not be put to practice until Bi-NBR data becomes available.

Built into the data access policy is the requirement to seek IEC approval for projects using registry data where a researcher requires data from a particular hospital or hospitals. A specific ethics application approval from that hospital(s) would be required before data would be made available. This ethics approval would be made jointly with the Bi-NBR. All other requests for aggregate data will be submitted in writing to the Head of the Bi-NBR. The Head of the Bi-NBR would take the data request to the next Steering Committee meeting. A decision on whether to grant access to the data would be considered following advice from the Steering Committee. Under no circumstances would data be provided that could identify individual hospitals or patients.

Additional ethics approval was sought for the long term outcomes pilot project. This was considered a separate research project and submissions for the IEC of all participating pilot sites were submitted.

Recommendations

OP35 is clear, useful and valid. Given the current maturity of the Bi-NBR, a full evaluation of this principle was not possible and no formal recommendations can be made at this time.

Information Output

OP36. Evaluation of Quality of Care and Benchmarking

Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.

Methodology

OP36 is linked to OP1. The aims of any clinical quality registry should include this element. The Bi-NBR has been developed to evaluate quality of care. The inclusion of the quality indicators provides the opportunity to benchmark across institutions due to the specific data processes that can be linked to outcomes. The quality indicators were developed based on best practice and will be measured against compliance with best practice guidelines where available. For example, the ANZBA Nutrition guidelines state for an adult with > 20% TBSA, and a child with > 10% TBSA, enteral or parenteral feeding should commence within 24–48 hours of admission. This has been included as a quality indicator and the Bi-NBR data will be used to assess compliance with this guideline. The inclusion of quality indicators about pre-hospital care also provides the opportunity for the Bi-NBR to influence community and emergency service education, providing information on current practices in terms of first aid management of burns against best practice. This could significantly influence the initial management of burns and impact on the long term outcomes, both measurable through the Bi-NBR.

Recommendations

OP36 underpins the aims of clinical quality registries outlined in OP1. The intention is clear and all clinical quality registries should comply.   Compliance with OP36 relies on ensuring compliance with OP16, OP17 and OP18. The Bi-NBR is compliant with this OP as stated but the value of the information collected for evaluating best practice adherence and benchmarking performance is yet to be tested. .

OP37. Timely reporting on outcome analyses

Australian Clinical Quality Registries must report without delay on risk-adjusted outcome analyses to institutions and clinicians.

Methodology

The reporting policy has been established but has yet to be fully tested as the first quarterly report is not due for completion until December 2009. There is a requirement for data to be reported back to the participating sites within two weeks from receipt of data. This policy will be first tested in December as the first quarterly report is due.

Recommendations

OP37 is a valuable addition and working principle for clinical quality registries. However, no guidelines are provided to establish reasonable timeframes for reporting or the definition of "without delay". Inclusion of some guidelines around acceptable timeframes may assist the

developers of new clinical quality registries, and would provide valuable information for ensuring adequate resources and infrastructure are put in place to meet the timeframes for reporting.

OP38. Peer Review

Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings.

Methodology

The Bi-NBR has not fully developed the peer review process for registry data as the first quarterly report is not due for completion until December 2009. Currently, the Steering Committee is responsible for reviewing the data however this will be further discussed following the initial quarterly report. It is likely that a peer review process as outlined in OP38 will be further formalised and those involved will be responsible to the Steering Committee. This process will be linked with the 'Outlier' policy to ensure all data are assessed by clinicians specialising in the area prior to release of the information.

Recommendations

OP38 is highly important and a useful stipulation for the development of clinical quality registries. Considering the wording of OP38 and the supporting documentation, the Bi-NBR is compliant with OP38, however the process is not yet finalised. This OP will be further evaluated and the policy for peer-review strengthened during the process of collation and distribution of the first quarterly report in December 2009.

OP39. Adhoc Analyses by Sites

Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.

Methodology

Data are currently able to be extracted centrally and provided to sites as requested. This is not a difficult operating principle to implement, nor costly. Online data extraction facilities are to be incorporated into the web-based information by the end of the year. Both methods allow ad hoc analysis of individual site data, but the latter is more timely and efficient, but with greater up-front resources and cost related to programming and establishing the needs of individual sites.

Recommendations

OP39 is an important principle, particularly for the site-level users. While the Bi-NBR is compliant with OP39, the current processes for ad hoc analyses are not ideal and further development is required. Therefore a full evaluation of this OP is not possible to date but will be a priority for future registry development.

OP40. Annual Report published

Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.

Methodology

A publicly accessible annual report will be produced which will include aggregate data detailing clinical findings at the end of 2010. Previous experience indicates that this is time consuming and more difficult for the first report, but with time becomes routine, provided resources are available for an intense period from data receipt to data output.

Recommendations

OP40 is clear, important and easily applied. No recommendations for change are made as the Bi-NBR has not yet had the opportunity to develop an annual report.

OP41. Procedures for Reporting

Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance.

Methodology

The reporting procedures continue to evolve for the Bi-NBR. It has been agreed that the first quarterly report will include risk-adjusted data on all key data elements. Following this report a more streamlined process will be developed for the subsequent report as the clinicians develop a greater understanding of the information collected, any limitations in the data and as priorities for reporting crystallise. Data elements that are not included in the quarterly reports will be available to sites on an ad hoc basis. Procedures include the implementation of the policies as outline in OP28. The success of implementing these policies and procedures will require ongoing monitoring.

Recommendations

OP41 is closely linked to OP28 which discusses the policies of addressing outliers or unexplained variance. Following on from OP28 and OP36-40, OP41 has a degree of redundancy and could be removed. At the very least this principle should be moved to OP36 to highlight the need for procedures that outline the reporting required. This would then link better with OP36-40.

