

Department of Epidemiology & Preventive Medicine

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

Towards an Australian Cardiac Procedures Registry

Final Report

November 2009

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Executive Summary

The Australian Clinical Quality Registries project was aimed at developing and validating principles and standards for registries that are national in coverage and primarily focused on supporting improvement in clinical practice. Through the development of a National Cardiac Procedures Registry (the Australian Cardiac Procedures Registry ACPR), there has been the opportunity to examine these principles and standards in depth and each of these is outlined in detail in the following report. This Executive Summary comments on the extent to which the project objectives have been achieved and identifies barriers and challenges to implementing the principles and standards. Comments related to each of the specific principles and standards are contained in the report.

- ACPR has developed a web-based cardiac surgery, percutaneous cardiac intervention and device registry. The portal satisfies technical standards for Level 1 to 3 registries in terms of user authentication, access and security issues. Level 4 data collection remains a major challenge due to specific clinical information required for risk adjustment. However, Level 4 data collection should be progressed on an institution by institution basis depending on the capabilities and resources available at the institution to progress the activity.
- Agreement on minimal data collection for the complex area of cardiovascular interventions was contentious with resistance towards a truly minimal data collection framework. The primary issue related to adequacy of risk adjustment and the resultant data collection set has moved towards the existing Australasian Society of Cardiothoracic Surgeons (ASCTS) and Melbourne Interventional Group (MIG) datasets for the cardiac surgical and coronary intervention arms, while the device data collection is not based on a local pre-existing model. The eventual adoption of revised and condensed ASCTS & MIG datasets enabled the goal of attaining an epidemiologically sound and minimal data set to be primarily achieved. Cardiac procedural data is unlikely to be collected by untrained administrative personnel in the absence of Level 4 collection.
- The device collection module did not include pacemakers and focussed on implanted defibrillators and cardiac resynchronisation devices. This should be considered a step forward in establishing an integrated registry with modular components with pacemakers identified as the next component for development. Along with expansion into pacemakers would be the need to develop and implement percutaneous valve procedure modules. This will allow the ACPR to be dynamic and responsive.
- Establishing the Governance Structure for the ACPR has involved engaging leadership of the Cardiac Society of Australia and New Zealand (CSANZ) and ASCTS as part of the process. This clinical leadership is critical as resistance remains in some sections of the clinical community as to the need of such participation. In discussion with the incoming President of the CSANZ, the adoption of the ACPR as part of the Professional and Ethical Standards Committee process has been proposed and this would secure its ongoing clinical engagement. The President of the ASCTS fully endorses the project and it is envisaged that continuation of the activity over the next 12 months will firmly cement the activity in these key clinical organisations.
- Opt-off consent for registry participation has been challenged by a number of Ethics Committee's with some requesting consent waiver. The risks and benefits of "opt-off" versus consent waiver are not fully understood by ethics committees and this should be the focus of further educational activities in regards to clinical quality registries.

- The Technical Standards for Clinical Quality Registries are essential industry wide standards and are appropriate for the conduct for this activity. However, they will not be understood by non-specialist personnel and this implies a competency requirement for establishing registries. Historically, clinical registries have been established within the clinical content expertise arena with limited IT support. The risk associated with conducting registry activity outside a regulated IT infrastructure framework is no longer acceptable. We recommend the establishment of accredited registry centres who specialise in clinical information data management to partner clinical specialty groups in the conduct of registry activity.
- Clinical Quality registries need to be developed using The Open Group Architecture Framework (TOGAF) architectural development cycle
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) should be adopted to ensure clinical quality registries as this is becoming a global clinical information standard. There is a need for further education across the clinical community on the use of SNOMED CT as an industry wide standard for further development.
- The Unique Healthcare Identifier should remain as a key priority for future clinical quality registries. The ACPR has been built to ISO27001 standards for identity management for provider and client information and this should be a mandatory component of clinical quality registries.
- A literature review on funding models for clinical quality registries has been conducted. The review formed the basis of potential financial strategies for sustainable funding which is currently being further developed through the commissioning of an independent consultant (Dr Heather Wellington) whereby canvassing of these options will be undertaken with key ACPR stakeholders. These stakeholders include the clinical societies, government and private funding groups and prosthesis / device manufacturers.

The ACPR will continue to support pilot sites in the collection and follow-up of participants during the remainder of 2009 and until project timeline completion in 2010. This will involve the provision of registry reports and collection of feedback information from pilot sites regarding reporting information. In addition, the final registry sustainable funding report from Heather Wellington will be provided to the Commission, with an expected delivery late January 2010.

The funding of the ACPR pilot project by the Australian Commission for Safety and Quality in Health has led to a number of key outcomes in the quest to provide information on the quality of care in the provision of high-cost, high risk cardiac services in Australia. Firstly, it has provided the structure for clinical leadership and stakeholders to meaningfully engage in the process and secondly, it has provided the process through which standardised data can be collected through a secure web-based system developed and operating according to regulatory standards.

Attributes of Australian Clinical Quality Registries

OP 1. Australian Clinical Quality Registries should be developed with clear and precisely defined purposes.

In broad terms, the key purpose of the ACPR is to identify differences in the quality of care across the cardiac procedural population in Australia and monitor this over time. This pilot will monitor the safety and quality of certain cardiac procedures, specifically as part of this pilot project; Percutanous Coronary Interventions (PCI), Cardiac Surgical operations (CABG / Valve surgeries), Implantable Cardioverter-defibrillator (ICD) devices and Cardiac Resynchronization Therapy (CRT) devices. It is anticipated that the establishment of the registry will lead to an improvement in clinical services provided and provide the mechanism through which the quality and safety of cardiac interventions can be benchmarked (both nationally and internationally) and routinely monitored for quality assurance. Additionally, this registry would provide timely information, adjusted according to the patient's level of risk, about the outcomes of established and emerging procedures performed by clinicians across Australia. It would provide the basis for a national, systemic approach to improving clinical practice while facilitating locally based efforts to monitor outcomes. It is anticipated that other cardiac procedures currently undertaken in Australia (such as permanent pacemaker insertion and electrophysiology studies and arrhythmia ablation procedures) as well as new and emerging procedures such as percutaneous valve repair/replacement will be added to an expanded ACPR platform to enable quality and safety monitoring data collection commenced in a systematic and routine fashion.

Issues:

The importance on safety and quality was emphasised in all discussions with key stakeholders involved with the project. The Australian Cardiac community has a deep and rich history in clinical research and the clear identification of the purpose of this current registry project as a safety and quality registry rather than a research focus registry was a major discussion point. The implication in relation to the amount and detail of the data collected was the primary issue in this principle. It was a major focus for discussion at all working group meetings and workshop. Agreement in principle of the purpose of the registry to focus on safety and quality at the ACPR workshop was achieved. Despite this agreement some clinicians have since commented that the data elements selected, defined and mandated for this pilot are inadequate or inappropriate. This is without the benefit having seen any actual reports arising from the data collection due solely to having minimal data collected as yet as part of the pilot study and therefore no actual reports having been produced. We feel that in due course, the purpose of the registry will be realised and clinicians and administrators will be satisfied. Minor alterations to data elements may need to be undertaken and this will be informed once sufficient data has been collected, reviewed and analysed.

Recommendation to facilitate ACPR expansion:

1. Clinical quality registers should be supported and facilitated by education campaigns undertaken by the relevant clinical society associated with the registry. These education campaigns should be focussed on the purposes of the registry in order to facilitate clinical uptake in the registry.

General recommendation - OP 1:

We agree that OP 1 is a requirement for Australian Clinical Quality Registries

OP 2. For Australian Clinical Quality Registries to provide the maximum value to the health system they should focus their core data collection on the essential elements required to serve their main purposes.

The ACPR core minimum datasets for PCI, surgery and device agreed to by the working groups through a consultative process were finalised and signed off by the working groups in mid June. These were developed with OP's 8-12 and 14-18 foremost in mind. Given the starting points of the ASCTS and MIG registries much knowledge existed and was known in relation to cardiac surgery and PCI procedures. As these collections were based on mature, well established international registry collections, the challenge was to pare down the data collections to fulfil the primary purpose of quality and safety reporting by addressing the key performance indicators. Additionally local factors needed to be taken into to account to allow for and explain where the methodology differed to international collections and from the operating principles – such as having to work around the absence of a unique national identifier. With respect to device data collection and the key performance indicators, internationally the routine collection of data in this area is far less mature, therefore more research and collaboration was required in order to achieve consensus.

Issues:

The process of defining and refining the core minimum dataset across all three craft areas took over four months to finalise following on from the first consultation at the workshop in February 2009. This involved considerable research, both prior to and following on from the workshop, and a multitude of communication between the operations group and the various clinicians. In many of the dealings with clinicians, a lack of a negative response was eventually taken as approval; otherwise the process would have been dragged out over a much longer period, without achieving any additional gains. Ultimately, some of the communication that occurred between clinicians was not made known to the operations team as it occurred within the craft groups amongst the clinicians themselves. Therefore the overall responsibility and approval of both the key performance indicators and the data elements for this pilot rested with the chairs of each craft group.

Recommendations to facilitate ACPR expansion:

- 1. Data collection elements and definitions should remain in place for a minimum of three years without any changes made.
- 2. Data review committees should be able to make recommendations for changes to be made to registry collection
- 3. All recommendations to alter data elements are to be approved by the Steering Committee
- 4. All registry changes are to be implemented systematically with accompanying education and training for sites
- 5. The updated registry systems should be made available to all sites at the commencement of the next three year cycle.

General recommendation - OP 2:

We agree that OP 2 is a requirement for Australian Clinical Quality Registries

OP 3. Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible;

As previously stated, the operating principles as well as previous register data collections informed the selection of the data elements. The data elements identified by each craft group were then researched within the METeOR Metadata repository and where an equivalent element was identified, it was adopted as the standard for that ACPR element. Issues arose where proposed could not be matched to an existing approved element or where an existing approved element was found to not be applicable to the ACPR cohorts. Some other approved METeOR elements that could have been used, such as those in the Acute Coronary Syndrome Data Set Specification (ACS DSS), apply specifically to the acute coronary syndrome cohort of patients and therefore needed to be adapted for use with the coronary artery disease cohorts (or even more basic, adapted to being "patient" level elements), such as will be enrolled in the ACPR. During the research phase it became clear that some of the METeOR data element definitions were developed with research purposes in mind, however these were considered to be unsuitable for operational use in a registry setting such as the ACPR. The ACPR data elements were then assessed with assistance from Centre Clinical Research Excellence in Patient Safety (CREPS) input to ensure they met the standard of being "epidemiologically sound". This review resulted in some changes to element descriptions and definitions that then needed to be communicated back to the craft groups for discussion and ultimately, approval. This was perhaps where most of the resistance arose especially in the cardiac surgery and PCI craft groups.

Issues:

In many instances METeOR definitions were not available for the cardiac procedures and the ACPR data sets and elements were required to be entered into the METeOR system. This was a time and resource consuming process and added considerably to the workload of the pilot project. The second issue in aligning existing ASCTS database and MIG database definitions will involve the existing registries adjusting their current elements collected to ensure the core quality and safety elements are addressed and where required adapting to the ACPR approved definitions. This work will be ongoing beyond this pilot as it will only be fully be informed once sufficient data has been collected, reports generated a review undertaken. In principle agreement has been obtained from the ASCTS and MIG groups in this regard.

There appears to be a general lack of awareness of METeOR among clinicians and this therefore impacts gaining their support. In order to address this we did not use our METeOR derived definitions documents, rather, we produced our own versions containing only the relevant information needed.

Recommendations to facilitate ACPR expansion:

As per OP 2

General recommendation - OP 3:

In principle we support OP 3 for Australian Clinical Quality Registries, however, the inconsistencies within METeOR definitions require addressing as do the difficulties with using the METeOR system.

OP 4. Methods used to collect data in Australian Clinical Quality Registries should be systematic, with identical approaches used at the different institutions contributing information;

While the CRF's are uniform across all institutions as is the training materials and site initiation using Standard Operating Procedures (SOP) documents this has not prevented different challenges in relation to the systematic collection of the data across ACPR pilot sites. Many of these challenges related to local issues and therefore required responses / solutions that took these local conditions into account. The question of who will be responsible for data collection at participating sites was a key challenge that was identified early on. OP's 8 & 13 emphasise the need for data to be collected by relatively untrained staff, this would reduce the cost and burden on clinicians and hospital staff delivering the care to patients. However this concept was identified early on as being problematic in relation to the data elements required to be collected for the ACPR - particularly in relation to the collection of clinical information required for appropriate risk adjustment. All pilot sites were encouraged to identify either current ASCTS data managers, research RN's or other RN's to oversee the activity. It is generally an expectation that junior medical staff assisting cardiologists and cardiothoracic surgeons will participate in the baseline data collection process, especially in relation to procedural data, however, a lack of uniformity of this across sites is apparent, even from the limited activity of the ACPR to date. Ad hoc reports from pilot site data managers indicate different levels of willingness to assist with baseline data collection and overall engagement with medical staff, from junior doctors to consultants, varies from institution to institution, even between units within the same institution. More detailed assessment of this engagement as well as an assessment of data collection metrics has been undertaken and will be presented in this report.

Issues:

The current inconsistency with infrastructure an information technology capabilities across hospitals performing cardiac procedures results in the requirement to utilise site based data collection personnel to undertake ACPR data collection activities. While it may ideal to remove clinicians from data collection processes, it is impractical when relatively complex data elements are required, as is the case with the ACPR. Gains will eventually be made when such data collections become routine, indeed this will influence ongoing sustainability. Also, documentation may eventually improve, especially if clinicians realise the usefulness of well documented procedure reports, progress notes and discharge summaries. Despite the cost associated with the manual data collection of ACPR data the need to identify differences in the quality of care and monitor this across the cardiac procedural population in Australia is paramount.

Recommendations to facilitate ACPR expansion:

Improvements in infrastructure and information technology (IT) and incorporation of NEHTA standards at hospitals will eventually reduce the burden of cost of the ACPR and registries in general.

General recommendation - OP 4:

In principle we support OP 4 for Australian Clinical Quality Registries, however we acknowledge that until infrastructure and IT issues are addressed and resolved there will be additional cost burden on registries and this will need to be reflected in the funding of registries.

OP 5. Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained and

OP 6. In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up;

Data collection has commenced across several sites with follow up collected at 30 days post procedure. It is planned that patients will be followed up again at one year via telephone contact or record review, however whether this actually occurs remains to be seen and the decision to do so will likely take into account the cost burden this will incur. Additionally, there are plans to link the ACPR cohorts with state admitted episodes datasets and the National Death Index, although the absence of a unique national identifier results in probabilistic matching being required to analyse these data. Information about events post procedure could be reliably ascertained from linkage with other databases, however other important information such medication compliance cannot be collected in this way.

Experience nationally and internationally within cardiac procedure realms would indicate these outcome time points to be appropriate. It remains to be seen what the lost to follow rates within the ACPR will be, however ASCTS has demonstrated virtually no lost to follow at 30 days in the surgical cohort.