Resource and Funds

OP42. Appropriate Resources and Funding

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

Methodology

The Bi-NBR has been able to function as a clinical registry with support from Julian Burton Burns Trust and the Australian and New Zealand Burns Association (ANZBA). This funding has been used for employing a project officer, database and data analysis personnel, and for administrative purposes. Individual sites have provided their own resources for the Bi-NBR data collection purposes, without any additional funding (in most cases). A small amount of money has been provided to sites for recruitment and follow-ups for the long term outcomes pilot project. As this is a pilot project, resource utilisation is being included to determine the ongoing costs of collecting this data as a routine component of the Bi-NBR. Like all clinical quality registries, establishing ongoing funding for the registry function is challenging. The Bi-NBR has achieved much with relatively little resource and the impact on the ACSQHC project has been significant in improving the registry and its usefulness to the burns community.

Recommendations

The Bi-NBR is partially compliant with OP42 given that the collection of data has largely been an in-kind contribution from participating sites. Establishing financial support for this element of the registry is a high priority for the future. It is anticipated that as the improved data flows from the registry, this will have benefits in attracting appropriate funding for the future. The changing healthcare climate with the push towards electronic health care records will impact on the funding required in the future and the needs of the registry will require regular update and revision.

Given the potential gains for health care quality from data collected by the Bi-NBR and other clinical quality registries, it is recommended that funding is provided through state governments with federal funding at a national level for benchmarking. Funding provided should address the collection of long term outcomes information given the importance and relevance of this information for evaluating the quality of care provided.

Summary of Operating Principles

Attributes		Implementation
1	Clear and defined purpose	Yes
2	Collect a core minimum dataset	Yes
3	Collect Epidemiologically sound data	Yes
4	Systematic data collection at all contributing sites	Yes
5	Burden and cost of outcome time considered	Yes
6	Outcomes properly ascertained	Yes
7	Complete collection from entire eligible population	Partial compliance
Data collection		
8	Minimise data collection burden	Yes
9	Data collection as close as possible to point of care	Yes
10	Uniformly and easily accessible from data source	Yes
11	Standardised data elements used	Yes
12	Data dictionaries used	Yes
13	Use existing data sources where possible	Yes
14	Use data linkage where possible	Yes
Data elements		
15	Collect individually identifiable patient or subject information	Partial compliance
16	Collect process of care information	Yes
17	Collect objective outcome information	Yes
Risk adjustment		
18	Collect objective, reliable co-variates for risk adjustment	Yes
Data security		
19	Secure access controls and securing messaging	Yes
20	Data collection, storage & transmission complies with legislation	Yes
21	Policies comply with Part B: Technical Standards – Standards Map	Partial Compliance

Data quality		**Implementation**
22	Reports percentage of eligible patients recruited	Yes
23	Data quality control plan used	Yes
24	Data checks/audits routinely performed	Yes
25	Data management processes used	Yes
26	Reports produced to specific timetable	Yes
Governance		
27	Formal governance structures	Yes
28	Quality of care policies developed	Yes
Custodianship		
29	Custodianship explicitly declared	Yes
30	Data access and reporting policies available	Yes
31	Third party access only via Steering Committee & IEC approval	Yes
Ethics and privacy		
32	IEC approval gained	Partial compliance
33	Personnel familiar with IEC and privacy guidelines/legislation	Yes
34	Participants or their next of kin informed of data collection	Yes
35	IEC approval sought for projects using register data	Yes
Outputs		
36	Quality of care assessed	Planned
37	No delay in reporting risk-adjusted outcome measures	Planned
38	Formal peer-review process prior to publication	Planned
39	Ad-hoc analyses by sites	Yes
40	Annual report publicly available	Planned
41	Documented procedures for reporting on quality of care, etc	Planned
Resources		
42	Appropriate and sustainable funding for registry function	Planned

PART E.   TECHNICAL STANDARDS

Methodology

Each of the Technical Standards is reviewed with the following methodology based on details in the contract:

n.n Technical Standard   **Proposed Usage: (Level)**

<u>Evaluation</u>

Assessment of implementation relevance and quality of standard.

<u>Implementation</u>

Assessment of implementation ease and cost (if relevant)

Whether the standard is:

- currently met
- partially met
- can be implemented in the short (within 1 year) to medium (1-3 years) term
- requires external changes
- requires further development and/or funding
- unable to be implemented

1. E-health interoperability

1.1 Interoperability Framework v2.0   Proposed Usage: Recommended (Level 3,4)

<u>Evaluation</u>   *Partially Relevant*

The Interoperability Framework was reviewed and assessed as being a sound framework for a new, large, organisation-wide software development project. The Bi-NBR started out with a 24 item minimum dataset which expanded to 42 data items with revision of the dataset and inclusion of the Quality Indicators. There are 17 sites with potentially double this number of users and 3,000-4,000 patients annually. It is a small project technically, quite dissimilar to a tertiary hospital-wide roll-out of a clinical system for instance. The Interoperability Framework was not assessed as being a 'good fit' for a registry of these dimensions, particularly if stand-alone.

<u>Implementation</u>   *Not currently met (Short to medium term)*

Implementing this standard would have been very difficult for the Bi-NBR due to the scale of the framework and dimensions of the registry. In addition, there was great expectation that the project needed to deliver in the short-term, as registry stakeholders were assembled, the minimum dataset defined and existing commitments to another funding body in place. As the framework was not in operation within the organisation, considerable delay and cost would have been borne to implement this standard prior to software implementation. It is anticipated that with the work done via the ACPR that the Interoperability Framework v2.0 could be implemented in the short to medium term as part of an organisation-wide adoption.

1.2 Unified Modelling Language v2.0   Proposed Usage: Recommended (Level 3,4)

<u>Evaluation</u>   *Partially Relevant*

UML was reviewed for relevant use within the Bi-NBR software development life cycle. Whilst the full benefit of UML would be realised within a more complex, high transaction environment, there were aspects of UML that could be utilised.

<u>Implementation</u>   *Partially met*

Activity diagrams were used to model data collection processes using Enterprise Architect.