General recommendations - OP 5 & 6:

We agree that OP's 5 & 6 are a requirements for Australian Clinical Quality Registries

OP 7. Australian Clinical Quality Registries must ensure that complete registry data are collected from the eligible population;

The ACPR aims to ensure that all patients undergoing cardiac procedures at participating units are included in the registry. We aim to achieve this through the following mechanisms;

- Hospitals participating in the registry will agree to submit all cases to the registry to avoid selection bias, cherry picking or gaming
- In the pilot, HREC approval was sought and obtained for opt-off consent, however, issues with managing this locally at sites have come to light (see Appendix 1). Also, much of the feedback from IEC's related to the opt-off consent request with several IEC's wanting to approve a waiver for consent.
- The registry aims to identify hospitals reporting incomplete procedures by a verification process through data linkage with admitted episodes databases
- Site data managers will use locally held information to ensure cases are not missed (e.g. operating registers)

Recommendations to facilitate ACPR expansion:

- 1. Amendment for existing approved sites to be granted an approved waiver for consent
- 2. New site IEC applications request an approved waiver for consent
- 3. Funding be sought and approved for state based project managers to oversee site data managers and co-ordinate with the data management centre. This will enhance communication and implementation of the registry

General recommendation - OP 7:

We agree that OP 7 is a requirement for Australian Clinical Quality Registries, however, IEC approved waiver for consent should be considered an acceptable alternative to opt-off consent and the final Operating Principles document should be updated to reflect this

Data collection

OP8. The collection of data for an Australian Clinical Quality Registry must not impact on the provision of health care and should not be a burden or incur a cost to consumers;

Background & Experience with ACPR project

The ASCTS and MIG registries datasets, upon which the ACPR surgical & PCI collections are based, were considered onerous and too detailed for complete adoption nationally for quality and safety reporting purposes. Although based on well-established international models, many elements pertain to research questions and therefore were omitted from the ACPR. In order to collect these comprehensive datasets, a registered nurse trained in the field of cardiology/cardiac surgery was required at each participating site to manage and oversee the project. Although the ASCTS register in particularly has slowly expanded over the past 10 years to include 21 hospitals across the country, it is not readily taken up by the remaining cardiac surgical sites due primarily to the considerable costs involved with data collection.

Given the knowledge and experience with the cardiac surgery and PCI registers, the ACPR was set up with the focus on extensively revising the existing datasets to obtain minimum datasets to minimise the burden of data collection while still be able to answer the key performance indicators. Through the workshop and many additional meetings the minimum core datasets for PCI, surgery and device have been developed. However, the reality is that the ACPR still requires specialised data collection personnel who have the required expertise to ensure data accuracy. Administrative personnel are unable to interpret clinical data and in this realm, dedicated and trained cardiac data collectors are required to fulfil these tasks.

It has been observed in this pilot that the burden of data collection rests primarily on the data collectors (specifically, junior doctors – residents, registrars and fellows, and data managers) and while there is 'in principle' agreement by senior clinicians and organisations to participate this does not really translate into assistance to undertake the actual activity.

Issues:

Until we have unique person identifiers and mature IT infrastructure to link with existing systems, data collection will be burdensome and will require dedicated, trained staffing.

Recommendations to facilitate ACPR expansion:

- 1. Ideally, junior medical staff (resident/registrar) should be completing data collection forms in a 'business as usual' way and as part of their local quality assurance programmes, whilst the project is overseen by a site based registered nurse or data manager. This process should be supported and facilitated by the higher management of the hospital which is now evident in some of the well-established ASCTS centres where the data collection is considered routine and not excessively burdensome. This will potentially reduce the cost of the ongoing data collection and enable the project to achieve the goal of implemented in all cardiac surgical and procedural units across Australia.
- 2. If forthcoming, the funding of state based project managers to oversee and train site study personnel and data managers will strongly enhance and support the implementation of the registry nationally

General recommendation - OP 8:

We agree that OP 8 is a requirement for Australian Clinical Quality Registries; however, it is naive to disregard the impact our immature IT systems will have in terms of cost, which in turn can indirectly affect the provision of patient care. It is true to say that data collection will not take place to the detriment or neglect of patient care, however, accurately assessing the impact of this is fraught with difficulty and will differ across organisations as generally some of the work is undertaken or facilitated by non-clinical areas (such as research and quality assurance departments) and is also affected by the local reporting tools used as well as the local infrastructure.

OP9. Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors

Background & Experience with ACPR project:

The current data collection process is a hybrid of paper data collection form and web portal capture. Although transmission is best facilitated via web-based entry system, units who do not want to use or unable to access the web data entry system, can fax hard copy of collection forms and data entry would be undertaken at CCRE. Different contributors (e.g. Resident/Registrar/Data Manager) generally complete different sections therefore the paper CRF represents the way to track and assess form completeness. It also provides a copy to be kept locally at sites for retrieval and viewing. Pilot sites who are well-established ASCTS/MIG units are capturing data on the form at the time of care or soon after the care event. Online data entry expectation is that data will be entered by day 31 post-procedure once the follow up is completed. For missing data or incomplete forms, data collectors use the primary source which is the patient medical record. Other units utilise the medical record for the entire data capture process. Thirty day follow up of the patient is performed by the data manager at 30 days post the cardiac procedure.

Issues:

The evaluation of completeness is assessed upon entry of the ACPR data into the web system. Issues related to accessibility of the data and its systematic capture has been assessed by interviewing pilot site data managers. Data accuracy will be assessed once auditing is undertaken, so this cannot currently be commented upon and dependent upon the observed compliance this may ultimately impact on our ability to perform accurate risk adjustment (OP18). A monthly "observed versus expected" case reporting log will be maintained for each contributing units to ensure timely data entry. Units falling below 20% of expected entries for each month will be contacted for review. To assess data completeness of cases entered, each unit will be able to see a summary of missing fields to be completed online.

The methods recommended to pilot sites to assist with implementation of the ACPR project were aimed at reducing the impact of undertaking the activity and were based on previous experiences with ASCTS & MIG and as such it is clear that at sites who did not previously to contribute to ASCTS & MIG or ASCTS alone had the most difficulty. Indeed, the two pilot sites who were ASCTS & MIG contributors reported the least difficulty, while the two sites who had participated in neither registry prior to the ACPR reported the most difficulty. A major challenge in capturing the data as close as possible to the procedure is that a percentage of procedures occur after hours and on weekends where minimal staff are present and this has resulted in missed cases. In order to address this, retrospective data collection by data managers has been required and they report this greatly increases data collection difficulty and also the amount of time required per case.

Recommendations to facilitate ACPR expansion:

As per OP 8

General recommendation - OP 9:

We agree that OP 9 is a requirement for Australian Clinical Quality Registries, however, challenges remain to achieve this ideal with respect to the ACPR.

OP10. Data should be uniformly and easily accessible from the primary data source.

Refer previous OP – 9.

OP 11. Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases (if approved by relevant ethics committees, etc.)

Data elements were developed and agreed to by craft groups and the management committee. The research phase undertook identification of national and international data elements related to the craft areas. Suitability of utilizing METeOR elements was assessed and where appropriate these were used. To date, METeOR standard definitions for demographics have been used but most of the clinical definitions were not suitable to the ACPR cohort (refer to discussion on OP 3).

Other tools for ensuring the interoperability of the registry such as ICD10-AM and SNOMED CT were investigated and have not been implemented within the pilot datasets however, there will be utility to collect ICD10-AM via direct linkage to compare with ACPR data collected. The applicability of SNOMED CT terminology and its usefulness in the cardiac context is further discussed in the Technical Standards.

General recommendation - OP 11:

Refer to Technical Standards

OP 12. Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc;

ACPR staff underwent METeOR training and subsequently, standardised data dictionary was developed and produced in METeOR format as data set specifications (Refer to documents previously provided in our 2nd progress report). These definitions have been entered to the Australian Institute for Health and Welfare METeOR system and will be submitted for addition to the National Health Data Dictionary in due course following their assessment as part of the pilot project. Therefore, the process for obtaining approval and acceptance of these as Data Set Specifications will be ongoing beyond the pilot phase. A review of the METeOR system has been undertaken and was previously submitted.

This key conclusion of this review highlights that although METeOR offers software developers the capacity to build systems interoperable in their processing of data elements, in the context of ACPR, the addition of new data elements was a large task due to the design/usability of the METeOR system. This resulted in a significant amount of man hours and dollars being spent on the preparation of the three Data Set Definitions as there were approximately 200 unique definitions specific to the ACPR cohort. METeOR, with all its shortcomings in usability, however does score well as a schema for electronic processing and presentation of data ensuring a standardised level of interoperability in data definitions and their associated meta data elements.