1.3 TOGAF "Enterprise Edition" v8.1   Proposed Usage: Recommended (Level 3,4)

<u>Evaluation</u>   Partially Relevant

As for the Interoperability Framework, TOGAF was reviewed and assessed as being a sound framework for a new, large, organisation-wide software development project. This framework required the adoption of a project management methodology not suited to the Bi-NBR's dimensions.

Implementation   *Not currently met (Short to medium term)*

Implementing this standard prior to software implementation would have been very difficult and costly for a project of this size. The Bi-NBR was also well progressed in development as outlined in TS1.1 making changes to the project management structure cumbersome. As the framework was not in operation within the organisation, considerable funding beyond the budget allocated to the project would have been required. Given that another project within the organisation (ACPR) has been progressing implementation of TOGAF, it is envisaged that this standard could be implemented in the short to medium term, via an organisation-wide implementation.

1.4 Information technology – Open Distributed Processing.   Proposed Usage: Recommended (Level 3,4)

Evaluation   *Partially Relevant*

As this technical standard was closely aligned with the use of the Interoperability Framework and TOGAF, which were not implemented by the Bi-NBR, ODP was not considered for implementation.

Implementation   *Not currently met (Short to medium term)*

It is anticipated that ODP could be implemented in the short to medium term as part of an organisational implementation

2. Clinical communications

2.1 Terminology   Proposed Usage: Required (Level 2)

Evaluation   *Partially Relevant*

On first reviewing SNOMED CT, it was assessed as having a high degree of granularity, having been built around the provision of clinical care. The Bi-NBR began as a clinical registry with a 24 item minimum dataset which selected a small number of data items from a small number of clinical concepts - some common such as patient, admission, inpatient and discharge, and some more clinically specific such as injury event and burn assessment. As the Bi-NBR moved to an Australian Clinical Quality Registry (ACQR), Quality Indicators associated with Burns care were added, which increased the granularity and made SNOMED potentially more relevant. However, as many of the concepts had not been developed for the burns context, the Burn Specific Dataset and the Quality Indicators could not be implemented using SNOMED. AMT is not relevant to the Bi-NBR as medicines are not collected.

Implementation   *Not currently met (Short to medium term)*

Implementing this standard prior to software implementation would have been very difficult for the Bi-NBR as the minimum dataset was well defined and registry stakeholders had already invested heavily in its content. Having subsequently met with NeHTA and learnt more about

SNOMED there are some Bi-NBR data elements that could be translated into SNOMED concepts. In the review process of the Bi-NBR, SNOMED CT will be further considered with support from NeHTA, to determine what can be implemented. It is likely that at least some of the Bi-NBR dataset could be implemented in SNOMED CT in the short to medium term.

2.2 Data specifications   **Proposed Usage: Required (Level 2)**

<u>Evaluation</u>   *Partially Relevant*

NeHTA's data specifications are also built around the provision of clinical care. This has necessitated a high degree of granularity of which only a small component is applicable to a registry with minimum dataset requirements. For example, of the Discharge Summary Data Specification (re: NEHTA_0513_2009_Discharge_Summary-Core_Structured_Document_ Template_v2.1_200908 28), three data elements would be included in the Bi-NBR. These are related to the Encounter data group – DateTime started, DateTime Ended and Separation Mode. Each of these are defined in METeOR's Admitted Patient Care National Minimum Dataset. The Medications, Health profile and Plan data groups were of no relevance to the Bi-NBR.

Whilst NeHTA's Diagnoses and Intervention data groups were found to be relevant, ICD10-AM are routinely used in every Australian hospital and were considered appropriate for Bi-NBR purposes. The Burn Specific Dataset and the Quality Indicators are not currently defined by NeHTA's data specifications.

<u>Implementation</u>   *Partially met (Short to medium term)*

The Bi-NBR was well progressed in Minimum Data Set (MDS) definitions at the commencement of the ACSQHC project. The Bi-NBR MDS already utilised relevant data elements from METeOR's Admitted Patient Care National Minimum Dataset. Given NeHTA's Discharge Summary Data Specifications are compatible with this NMDS (same value domain for separation mode discharge disposition for instance) there are no foreseeable issues if it were implemented in the hospital setting.

The Bi-NBR MDS utilised METeOR's Injury Surveillance Dataset Specification to define injury event data elements such as activity, intent and place. Greater granularity was incorporated to make each applicable to the burns clinical context. There is currently no relevant NeHTA Data Specification for injury event. In order to implement this standard, the Burns clinical context would also need to be developed.

The ICD10-AM classification was used to identify diagnoses, procedures, co-morbidities and complications rather than NeHTA's Diagnoses and Intervention data groups. ICD10-AM is routinely used in every Australian hospital, are readily obtained electronically and were considered appropriate for Bi-NBR purposes.

As the registry is reviewed and modified and a more complete representation of the burns context incorporated into NeHTA's data specifications, these specifications may be implemented in the short to medium term.

2.3 Data Exchange   Proposed Usage: Required (Level 3, 4)

Evaluation   *Partially Relevant if Level 3 or 4*

The Bi-NBR minimum dataset contains data items that are readily available in hospital administrative systems and that are incorporated into the HL7 Patient Administration protocol. However as the HL7 protocol was developed for clinical care and hospital administrative functions, it has a high degree of granularity not relevant to the Bi-NBR. Burns-specific data items and quality indicators are less likely to be captured by Local Clinical Systems and are therefore not captured by HL7.

Implementation   *Not currently met (Short to medium term)*

It was envisaged that data exchange of hospital administrative data could occur within the project timelines. However, the absence of identifying data meant that each burn unit had to de-identify data before transmitting. This was too difficult for burn sites to do using flat file formats let alone HL7, and it was decided that it would be far easier to establish HL7 with identifying data coming directly from hospital administrative systems.

The Bi-NBR is currently operating as a Level 2 registry. It is anticipated that identifying data are authorised to be received by the Bi-NBR in the short to medium term making it possible to use relevant parts of the HL7 Patient Administration protocol.