General recommendation - OP 12:

We agree that OP 12 is a requirement for Australian Clinical Quality Registries, however, challenges will exist in achieving this ideal with respect to the METeOR system.

OP13. To avoid duplicating data capture, Australian Clinical Quality Registries use data from existing data sources, including administrative data, where they are of a satisfactory quality;

We are currently exploring the ability to link into existing local data sources. We believe custom solutions may be able to be utilised to enhance this process.

The quality of administrative data obtained from some pilot sites will be compared with the registry data collected. If the quality is found to be satisfactory, administrative datasets can be used to complement registry data, to avoid duplicating data capture and hence reduce data collection and entering by sites. One of the major limitations is gaining access to staff time at the participating institutions.

General recommendation - OP 13:

In principle we support OP 13 for Australian Clinical Quality Registries, however as our work in regards this is ongoing we acknowledge that more will be known over the coming months

OP14. Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registers or other databases;

Adequate identifying information formatted according to national standards is collected to enable probabilistic matching, however, where approved possible direct linkage will also be undertaken.

General recommendation - OP 14: Refer previous OP 13

Data Elements

OP 15. Australian Clinical Quality Registries should collect individually identifiable patient or subject information;

Appropriate identifying information is collected in the ACPR: last name, first name, middle name, hospital identifier, Medicare number, DVA File number, postcode, date of birth, gender and primary operator.

General recommendation - OP 15:

We agree that OP 15 is a requirement for Australian Clinical Quality Registries

OP16. Where patterns or processes of care have an established link to outcomes and process measures are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries;

Process of care measures include admission and discharge details, door to balloon time in primary PCI, total arterial grafting in cardiac surgery cases as well as length of stay data for all areas. Many of these data elements will be calculated from primary data rather than the requirement for direct entry. See Sample CRF's and data dictionaries previously provided.

General recommendation - OP 16:

We agree that OP 16 is a requirement for Australian Clinical Quality Registries

OP 17. Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools;

Key outcome measures for each procedural activity have been agreed to by the clinical craft groups and are outlined below. Thirty day outcome data will be collected at pilot sites by the data managers. This will encompass vital status and complications.

The Key Performance Indicators for <u>PCI</u>:

- 1. Mortality to 30 days (beyond the pilot phase, 12 month mortality)
- 2. Peri-Procedural Myocardial Infarction
- 3. Target vessel failure to 30-days (beyond the pilot phase, to 12 month)
 - Target Vessel Revascularisation
 - Stent thrombosis
- 4. Urgent CABG (in hospital)
- 5. Procedural success
- 6. Major bleeding (in hospital)
- 7. Stroke to 30 days
- 8. Door To Balloon Time

The Key Performance Indicators for Cardiac Surgery:

- 1. Mortality to 30 days (beyond the pilot phase, 12 month mortality)
- 2. Deep sternal wound infection to 30 days
- 3. Unplanned return to theatre for Bleeding (in hospital)
- 4. Stroke to 30 days
- 5. Readmission to hospital

The Key Performance Indicators for Devices:

- 1. Mortality to 30 days (beyond the pilot phase, 12 month mortality)
- 2. Re-operation
- 3. Readmission to hospital
- 4. Procedural Adverse Events
- 5. Early Procedural Complications (<1 month)
- 6. Late Procedural Complications (>1 month, beyond the pilot phase)

General recommendation - OP 17:

We agree that OP 17 is a requirement for Australian Clinical Quality Registries

Risk adjustment

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

Relevant objective data elements will be collected to enable statistical risk adjustments to be performed for appropriate benchmarking comparisons between units and clinicians.

Issues:

For cardiac surgery we have developed a local risk adjustment model that discriminates and calibrates well for the Australian population. Additional work to develop similar models for valves is currently ongoing with ASCTS. This is not the same situation with respect to PCI and Devices. We will use existing published models for adjustment with the expectation to develop a new model following the collection of 10,000 cardiac PCI procedures and a suitable number of Device procedures. Once sufficient time has elapsed, assessment will be made to ensure ACPR risk adjustment is appropriate and accurate.

General recommendation - OP 18:

We agree that OP 18 is a requirement for Australian Clinical Quality Registries

Data security

Please refer to Technical Standards report

OP 19. To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems;

OP 20. The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines;

OP 21. Institutional policy principles set out in Part B: Technical standards should be met;

General recommendation - OP's 19-21:

We agree that OP's 19-21 are a requirement for Australian Clinical Quality Registries

Ensuring data quality

OP 22. Australian Clinical Quality Registries should report as a quality measure the percentage of eligible patients recruited to the registry;

Site based data collectors will ensure all cases are recruited and comparison with administrative databases will ascertain all cases are captured. We will cross-check registry data with admission and discharge information in order to confirm complete ascertainment of cases from each participating Unit.

The recommendation to data managers at pilot sites has been to routinely cross check theatre or catheter laboratory procedure registers with case report forms to ensure all cases have been collected. Where omissions are discovered, the data manager must ensure this is completed. This may involve either completing the case report form themselves or liaising with the relevant medical staff who should have undertaken the data collection in the first instance. The experience across the pilot sites has varied, and sites with established registry participation report less resistance & high compliance compared with sites that are new to this type of data collection.

By utilising the admitted episodes data we aim to check that all episodes of procedure codes for a period were collected. An issue with this is the somewhat retrospective nature of admitted episodes coding in health information departments with an expected minimum time for coding completion to be six to eight weeks.

General recommendation - OP 22:

We agree that OP 22 is a requirement for Australian Clinical Quality Registries

OP 23. Australian Clinical Quality Registries should have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected;

To achieve high quality data, standardised data dictionaries have been established and training given to data collectors to ensure they comprehend and understand them. Ongoing queries around data items and definitions will be resolved by project manager and the data management committee. In addition, regular meetings will be held with data collectors to identify problems and inconsistencies in data that has been collected. Initial and ongoing training for data collection will be provided as well as cross-checking data with other data sources such as hospital administrative data. It is expected that data managers communicate and liaise with medical staff as well as giving feedback to the data capture completeness and quality. The registry will be able to provide assessment of data completeness, outstanding follow ups and the like; however, it is of utmost importance that data managers regularly give feedback locally to clinicians to address issues with the aim to enhance the data collection. Eventually the collection of such data will be considered a routine part of cardiac care. The presentation of local reports showing performance will enable data managers to achieve this task.

General recommendation - OP 23:

We agree that OP 23 is a requirement for Australian Clinical Quality Registries

OP 24. Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible;

A standardised audit plan will be developed based on the model used in the ASCTS project. Onsite auditing process will be performed by trained clinical staff to assist in determining data completeness and accuracy, and to prevent 'gaming'. Cardiac units will be randomly selected and 5% of annual cases are evaluated. The objective measures of data accuracy will be reported back to units.

Auditing Process

All sites will be randomly selected each year for an audit. Representatives of Monash University will conduct the audit. The auditing procedures followed are outlined below.

1) <u>Review of total numbers of procedures</u>

The total case numbers derived from central database will be compared against 2 of the following

- i) admissions
- ii) theatre/procedural lists
- iii) other database if available

MONITOR PREPARATION:

ACTION	TIMING
Advise site of time period, requirements and date of audit	1 month prior to audit
Extract patient numbers by month	Within 1 week prior to audit
Extract electronic table of patients by UR and DOB	Within 1 week prior to audit
Print list of UR and names	Within 1 week prior to audit

SITE PREPARATION:

ACTION	TIMING
Obtain case numbers from admissions	Prior to audit
Obtain theatre/procedural lists	Prior to audit
Ensure access to other databases available for date	Prior to audit
of audit	

CONDUCT:

ACTION	STANDARD	INVESTIGATION IF FAILS
		STANDARD
Compare numbers against	No discrepancy	Comparison of individual procedures to
theatre/procedural lists		determine discrepancy
-		
Compare numbers against admission	No discrepancy	Comparison of individual procedures to
lists		determine discrepancy
		1 7
Compare numbers against available	No discrepancy	Comparison of individual procedures to
databases		determine discrepancy
		1 5

2) <u>Full review of a subset of cases against medical record</u>

a) Random selection of cases

- Monitor to randomly select 5% of procedures for requisition (usually 17-40, may need to select a few more cases on the assumption that some records may be unobtainable)
- Site to request medical records in time for audit (may have to split across days)

b) Specific selection of cases

- Monitor to select 4 procedures for requisition
 - 2 cases high-risk with excellent outcomes
 - 2 cases high-risk with poor outcome (i.e. major complications or mortality)
- Site to request medical records in time for audit

MONITOR PREPARATION:

ACTION	TIMING
Advise site of time period, requirements and	1 month prior to audit
date of audit	
Advise site of exact records to request	1 month prior to audit
Print patients data from central database to	1 week prior audit
compare against the medical records	

SITE PREPARATION:

ACTION	TIMING
Request Medical Records for date of audit	Prior to audit

CONDUCT:

ACTION	STANDARD	INVESTIGATION IF FAILS STANDARD
Monitor to compare patients data extracted from central database against the medical records and note down any discrepancies found	99% accuracy in key data fields (ie approximately 1 error per 3 records)	Comparison of individual procedures to determine discrepancy

Audit Results and Subsequent Actions

- Each individual site will receive the results of their audit.
- De-identified audit results will be provided to the Steering Committee.

General recommendation - OP 24:

We agree that OP 24 is a requirement for Australian Clinical Quality Registries

OP 25. Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks;

Rigorous validation, constraints and logistic checks will be put into place at the point of web-based data capture to prevent inaccurate data being entered, including reminder mechanisms for the management of incomplete procedure records (see Technical Standards).

General recommendation - OP 25:

We agree that OP 25 is a requirement for Australian Clinical Quality Registries

OP26. Australian Clinical Quality Registry reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur.

Utilising the web portal, the project will develop a 'real-time' feedback after the accumulation of specific completed and verified case numbers within the final ACPR database. It will provide a comprehensive assessment of the data including an overview of the types of cardiac procedures performed, with detailed procedural and outcome information, for a specific unit or individual clinician for a given period of time. Cardiac unit heads and individual clinicians will be able to access unit or clinician online quality control reports of each of the key performance indicators to assess performance measures and to look up their cases in real time for in-house auditing purposes and reporting.

Issues:

Non-registered clinicians will not be able to access their own reports online since the linkage of all procedures to a clinician will be enabled (refers to OP32).

General recommendation - OP 26:

We agree that OP 26 is a requirement for Australian Clinical Quality Registries

Organisation and Governance

OP 27. Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry;

ACPR Pilot Project Governance is under the guidance of the ACPR Interim Steering Committee (SC) as outlined in the Terms of References (TOR) however day to day management during the pilot project has been undertaken by the ACPR Operations Committee. The Operations committee reports to the Management Committee and Interim Steering Committee. Monash University, School of Public Health & Preventive Medicine will own the ACPR pilot registry software system and will also ensure appropriate management and security processes are implemented and maintained. The ACPR data will remain the property of the contributing pilot sites and clinicians and will be available for their use.

The aim of this pilot project was to develop a quality clinical registry that could ultimately be adopted for use across Australia and as such, the overarching governance principles have been put together with this in mind. It would be anticipated that the Interim Steering Committee would continue until the inaugural ACPR Steering Committee was enacted.

Steering Committee

Key aims of the Steering Committee include:

(a) Ensure the register is conducted according to the 'Operating Principles and Technical Standards for Clinical Quality Registers'

- (b) Maintain stakeholder 'buy-in' through support and promotion of the registries activities
- (c) Approve the production and dissemination of registry reports

(d) Provide advice and input into the on-going development and maintenance of sustainable funding (accurately identifying ongoing costs and negotiation with funders)

- (e) Provide governance that is functional and effective
- (f) Ensure infrastructure requirements adequately meet the needs of the registry

The responsibilities of the Steering Committee are to:

- Provide oversight over all ACPR activities, including that of all Sub-Committees; the Management Committee;
- Provide ongoing review of the objectives of ACPR and its effectiveness in meeting them;
- Provide guidance on the alignment of the project's scope with the requirements of the stakeholder groups;
- Endorse policies to address issues of clinical interest or significance that may arise from time to time. These will include matters related to quality of care;
- Facilitate policy support for issues identified by the Management Committee;
- Provide advice on the budgetary strategy, defining and realising benefits;
- Monitor the quality of ACPR's data management processes and timeliness of reporting;
- Monitor and endorse policies for appropriate data access, quality and assurance initiatives, and collaboration rights for research activities derived from the project;
- Review and advice on output from ACPR;
- Review and provide comment on reports published by the ACPR project;
- Provide advice on ACPR data collection and interpretation of the data;
- Review quality and safety publications arising from the ACPR; and
- Review and advice on communication strategy, including communication with the community and consumers.

Membership:

The constitution of the ACPR Steering Committee would include the following key stakeholders:

- President of the CSANZ (or nominee);
- President of the ASCTS (or nominee);
- Health jurisdiction representation ;
- Representation from the Therapeutic Goods Administration (TGA);
- Representation from the NHF;
- Representation from Consumer Health Forum (CHF);
- Representation from the Percutaneous Coronary Interventions (PCI), Electrophysiology and Surgical Working Groups of the CSANZ;
- Representation from the Data Management Centre;
- Representation from ACSQHC; and
- Representation from NHMRC Centre for Research Excellence in Patient Safety (CREPS)

The Steering Committee may be chaired by the Chief Executive of the ACSQHC, Professor Chris Baggoley.

Operations of the Steering Committee

The Steering Committee will be lead by the Co-Chairs. The Chairs are responsible for the business of the meeting to be conducted, and ensuring appropriate governance process is followed. The Chairs are supported by the ACPR Operations Committee who are responsible for the the general organisation and planning of the Steering Committee meetings.

- Secretariat support will be provided by the ACPR Operations Committee.
- Meetings of the Steering Committee are bi-monthly and are as face-to-face and/or teleconference. Interstate members may request travel arrangements in order to attend in person at up to two meetings per year (subject to available funding).
- An Agenda is distributed prior to each meeting, Minutes of the meeting are taken and the Minutes are disseminated after the meeting. Action items are noted.
- A quorum is set at 50% of current membership.

The first ACPR Steering Committee Meeting was held on the 10th of August 2009, with the 2nd meeting scheduled for the 11th November 2009. The initial meeting was successful with all except one member participating. There was productive engagement in regards to the project moving forward and the sustainable funding model.

In the pilot testing phase, the ACPR Steering Committee is Co-Chaired by Dr Leo Mahar and Mr Gil Shardey.

Procedural Working Groups

The Procedural Working Groups focus would include;

- Maintaining the currency of the ACPR data sets in line with changing clinical practice,
- Under-taking peer-review performance monitoring, and
- Preparation of reports for submission to the ACPR Steering Committee.

Membership of the ACPR Procedural Working Groups would include, amongst others: Representation from the professional bodies, including RACS, RACP, CSANZ, NHF and ASCTS, and Representation from Data Management Centre

Over the course of the pilot study the following committees have been established:

ACPR Operations Committee

The responsibilities of the Operations Committees are to:

- Manage all ACPR activities as per the contractual arrangements with ACSQHC
- Report to ACSQHC
- Report to the Management and Steering Committees

Membership:

- Project Principal Investigator
- ACPR Project Managers
- Representation from Data Management Centre
- Co-chairs of craft working groups

Meeting frequency: Fortnightly and as required

ACPR Management Committee

The responsibilities of the Management Committee are to:

• Review and provide advice on ACPR project to Operations Committee

Membership:

- The Operations Committee
- Project Associate Investigators
- Pilot site representatives

Meeting frequency: Monthly

The following committees require development and implementation:

ACPR Sub-Committees

Peer Review and Quality Assurance Committee

The responsibilities of the Peer Review and Quality Assurance Committee are to:

- Oversee the confirmation, further investigation and, if necessary, review of performance outliers (both favourable and unfavourable) as required
- Oversee the management of Cardiac Units or Cardiac Clinicians identified for review
- Be responsible to Interim Steering Committee via the Management Committee

Membership:

To be determined, but should include: Project Supervisor, Data Manager Centre and one representative from each of the craft groups (cardiac surgery, PCI and Device)

Meeting frequency: To be determined

As detailed in the Ethics & Privacy section of this report, formal contingencies plans to deal with issues arising from the analysis of registry data are yet to be finalised due to limited data being received within the ACPR. The structure is in place for these plans to be activated via the following ACPR committees: Report and Research, Statistical Review and Steering Committees.
Peer Review Process

The information transfer process for peer review committee activities is outlined below.