2.4 Datatypes   Proposed Usage: Required (Level 2)

Evaluation   *Relevant*

The ISO/IEC 11404 international standard for ensuring Language Independent datatypes was reviewed for relevance to the Bi-NBR. Based on the terminology and data specifications defined in 2.1 and 2.2, the datatypes used in the Bi-NBR were confined to Integer, Real, Date-and-Time and Character.

As the Bi-NBR moves to interface more directly with hospital information systems (Level 3 and 4), conformance with this standard will become increasingly relevant.

Implementation   *Currently met*

All Bi-NBR Datatypes currently used conform to the ISO/IEC 11404 international standard.

3. Unique Healthcare Identifiers

3.1 Healthcare Provider Identification   Proposed Usage: Required (Level 2)

Evaluation   *Partially Relevant*

As there are only 17 organisational Healthcare Provider Organisations contributing to the Bi-NBR, it is not difficult to uniquely identify a Healthcare Provider Organisation and thus the relevance of AS 4846-2006 is lessened.

The Bi-NBR does not currently plan to individually identify health care providers such as Burns surgeons. It will be incumbent upon the contributing organisation to do so if required. Therefore HPI-Is are not considered relevant to the Bi-NBR.

Implementation   *Currently met*

The Healthcare Provider Organisation is currently uniquely identified via a numeric code. To replace this with the Healthcare Provider Identifiers – Organisation (HPI-Os) when introduced would not be considered difficult or costly. Organisation Names and Geographic area are currently captured, and communication and address details could be added if required.

3.2 Healthcare Client Identification   Proposed Usage: Required (Level 3,4)

Evaluation   *Not Currently Relevant*

AS 5017-2006 was reviewed for relevance to the Bi-NBR. The identifying data items defined by this standard that are currently able to be stored centrally by the Bi-NBR are limited due to ethics restrictions. Subject to future ethics amendments, the data items contained within AS 5017-2006 would be considered sufficient to uniquely identify a Bi-NBR patient. The introduction of the Individual Healthcare Identifier (IHI) due to begin implementation by Medicare in mid-2010, will be a significant achievement and will greatly reduce the operating costs of the Bi-NBR and registries in general.

Implementation   *Partially met (Short to medium term)*

The capacity to implement this standard is very much dependent on ethics approval. A composite key of data items from AS 5017-2006 such as names and addresses were planned to be used for sites submitting identifying data, however approval for this did not occur within the project timelines. Currently Date of Birth, Gender and Date of Death are collected as per AS 5017-2006 and used in concert with date of injury to uniquely identify a patient-burn event at each site.

In the absence of a true Individual Healthcare Identifier (IHI), an interim numeric registry identifier has been used. Having reviewed International Standard [ISO7812] (that governs magnetic-stripe identification cards, such as door entry cards, ATM cards, credit cards), on which the IHI is based, to replace this with the Individual Healthcare Identifier (IHI) when

introduced would not be considered technically difficult or costly. It remains to be seen if it is difficult to achieve ethics approval however.

4. Identity management

4.1 Authentication Assessment Methodology   Proposed Usage: Required (Level 3,4)

Evaluation   *Relevant*

The Authentication Assessment Methodology v1.0 was reviewed as the basis for determining authentication requirements and subsequent adoption of Identity Management resources. The methodology was found to be useful in developing a long term plan of the Bi-NBR's authentication needs. It was also found to be consistent with the Australian Government Authentication Framework (TS4.4.)

Implementation   *Currently met*

The methodology was implemented to develop a long term plan of the Bi-NBR's authentication needs.

4.2 Framework for Analysing, Planning and   Proposed Usage: Required (Level 3,4)
   Implementing Identity Management v1.0

Evaluation   *Relevant*

The IdM framework was useful in understanding Identity Management resource availability.

Implementation   *Currently met*

 The framework was used to evaluate Identity Management resources in TS4.3.

4.3 Identity Management Resource Set   Proposed Usage: Required (Level 3,4)

Evaluation   *Relevant*

Identity Management Resources were reviewed for appropriate access control, authentication, authorisation and auditing techniques.

Discretionary access control (DAC) using a role-based method was deemed sufficient to allow hospital data collectors to access only their own data, as well as allow central Bi-NBR project staff to view patients across all sites. Mandatory access control (MAC) was considered overly detailed for the purposes of the Bi-NBR as the same level of access was required by each site. Role-based (RBAC) was not considered relevant to the registry as there are only 2 roles – hospital data collector and registry project coordinator. Policy-based access was not deemed necessary to implementing the Bi-NBR.

Authentication mechanisms relevant to the needs of the Bi-NBR included Public Key Infrastructure using Secure Sockets Layer (SSL), user name and password pairings, password

policies and supplementary knowledge-based authentication. Access tokens, biometric devices and behavioural authentication were not considered for implementation.

The coarse grained *authorisation model* was deemed a 'good fit' for administering a small number of roles. The fine grained model was considered too granular for the needs of the Bi-NBR.

Audit Logging activities were considered relevant, to recording successful and unsuccessful user access to the application object. *System Logging* was also relevant to monitoring of record creation and change.

*Directory Service*s were not considered relevant to the needs of the Bi-NBR.

<u>Implementation</u>   *Currently met*

Access Controls

Discretionary access control (DAC) using a role-based method was implemented with minimal cost and difficulty.

Authentication Mechanisms

Public Key Infrastructure was implemented using Secure Sockets Layer (SSL) without difficulty or significant cost. Individual user names and passwords were administered to authenticate access to the Bi-NBR. Password policies were also implemented to prevent unauthorised access. Password policies included locking account access after three unsuccessful attempts, database password encryption and mandatory password strength. Supplementary knowledge-based authentication using a question and answer pairing was also implemented to provide the functionality to reset passwords. In addition, implementing user profile control has been found to minimise the level of support required with these password policies in place.