Step 1 at week 0:

Outlier identified by Central Data Agency (CDA) on a key performance indicator (KPI) for a Unit. Outlier defined by the KPI result being greater or less than 3 standard deviations from state mean.

Step 2 at week 4:

CDA contacts Head of Unit to request internal audit of KPI data. Unit provides internal audit of KPI data to CDA within 4 weeks. CDA notifies Peer Review Committee of request for a Unit to undertake an internal audit.

Step 3 at week 8:

CDA to review internal audit result. Teleconference arranged with CDA and Unit to discuss internal audit data within 8 weeks of KPI outlier identification.

Step 4 at week 12:

CDA reviews the most recent KPI data at 12 weeks since the outlier identification at week 0.

If KPI within limits - no action is required.

If KPI outlier confirmed - Peer Review Committee notified

Step 5 at week 16:

CDA to arrange an external audit of unit within 4 weeks of re-confirmation of KPI outlier. Audit team consists of CDA Project Manager & CDA Director, and Peer Review Committee member. External Audit team to discuss KPI outlier with Head of Department and Clinicians to discuss the units plans for outlier remediation.

Step 6 at week 20:

External audit team reports to Peer Review Committee within 8 weeks of KPI outlier confirmation. Peer Review Committee to comment on units plan and make recommendations in relation to KPI remediation. Report provided to unit within 8 weeks of KPI outlier confirmation.

Step 7 at week 24:

CDA reviews the most recent KPI data at 24 weeks since the outlier identification at week 0 and week 12.

If KPI within limits - no action required.

If KPI outlier confirmed - Hospital Administration and Department of Health notified



Data Management and Audit Committee:

The responsibilities of the Data Management and Audit Committees would be to:

- Oversee all issues regarding the collection, transmission, receipt and warehousing of data (Data Management Centre) including:
- security of data
- privacy issues: patient, unit, clinician
- data compilation, verification, analysis
- Review all risk adjusted data for consistency
- Review and assess data for outliers
- Initiate the process of peer review by contacting the committee chair in writing
- Be responsible to the Steering Committee and Management Committee

Each contributing centre retains ownership of its own data and governance of the combined registry data rests with the ACPR Steering Committee. The ACPR Steering Committee will develop policy guidelines in relation to access to information, and reporting standards for the release of information. Monash University Clinical Informatics and Data Management Unit acts as custodians of the combined registry data and report to the ACPR Steering Committee.

Membership:

To be determined, but should include: Project Supervisor, Data Manager Centre Meeting frequency: To be determined

Statistical Review Committee:

The responsibilities of the Statistical Review Committee would be to:

- Design and assess the statistical methods to be used to analyse the data
- Design and assess risk stratification algorithms
- Produce risk stratification algorithms that can be applied to patients on a per case basis
- Statistically identify outliers and review outliers
- Be responsible to National Steering Committee

Membership:

To be determined, but should include: Project Supervisor, Data Manager Centre and Statistician Meeting frequency: To be determined

Dataset Committee:

The responsibilities of the Dataset Committee would be to:

- Biennially review of the Dataset and Definitions
- Be responsible to the National Steering Committee

Membership: To be determined Meeting frequency: To be determined

Reporting and Research Committee:

The responsibilities of the Reporting and Research Committee would be to:

- Review all requests for information from the database by external agencies
- Review all data produced by the database: annual reports, articles submitted to journals, papers presented at meetings
- Design and supervise research projects including those derived from the dataset and specific projects including longitudinal studies

Steering committee's approval to use ACPR data for research purposes would be required. Furthermore, consent for research projects arising from register data would then be required to obtain additional ethics approval. No formal requests for the use of ACPR data have been received as yet.

Membership: To be determined Meeting frequency: To be determined

Issues:

1. It is difficult to comment on the actual assessment of these OP's due to the time constraints with this pilot project, however, these OP's are sound and logical and in principle are key requirements for a quality clinical registry.

General recommendation - OP 27:

We agree that OP 27 is a requirement for Australian Clinical Quality Registries

OP 28. Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes a formal plan ratified by the Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately;

Refer peer review process for previous OP – 27.

General recommendation - OP 28:

We agree that OP 28 is a requirement for Australian Clinical Quality Registries

Data custodianship

OP 29. Custodianship of clinical register data needs to be made explicit in Contracts and/or Funding Agreements;

The concept that custodianship of register data be made explicit is sound and logical. The challenge with this register is that it is a pilot study and formal stewardship of the register is yet to be declared. It is thought that acceptance by the clinician and craft groups would be considerably enhanced were the stewardship of the ACPR undertaken by the Cardiac Society of Australia and New Zealand (CSANZ). This has been discussed amongst the clinicians and craft groups and has been met with approval. It is also felt that this clinician, craft group and society buy-in will facilitate uptake of the ACPR throughout Australia.

For the purposes of this pilot, custodianship of the data has been made clear in the Data Collection Agreement signed by each pilot hospital and Monash University and custodianship resides with Monash University. While not explicitly stated in the contract (however, it is stated in the tender response document that forms the protocol for this study – see page 24) there is certainly an understanding that pilot sites (and later in any expanded national registry this would apply to all contributing sites) would retain ownership of its own data while governance and custodianship of the combined register data rests with the ACPR Steering Committee.

Guidance in relation to appropriate custodianship / ownership is not explicit in the operating principles and is perhaps a criticism. In creating the ACPR contract, the university solicitors were engaged and instructed the management team of the pilot study as is university policy. As we the researchers did not ask for a statement declaring sites retain ownership of their own data this has been overlooked.

Perhaps the OP's could be expanded to include discussion related to ownership of site data with a recommendation that sites always retain ownership. Custodianship should never rest with individual sites; however it would be appropriate that representatives from sites be members of the various committees that oversee and manage the combined registry data.

The following are excerpts from the Data Collection Agreement used for ACPR participating pilot sites:

Each Party agrees that it will not disclose or publish in any manner any Confidential Information owned by the other Party without obtaining written consent from the owner. For the purpose of this clause, "Confidential Information" means all trade secrets and know-how, pre-existing intellectual property, financial information, patient data and other valuable information of whatever description and in whatever form that is not in the public forum, but excludes the interpretation, analysis and application of general information generally known to the public.

TPH (The Participating Hospital) acknowledges that a joint publication may be anticipated and be authored by more than one of the investigators participating in the study referred to in the Study Details. Any such publication will be subject to the publication terms of Monash, a copy of which is set out in Item 7 of the Schedule to this Agreement.

Any intellectual Property developed by Monash, and by TPH as a direct result of the provision of the TPH Services during the term of this Agreement, will be owned by Monash as at the date the same is created.

For the purpose of this clause, "Intellectual Property" includes but is not limited to all inventions, discoveries, innovations, technical information and data, prototypes, processes, improvement, patent rights, circuitry, computer programs, drawings, plans, specifications, copyright, trade mark rights, design rights, plant variety rights and Confidential Information.

In order to carry out the Study, Intellectual Property which is part of a Party's Background Intellectual Property may be used. Any such background Intellectual Property remains the sole property of that Party. For the purpose of this clause, "Background Intellectual Property" means preexisting and or independently developed Intellectual Property made available by a Party for the purpose of undertaking the Study. TPH grants to Monash a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Background Intellectual Property belonging to TPH for the exploitation (if require by Monash) of any Intellectual Property created pursuant to this Agreement.

General recommendation - OP 29:

We agree that OP 29 is a requirement for Australian Clinical Quality Registries.

Further, clear unambiguous statements of data ownership and data custodianship for any clinical quality registry should be publically accessible on the web-site associated with the registry and this should be mandated in the operating principles.

OP 30. Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data;

Data access and reporting policies for the ACPR have been based upon the existing ASCTS Registry and its policies. These policies take into consideration privacy legislation, confidentiality and ethics agreements. The Steering Committee will monitor and endorse these policies ensuring appropriate data access, quality and assurance initiatives, and collaboration rights for research activities derived from the ACPR project and will take advice from the Reporting and Research Committee. The scope of requests for access to ACPR data is currently an unknown variable due to the timelines of this pilot project, however, it is anticipated that in time there will be many such interested parties. As well as making these policies and request forms available to those who contact us requesting them we will also ensure they are posted onto the internet for easy access by any interested parties.

General recommendation - OP 30:

We agree that OP 30 is a requirement for Australian Clinical Quality Registries. Further, data access and reporting policies of clinical quality registries should be made available on public access web-sites for the specific registry and this should be mandated in the operating principles.

OP 31. Third parties wishing to access data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data or contact with patients is sought;

A Research Committee will be established as part of the governance process and any request for research using ACPR data would require approval of the committee. Terms of reference for the Committee will be established. There has been a standard operating procedure and request for data use form developed. This committee will report to and be overseen by the ACPR Steering Committee.

General recommendation - OP 31:

We agree that OP 31 is a requirement for Australian Clinical Quality Registries.

Further, guidelines (including access forms and an outline of process and costs etc) for thirdparty access to clinical quality registry data should be publically available on the registry web-site.

Ethics and Privacy

OP 32. Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry and

OP 34. Participants or their next of kin should be made aware of the collection of register data. They should be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This should be at no cost to the registry participant;

Background & Experience with ACPR project

The ACPR Pilot project has been developed, where possible, in accordance with the draft operating principles and technical standards and as such it was agreed that IEC approval would be sought for all sites who agreed to participate. In accordance with other operating principles, key elements of the IEC submissions for ACPR therefore required the IEC to approve the collection of identified data with opt-off consent. Many challenges have been faced with the IEC review and approval of the ACPR Pilot & these will be expanded upon later in this section.

The original background projects that informed the ACPR Pilot (cardiothoracic surgery registry [ASCTS] and percutaneous coronary intervention registry [MIG]) were originally developed in Victoria and IEC approvals were sought and at that time (between 1998 & 2007) ethics committees either approved the studies with opt-off consent (most MIG and ASCTS sites) or approved them as a quality assurance activity (one MIG site and several ASCTS sites). The ASCTS study has always collected identified information (name, address, medicare number & DOB). The MIG study however, only collected partially identified information (first 3 initials of name, DOB, medicare number) and this had implications for linkage with the NDI and as such an amendment was submitted and eventually approved at all sites allowing the patients full name to be collected. The overarching purpose of the ACPR is to develop a platform that could ultimately be scaled up nationally.

Issues:

1. National Ethics Application Form (NEAF):

A decision was made early on in this project to utilise the NEAF. Our experience with 11 sites across 4 states and 1 territory where the selected ACPR pilot sites were located has varied and has required a large continuing effort to ensure the relevant additional documentation was completed to enable the submission to IEC's and ultimately obtain approval.

NSW Area Health Services generally appeared most familiar with the NEAF, however, we have not tested this assumption as neither of the 2 NSW public hospitals invited to participate as pilot sites have, up until this point agreed participation.

Victorian sites accept the NEAF, however it is here where individual IEC's have mandated varying additional requirements and documentation. The Victorian DHS is rolling out a similar system to NSW whereby overall ethical assessment will be undertaken by one of six approved HREC's and local IEC's will be required only to review local site issues, such as contractual and departmental concerns. Whether this improves the IEC process in Victoria remains to be seen, however, the NEAF will be the common format accepted and this will be a positive step.

ACT readily accepted the NEAF, however, the requirements related to additional information were unclear as the IEC website was several years old and was apparently due for updating. This did not affect submission or approval and the minimal issues raised by the committees review were addressed satisfactorily.

The 2 hospitals in SA differed in their preference of the NEAF, however, both accepted it. One of the SA IEC's stated a preference for local documentation to be used however, upon review of the documentation we felt concerned that the breadth of information contained within the NEAF would be difficult to translate to such a limited proforma, hence we submitted the NEAF anyway.

Our remaining IEC experience related to private hospitals, one in Queensland, the other in NSW who used a Queensland based IEC. Both these IEC's accepted the NEAF and once the issues raised by the committees review were addressed satisfactorily, approval was given.

Like other registry projects where national coverage is required with IEC approval, we are aware that the IEC process is time consuming and labour intensive. In order to roll out this project nationally, a clearly defined strategy to deal with the approximately 100 additional IEC's applications will be required. To enable success of a national rollout in a satisfactory timeframe, IEC's must become enabled with respect to understanding the concepts related to quality clinical registries and as such the National Statement requires updating. In fact, a review of the National Statement shows that the terms "opt-off" (as it relates to consent) and "register" or "registry" are not included anywhere in the document. Given the fact that the National Statement is what informs IEC's this matter needs addressing urgently.

2. Opt-off Consent for Participants:

A common theme that emerged from many IEC reviews was related to the opt-off consent requirement. Nearly all IEC's voiced an opinion that opt-off was not a valid form of consent and some offered an approved waiver for consent while others suggested the activity fell under the quality assurance scope and it should be approved as such. In personal correspondence with an IEC officer, a reason offered for this confusion was that there is a "non-fixed definition of opt-off" and that committees apply varying degrees of strictness with respect to the requirement in ensuring all subjects have received and understood the PIS. Indeed, our experience within this pilot has proved this to be the case as the process of managing opt-off amongst the pilot sites has differed with respect to the local IEC opinions. In dealing with our responses to IEC's it became clear to us early on that we had perhaps contributed to the confusion with our answers to some of the questions in the NEAF. In order to ensure complete registry data be collected from the eligible population (relates to OP 7), it is well documented that opt-off consent utilising a patient information sheet is superior over opt-in and the OP designated this as the best approach. Those committees wanting to approve the project without opt-off were requested to review our revised submission as we felt we had more clearly explained our purpose and this succeeded in IEC's approving the project with opt-off consent. Our rational for continuing to pursue IEC approval for opt-off consent was that it is considered that classifying project as quality assurance places limitations on the use of registry data. Whether there is any such limitation or issue with obtaining an approved waiver following IEC review is unclear.

Given that we were still in discussion with one local Victorian IEC, in October we attended the IEC meeting in order to directly address issues and answer questions that the committee had. To this end, we have received a response on 5th November 2009. This response neatly sums up the key issue with opt-off consent and combined with our experience with this pilot, highlights the key challenges faced with implementation of a large scale project utilising the opt-off model. It reads in part:

"In regard to the method of consent we advise that the committee believe that waiver of consent is the better way to approach these sorts of data collection projects. A waiver of consent would allow you to collect the relevant information for all patients under the same conditions for all patients. As there are no controls in place to check that participants have received, read and considered the information about the study, opt-out consent will allow for the situation where some patients will be aware of their information being collected and used whilst others may not."

Despite this, the committee did agree to our request and approved opt-off.

As previously mentioned, the processes around opt-off have varied from pilot site to pilot site. Like other aspects related to the implementation of collecting ACPR registry data, those sites with existing participation in the ASCTS and MIG registries have reported less difficulty overall. This has lead this group to conclude that for a registry of the magnitude of the ACPR (expected 80-90 thousand episodes of per year) that an approved waiver of consent would be preferable to opt-off consent.