Authorisation

The coarse grained *authorisation model* was implemented to administer a small number of roles with minimal cost and difficulty. Implementing the fine grained model would have been unnecessarily costly and difficult.

Audit

Audit Logging was implemented with minimal cost and difficulty, recording user names and dates and times of successful and unsuccessful user access to the application object. *System Logging* was similarly able to be implemented by logging user names and dates and times of the creation and modification of records.

4.4   Australian Government Authentication Framework   Proposed Usage: Required (Level 3,4)

Evaluation   *Relevant*

The National e-Authentication Framework (AGAF) was reviewed as the basis for determining authentication requirements and techniques. As there are only 17 Healthcare Provider Organisations contributing to the Bi-NBR, it is not difficult to uniquely identify Healthcare Provider data collection staff. The relevance of AGAF is lessened because of this.

Evidence of Identity is assumed to have occurred through each participating hospital's administration and therefore a 100 point check for a moderate assurance level has not been considered necessary for the Bi-NBR.

Implementation   *Currently met*

As the number of registries managed by any one group increases, the need for a more comprehensive framework is increased.

4.5 ACSI 33   Proposed Usage: Required (Level 3,4)

Evaluation   Partially *Relevant*

The Department of Defence's Australian Government Information and Communications Technology Security Manual (ACSI 33 December 2008) was reviewed for relevance to the Bi-NBR. The identification, authentication, authorisation and encryption principles were found to be both sound and useful in guiding security policies. Examples are given below of how these principles were implemented. Their relevance to the Bi-NBR was limited due to the small number of users, the simplicity of the access control model and the tight-knit nature of the burns community. For instance an access control list would not be required as there are only 2 user groups and one resource to be accessed, namely all functions of the web application. ACSI 33's intra-organisational policies such as product, media and communications security were not evaluated, as they were considered out of scope for a registry which is primarily concerned with inter-organisational policies. Monash's network access policies were reviewed for compliance with ACSI 33.

Implementation   *Currently met*

Password selection policy (C#421) was able to be implemented with ease. C#421 states that 'a minimum password length of seven characters, consisting of at least three of the character sets: lowercase characters (a–z), uppercase characters (A–Z), digits (0–9) or punctuation and special characters'. Suspension of access (C#429) after failed logon attempts was also able to be implemented with little difficulty. The Bi-NBR implemented DSD approved cryptographic protocol Secure Sockets Layer Version 3.0 for protecting data transmission between web browser and web and database servers. All Monash network-based services are already controlled via the Monash Network Access Control Policy.

4.6 Security Techniques   Proposed Usage: Optional

Evaluation   Partially *Relevant*

AS/NZS ISO/IEC 17799:2006 was reviewed for user password management and use, and user authentication

Implementation   *Partially met*

Aspects of this standard are embedded in ACSI 33 and were addressed in the previous Technical Standard.

4.7 OASIS eXtensible Access Control Markup Language   Proposed Usage: Optional (XACML) TC

Evaluation   *Partially Relevant*

The use of SAML and a federated login system is not currently relevant to the Bi-NBR. Registry staff only work on the Bi-NBR, and so the need to authenticate for multiple registries is not present. Similarly for hospital-based staff, they are unlikely to be contributing to multiple external registries, but is more relevant to their use of multiple clinical systems locally. As an organisation-wide registries portal is developed however a federated login system across other registries within Monash University may have some merit. ACPR's investigations into the use of SAML and a federated login system determined that due to the infancy of the technology and lack of .NET implementation, XACML would be difficult to implement.

Implementation   *Not currently met (Medium term)*

A federated login system was not attempted to be implemented until an organisation-wide successful implementation due to limited resource availability and limited benefit to the registry.

4.8 OASIS Security Services (SAML) TC v2.0.   Proposed Usage: Optional

Evaluation   *Partially Relevant*

As for TS4.8, ACPR's investigations into the use of SAML determined that due to the infancy of the technology and lack of .NET implementation, SAML would be difficult to implement.

Implementation   *Not currently met (Medium term)*

Web Single sign-on implementation was not attempted, pending a successful organisation implementation. It is anticipated that in the medium term, as a registries portal is developed within the organisation, that the Bi-NBR is incorporated using SAML.

5. Secure Messaging

5.1 Web Services   Proposed Usage: Required (Level 3,4)

Evaluation   *Partially relevant*

Resources did not permit a full review of each technical standards document, but the principles are sound and relevant to the Bi-NBR. Local Burns Databases have been or are in the process of being developed at some Bi-NBR sites to capture Burns-specific data items and quality indicators not captured by Local Clinical Systems. One hospital had expressed interest and possessed the capacity to test secure messaging standards.

Implementation   *Partially met (Short to medium term)*

With the addition of the Quality Indicators to the dataset and changes in IT personnel at that site, software changes required by that site to incorporate the revised dataset were also delayed beyond the project timelines. Therefore the Bi-NBR is currently operating as a Level 2 registry. Web Services have been implemented in the .NET environment to achieve other registry functions. It is envisaged that Web Services for Secure Messaging could be implemented in the short to medium term, subject to site availability.

5.2 XML   Proposed Usage: Required (Level 2,3,4)

Evaluation   *Partially relevant*

Resources did not permit a full review of each technical standards document, but the principles are sound and relevant to the Bi-NBR when Secure Messaging becomes possible.

Implementation   *Partially met (Short to medium term)*

XML has been used to implement Web Services in the .NET environment to achieve other registry functions. It is envisaged that the XML standards referenced could be implemented for Secure Messaging in the short to medium term.

6. Supply Chain

6.1. Supply Chain   Proposed Usage: Required (Level 2,3,4)

Evaluation   Not Relevant

The Bi-NBR does not record products such as devices or implants.

Implementation   Not Relevant

This standard was not considered for implementation.

7. Engagement & Adoption

7.1. Understanding Standards   Proposed Usage: Optional

Evaluation   *Relevant*

HB 107-1998 is important to facilitate the correct interpretation and effective use of Standards.

Implementation   *Partially met (Short to medium term)*

Whilst standards are understood by technical staff, an organisation-wide implementation is still to occur.

7.2. Corporate governance of ICT   Proposed Usage: Recommended (Level 3,4)

Evaluation   *Relevant*

The six Principles for Good Governance of ICT were found to be a useful framework for ensuring the optimal, ethical and responsible utilisation of ICT within the organisation.

Implementation   *Partially met (Short to medium term)*

An organisational implementation of this standard will occur in the short to medium term.

8. Summary of Technical Standards

Technical Standards	Currently met	Partially met	Can be met in Short to medium term	Unlikely to be met in short to medium term	Not Relevant
E-Health Interoperability					
Interoperability Framework v2.0			■		
Unified Modelling Language v2.0		■			
TOGAF "Enterprise Edition" Version 8.1			■		
Information Technology - ODP			■		
Clinical Communications					
Terminology (SNOMED)			■		
Data Specifications		■			
Data Exchange (HL7)			■		
Datatypes	■				
Unique Healthcare Identification					
Health Care Provider Identification	■				
Health Care Client Identification		■			
Identity Management					
Authentication Assessment Methodology v1.0	■				
Framework for Analysing, Planning and Implementing Identity Management v1.0	■				
Identity Management Resource Set 16	■				
AGAF	■				
ACSI 33	■				
Security Techniques			■		
OASIS eXtensible Access Control Markup Language (XACML) TC			■		
OASIS Security Services (SAML) TC v2.0			■		

Technical Standards	Currently met	Partially met	Can be met in Short to medium term	Unlikely to be met in short to medium term	Not Relevant
Secure Messaging Web Services XML		■			
Supply Chain					■
Engagement & Adoption Understanding Standards Corporate governance of information and communication technology			■		

PART F.   DISCUSSION

Overview

The previous sections have discussed in detail the challenges faced by the Bi-NBR in applying each operating principle and technical standard, the strategies used to overcome challenges where possible, recommendations for revision of the Operating Principles and Technical Standards document, and plans for the future. This discussion will focus on the achievements of the Bi-NBR relative to the project aims, and provide a discussion of the key outcomes of the evaluation of the Operating Principles and Technical Standards document.

Progress of the Bi-NBR as a clinical quality registry

The aims of the ACSQHC clinical quality registry project were clear:

i.   inform the development of Australian Clinical Quality Registry Operating Principles and Technical Standards through the application of the draft standards against an existing national registry or to the development of a new registry.

ii.   identify any issues or barriers relating to the draft standards which would limit uptake by registries.

iii.   provide recommendations which will maximise benefit and knowledge gained, thus promoting best practise and optimal information for Government and other key stakeholders to make decisions on the final principles and standards to be adopted.

The opportunity to participate in the ACSQHC clinical quality registry project came at a critical time in the development of the Bi-NBR. The Bi-NBR had been developed with strong clinical support but without registry methodological expertise. The resultant product was a registry with the aims of a clinical quality registry but neither the minimum dataset nor the methodology to achieve the set aims. The Department of Epidemiology and Preventive Medicine, through a tender with the ANZBA and underpinned by funding from the Julian Burton Burns Trust, assumed the management and custodianship of the Bi-NBR in the 6-months prior to the advertisement of the ACSQHC project. Overall, participation in the ACSQHC project has resulted in a functioning clinical quality registry with strong prospects for the future. The responsibility of undertaking the evaluation of the draft Operating Principles and Technical Standards for Clinical Quality Registries provided a framework to stimulate thinking, progress the changes beyond what was possible with existing resources, provide a better end-product for users and stakeholders, and cement a clear plan for the future of the registry.

The project plan for the Bi-NBR was ambitious with substantial key measurable outcomes identified for the 12-month project. While the registry existed prior to the project, the registry was essentially in its infancy with considerable effort required to establish basic operating principles such as IEC approval and a minimum dataset capable of meeting the aims of the registry. All identified deliverables were achieved over the 12-month project and included:

i.   Completion of all scheduled reports to the ACSQHC

ii.   Development of key quality indicators and outcomes

iii.   Update of the minimum dataset and data dictionary

iv.   Implementation of the updated minimum dataset and key quality indicators

v.   Commencement of a pilot project to collection quality of life and functional outcomes following burn injury

vi.   Development of a revised centralised web-based information systems and establishing and establishing administration dataset linkages between the Bi-national Burns Registry and Burn Unit data collection system

vii.   Establishing a routine reporting schedule and content

Further achievements were the confirmation of IEC approval for 11 out of 17 burns units to date (with a number pending), all but one site approving an opt-off consent process, and a strengthening of the governance procedures for the Bi-NBR. There is strong support from all burns units in Australia and New Zealand for the registry and submission of data from all sites is entirely feasible in the short to medium term as each site works through the IEC approval process with the Bi-NBR project staff. Evidence of the strong support for the Bi-NBR was provided by the addition of two presentations* at the ANZBA Annual Scientific Meeting in Wellington, New Zealand in September 2009 and the organisation of a Bi-NBR information booth by ANZBA at the same meeting.

*Picton N on behalf of the Bi-NBR Steering and Reference Committees. Development of the Bi-National Burns Registry. Proceedings of the 2009 Australian and New Zealand Burns Association Annual Scientific Meeting, Wellington, New Zealand, 22-25 September 2009.

*Watterson D on behalf of the Bi-NBR Quality Indicator and Long Term Outcomes Working Party and Steering Committee. Measuring quality of care and long term outcomes for those registered with the Bi-National Burns Registry. Proceedings of the 2009 Australian and New Zealand Burns Association Annual Scientific Meeting, Wellington, New Zealand, 22-25 September 2009.

Evaluation of the Operating Principles

The draft Operating Principles and Technical Standards for clinical quality registries was a detailed and comprehensive document. From the perspective of a developing clinical quality registry (Bi-NBR), the document was enormously beneficial for evaluating the existing processes of the registry, providing a standard to achieve, and to identify gaps in the functioning of the registry. The major limitation of the ACSQHC project was the inability to fully evaluate all operating principles and technical standards in the short project timeframe. The registry development tasks that involved application of many of the operating principles and technical standards were time consuming and 12-months was insufficient to fully assess their specificity and validity. As the Bi-NBR and other pilot registries mature, the capacity to fully evaluate the operating principles and technical standards will be realised. Given the diversity of clinical areas studied, their population size, and the aims of the registries, the experiences of one registry cannot be easily extrapolated to another and therefore time to fully evaluate the operating principles and technical standards would be enormously beneficial in finalising the document. For example, the challenges of applying OP41 ("...documented procedures for reporting on quality of care, including addressing outliers or unexplained variance") are substantially different for a population such as burns where the number of incident cases, burns units and expert burns clinicians is relatively small, compared to a high volume population such as cardiac procedures.

Despite the limitations imposed by the timeframe of the project, participation in the ACSQHC project was enormously beneficial and clear challenges, recommendations and plans for the future were able to be realised. Overall, at the completion of the ACSQHC project, the Bi-NBR was compliant with 33 of the 42 operating principles and partially compliant with three. The Bi-NBR plans to comply with the remaining six operating principles but due to the phase of maturation of the Bi-NBR, application and full evaluation of these remaining operating principles was not possible in the ACSQHC project timeframes.

From the experiences of the Bi-NBR, the key barriers to implementing the operating principles were:

i. Ethics - The reception of IECs to the Bi-NBR was significantly different by state and setting, despite the submission of standardised information. The responses varied from approval as a quality assurance/audit project or institutional sign-off only required, to approval with opt-off consent, to the requirement for opt-in consent. Although the Bi-NBR did not request (in most cases) the submission of identifiable data, the willingness of the IECs to approve an opt-off consent process was highly variable with the greatest resistance experienced at paediatric and Queensland sites. At the time of writing of this report, IEC approval had been obtained from 11 of the 17 burns units and opt-in consent was only required at one paediatric site. However, the inability to secure opt-off consent across the board has the potential to limit complete case capture and introduce selection bias, threatening compliance with OP7. A co-ordinated approach to educating IECs from organisations, such as national and state health departments and the ACSQHC, about clinical quality registries is necessary to ensure the integrity of clinical quality registries and to enable these registries to meet the necessary standards to achieve their aims.

ii. Time – The 12-month project timeframe stimulated rapid development of the Bi-NBR but, to meet the registry's project aims, decisions were made early on that impacted on the capacity of the Bi-NBR to comply with the operating principles. For example, the decision was made by the Steering and Management Committees to seek IEC approval to store only de-identifiable data centrally, as several applications were already under consideration and rapid approval for data collection was necessary to achieve the project deliverables. The outcome was the inability to comply with OP15 and limited ability to comply with OP14. Furthermore, the tight project timeframes and the stage of maturation of the Bi-NBR prevented full evaluation of a number of the operating principles. Therefore, there is the potential to finalise the Operating Principles and Technical Standards without the full input of all pilot registries. This could have implications for registries like the Bi-NBR in the future.

iii. Documentation and data standards – Many of the operating principles relate to data quality, integrity, standardisation, validity and utility. There is a clear theme throughout the Operating Principles and Technical Standards document to utilise administrative and existing data sources. While this is a sound principle, there are difficulties implementing this in practice due to the limited data items collected by administrative datasets and questions around the standardisation and validity of administrative data. In the case of the Bi-NBR, administrative data does not capture burns-specific information. Where administrative data do, the quality of the data is of concern. For example, the %TBSA collected as part of the ICD-10 codes is not

standardised across settings. Some burns units have a highly interactive relationship with coders to ensure the quality of this key piece of burns data while others have none. Similarly, the ICD-10 procedure codes are not sufficient for assessing the quality of burn care provided due to a focus on techniques and treatment practices that are either non-specific or out of date. The need to collect detailed clinical data to function as a clinical quality registry often requires sourcing of data directly from clinical notes and other hospital data collection systems where data standardisation across units does not exist.

iv. METeOR – The Bi-NBR's experience with the METeOR system warrant special mention. Under advisement and recommendation, the Bi-NBR invested significant time and financial resource in entering the minimum dataset into the METeOR system to produce a high quality data dictionary. While the process was useful for refinement of data definitions and minimum dataset items, the outcome was a data dictionary which was not useful for data collectors and registry staff. Therefore, a working data dictionary for the data collectors and registry staff was developed. The duplication of effort was costly and further worsened by the lack of support for METeOR users following initial training. If the purpose is to develop a working data dictionary which clinicians, data collectors and registry clients can use, METeOR should not be recommended or its usefulness should be clarified.

v. Generality of operating principles – The operating principles are meant to provide guidelines for registry development. However, a number of the operating principles are vague and the language used is not particularly useful for registry developers. Terminology such as "appropriate", "without delay", and "reasonable". When attempting to apply the principles, questions were raised about definitions of many of these descriptors. For example, what is an acceptable loss to follow-up? What is appropriate funding? When would it an unacceptable delay? It is acknowledged that these are difficult questions and will vary to some degree by context. However, with the push towards linkage of data from registries and comparison, these questions become methodologically important.

Evaluation of the Technical Standards

The draft Technical Standards for clinical quality registries document was a placeholder to tens of lengthy standards documents, often embedded with links to further documents. A significant period of the project (3-4 months) was required to both recruit staff with the expertise to undertake the evaluation as well as actually review the standards.

 In the early stages of the project, it was envisaged that development of the Bi-NBR technical framework would be tied with the Australian Cardiac Procedures Registry (ACPR). However, feedback from the ACSQHC April Progress Report to the ACPR was that due to the size of the project and budget, a more complete implementation of the NeHTA Technical Standards was expected. This required that the ACPR initiate a new project management and organisational model (Interoperability Framework v2.0), not previously practiced within the organisation.

Given the level of progression of the Bi-NBR in assembling registry stakeholders and defining its minimum dataset and in order to honour existing commitments to another funding body, the decision

was made by the Bi-NBR Management Committee to separate development of the two registries. As implementation of the Bi-NBR information system based on the complete technical standards would have been delayed from 3 to 6 months, it was proposed that when the ACPR had implemented NeHTA standards in greater detail that the Bi-NBR would do subsequently.

In general the technical standards were assessed as being sound in principle, a useful roadmap and something to work towards in the short to medium term on an organisation-wide basis. The Identity Management resource kit was particularly useful to assess different authentication mechanisms and ensure compliance.

Barriers to implementing many of the technical standards in the Bi-NBR were encountered and these were:

i.   Time and Resources – time to recruit staff with expertise and then review the volume of standards. Time to implement standards. The 12-month project timeframe didn't allow sufficient time to test data transmission standards, as local burns databases required changes to match the Bi-NBR that could not begin until after the implementation date of the registry (July 2009.)

ii. Existing organisational practices - as the Interoperability Framework and TOGAF were not in operation within the organisation, considerable delay and cost would have been borne to implement this standard prior to software implementation. Given that another project within the organisation (ACPR) has been progressing implementation of TOGAF and the Interoperability Framework, it is envisaged that this standard could be implemented in the short to medium term, via an organisation-wide implementation.

iii. Characteristics of the registry – many standards were best suited to a new, large, organisation-wide software development project. The Bi-NBR has a 42 item minimum dataset with 17 sites, potentially double this number of users and 3,000-4,000 patients annually. It is quite different to a tertiary hospital-wide roll-out of a clinical system. The Interoperability Framework and TOGAF were assessed as not being a 'good fit' for the Bi-NBR, if stand-alone. Implementing this standard would have been very difficult for the Bi-NBR prior to software implementation due to the scale of the framework and progression of the registry.

iv. Clinical context – apart from hospital administrative data, little burns clinical data is captured by local clinical systems and hence HL7. NeHTA's data specifications also do not capture injury event or other burns data items. Some burns concepts have been identified in SNOMED, but it has taken time to understand and cumbersome to navigate for a small slice of data.

v.   De-identified data - the decision was made by the Steering and Management Committees to seek IEC approval to store only de-identifiable data centrally. It was hoped that the Bi-NBR could operate at Level 4 but without identifying data, data exchange with hospital administrative systems was difficult, requiring manual intervention by each burns unit.

Future directions for the Bi-NBR

The past 12-months have been an intense development and building period for the Bi-NBR with numerous key outcomes achieved. The Bi-NBR is now finalising IEC approval for the outstanding sites (all who have confirmed support and agreed participation in the Bi-NBR), commenced data collection, developed and implemented clinical quality indicators, and commenced the pilot long term outcomes project. The first quarterly report for the Bi-NBR will be completed and distributed in December 2009. Further funding for the Bi-NBR is currently being negotiated. Nevertheless, using the Operating Principles and Technical Standards as a guide, and through our experiences over the past 12-18 months, there are numerous challenges ahead. These include:

i. Establish secure ongoing funding for the Bi-NBR
ii. Progression of the Bi-NBR towards collection and storage of identifiable data at the centralised registry
iii. Completion of the long term outcomes pilot project and development of a methodology for routine collection of this information by Bi-NBR participants
iv. Evaluation and refinement of the selected clinical quality indicators and minimum dataset items
v. Validation of several dataset items and further development of standardised methods for capturing key clinical data including investigating the use of SNOMED
vi. Refinement of the processes for monitoring and reporting quality of care
vii. Exploration of the potential for key data linkages
viii. Refinement of data access policies and the development of a clinical research plan or strategy
ix. Increased scientific output including presentation of the data at key clinical meetings and peer-review publication in scholarly journals.
x. An organisation-wide adoption of TOGAF and the Interoperability Framework, incorporating the Bi-NBR
xi. The adoption of Unique Healthcare Identifiers as they begin implementation in mid-2010
xii. Progression of data linkages with sites to enable submission of ICD-10 diagnoses and procedures to the Bi-NBR in de-identified format
xiii. Development of secure messaging methods for transmission of local burns database data to the Bi-NBR for relevant sites
xiv. Review of Level 2 Registry data entry methods post first quarterly report
xv. Additional functionality to be built into the web-based information system to provide standardised reports and data extraction functions

PART G.   EXPENDITURE

Expenditure: 1 Dec 2008 - 31 October 2009

Staff	Level (including on-costs)	Cost
Project Coordinator	1 x 1.0 $84,837	$50,902.00
Database Manager	1 x 0.8 $66,798	$33,399.00
Administrative Costs		$5,000.00
Site data collection (allocated)	16 x 0.1 $75,081	$120,128.00
Travel (allocated)		$20,000.00
TOTAL		**$229,429.00**

PART H.   REFERENCES

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2. Donabedian A (1988) The Quality of Care. How Can it Be Assessed? Journal of the American Medical Association. Vol 260 (12).

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PART I.   GLOSSARY AND ABBREVIATIONS

Term	Acronym	Definition
Minimum Dataset	MDS	Bi-NBR Minimum Data Set
Burn Specific Dataset	BDS	Subset of Bi-NBR Minimum Dataset
Quality Indicators	QIs	Bi-NBR Quality Indicators developed during the ACQSHC project, in addition to the Minimum Dataset
Australian Clinical Quality Registry	ACQR	Quality Registry, includes Quality Indicators
Clinical Registry	CR	Includes Minimum Dataset only
National Health Data Dictionary	METeOR	Online registry of AIHW
National Minimum Dataset	NMDS	National Health Data Dictionary published minimum dataset
Local Clinical System	LCS	Includes hospital administrative systems eg. Patient Management System, Pathology systems, ED systems
Local Burns Database	LBD	Burns Database established at each site, usually peripheral to Local Clinical Systems

PART J.   APPENDICES