3. Qualified Privilege (QP):

QP is seen by some clinicians and hospitals as the way to protect them from individual scrutiny into their practice and to maintain anonymity. Whilst we have not sought QP as part of this pilot, nor do we wish to seek it, it may be that until clinicians and hospitals are satisfied that appropriate protection exists within the registry that in order to continue the current activity beyond the pilot and later expand nationally, that we undertake applications for QP. In this pilot project, some clinicians have declined to register with the ACPR, thus not enabling us to link all procedures to a clinician. The ability to report on registry findings (refers: OP 36 OP 37 OP38 OP 41) especially the peer review process is incumbent upon clinicians registering and thereby allowing linkage of "procedure to clinician". Our process to deal with this resistance is to allow procedures to be entered that link to a particular site only, thus still allowing the capacity for site aggregate reporting.

4. Consent to Collection of Identified Clinician Data:

An ethical issue raised by an IEC and clinicians related to the collection of identified clinician information. Despite assurances that clinician information (similarly patient and hospital site information) would be dealt with and stored according to the proposed NEHTA standards, concern remains with individual clinicians and sites and as such we will allow the collection of patient procedural data that while linked to a site, does not mandate linkage to an individual clinician. We will continue to engage with the clinician groups and their professional organisation to allay concerns, however, it is our belief that it will take considerable time to have the notion of identified clinicians data linked to their procedures fully accepted by the cardiac medical community. This resistance so far has arisen mainly in relation cardiologists, however, as yet not all surgeons have registered so it may be that the lack of QP (as they currently have with the ASCTS register) may be of significant enough concern to prompt them to also decline registering for linkage of ACPR procedures to themselves. Requirement for hospitals to participate in an approved quality clinical register related to activities undertaken at the site would assist in this regard - such as inclusion to satisfy the Australian Council on Healthcare Standards (ACHS) accreditation. Similarly the requirement for clinicians to satisfy credentialing requirements with their professional body would encourage participation.

General recommendation – OP 32:

We agree that OP 32 is a requirement for Australian Clinical Quality Registries. However, the *National Statement on Ethical Conduct in Human Research* must be updated to enable IEC's to more systematically review submissions that relate to quality clinical registers. We are hopeful the Law Reform Commission review of privacy legislation (when available) results in changes to the legislation in relation to privacy laws and that due consideration be given to the development of national privacy laws. This will also assist approved national quality clinical registers to gain local IEC approval.

General recommendation – OP 34:

Because this principle implies that opt-off consent is the preferred approach for clinical quality registries, and due to the complexity that managing very large studies with opt-off consent would entail, coupled with the variation in interpretation by IEC's we believe that an approved waiver should also be considered appropriate for clinical quality registries. This will however, fundamentally alter this principle as, by the very nature of waiver, neither participants nor their next of kin will be informed of the data collection or its purpose. Where a registry methodology includes any form of centralised follow-up (as opposed to

participating sites contacting patients for follow up information), we agree that opt-off consent should be the standard.

OP 33. Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research. Participants or their next of kin should be made aware of the collection of register data;

Background & Experience with ACPR project

Given the level of maturity with the conduct of clinical trials in the cardiology and cardiothoracic areas of health, an assumption could be made that hospital based staff are familiar with and abide by the National Statement. With submission to local IEC's it is a requirement that listed investigators sign a declaration that they have read and will observe the principles set out in the National Statement. Similarly, section 9.3 of the NEAF asks researchers to sign such a declaration. Therefore all researchers involved with the ACPR Pilot have signed such a declaration, whether they be hospital or university based.

With respect to the ACPR Pilot we have included an additional declaration on the Site User Registration Form where users are again asked to sign that they have read and agree with the National Statement. Additionally we have uploaded the National Statement to the ACPR website, the address of which has been communicated to all sites and researchers.

Issues:

Whilst researchers have agreed and signed several times that they are familiar with the National Statement, no formal assessment is made of this. Nor do we feel this is appropriate. Of concern is the knowledge and awareness of the privacy principles as they relate to each state and territory. Again, other than researchers signing the NEAF and local IEC declarations, we have undertaken no formal assessment of this.

The NEAF is necessarily vague when it comes to privacy principles due to the differences across states and territories. Until common legislation is enacted with national coverage, national registry projects will be required to complete a multitude of different forms within states and between hospitals that address the privacy issues. We eagerly await National Law Reform Commission review of Privacy Legislation due later this year and look forward to the NEAF being modified such that IEC's no longer require additional documentation to enable them to assess an application in relation to privacy principles.

In Victoria, one IEC has taken issue with the paper case report forms produced for use in the registry and requested that the following principle be complied with in relation to the paper case report forms that will remain locally at the site:

To maintain security procedures for the protection of privacy, including (but not restricted to): removal of identifying information from data collection forms and computer files, storage of linkage codes in a locked cabinet and password control for access to identified data on computer files.

No other HREC has taken issue with the paper case report forms we developed and despite our response that the ACPR web based register and database would do precisely as required by the relevant standards the IEC still wanted us to modify the paper case report forms even though they were only for local site use and storage. A solution we will put forward to that committee is that the top half of the first page is removed and the remainder is indentified by marking the hospital UR number on the remaining pages. These can then be stored separately. It is our feeling that once the data is entered into the web system and verified that the paper case report form could be securely destroyed as the information would be available in the web based system, however, we are aware that this would contravene local IEC requirements related to maintenance of study records of subjects at sites. We would go so far as to suggest that a database system that securely houses and stores

personal and medical information for registry purposes would negate the need to keep the paper copy of the data at sites.

General recommendation – OP 33:

We agree that OP 33 is a requirement for Australian Clinical Quality Registries.

OP 35. Where projects are undertaken using register data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity;

As yet there is limited data within the ACPR and no requests for register data have been received. Nor do we expect any for some time to come, however, we feel the appropriate governance has been put in place to deal with requests for register data and these will become activated when such a request is received.

Access to projects requiring registry data must be accompanied by a) a completed registry data access form, and b) approval notice from the ACPR Steering Committee (or designated representatives) that access to data is consistent with clinical quality reporting. Projects which require additional information from registry participants medical records or identification of individuals to be contacted will also require separate Ethics Committee approval.

General recommendation – OP 35:

We agree that OP 35 is a requirement for Australian Clinical Quality Registries.

Information output

Since the ACPR is a newly established registry, the testing and evaluation of OP36 to OP41 will not be undertaken during the pilot project due to time constraints. Given the importance of these principles for the ACPR and its mandate as a clinical quality registry, a detailed plan has been proposed and will be discussed below.

OP36. Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance.

We are in the process of developing systems for descriptive reporting for individual cardiac units (refer OP26). Units will be able to compare their data against the group data in terms of data completeness and volume case entered/submitted. ACPR reporting system will deliver benchmarking tools enable individual sites to compare their performance for each of the performance indicators (refer to OP17) to aggregated group data. Similarly, web reports will be available for registered clinicians which assesses clinician's performance against key quality of care indicators. Such reports will be generated from completed and verified records stored within the ACPR final database and not from the staging database (see Technical Standards).

Sample Web report for performance indicators following Isolated CABG



Figure 1: KPIs for CABG: comparison between unit and pooled data



Figure 2: Resource utlisation for CABG: comparison between unit and pooled data

General recommendation - OP 36:

We agree that OP 36 is a requirement for Australian Clinical Quality Registries.

OP 37. Australian Clinical Quality Registries must report without delay on risk-adjusted outcome analyses to institutions and clinicians;

As explained before within the OP18, where appropriate risk models exists (cardiac surgery) case by case cumulative chart reporting will be developed. Current risk models are not available for PCI, CRT and ICD, however, relevant data elements are be collected to enable risk adjustments to be performed for appropriate benchmarking comparisons between units and clinicians.

General recommendation - OP 37:

We agree that OP 37 is a requirement for Australian Clinical Quality Registries.

Sample CUSUM chart from the ASCTS Registry for risk adjusted 30-day mortality following isolated CABG 2007 - 2008

The CUSUM scores for each case in the combined units fall within the rejection (red) line and hence, the performance of all involving hospitals is at a satisfactory level.



OP 38. Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings;

A Reporting and Research Committee will be developed and will be responsible to:

- 1) Review all requests for information from the database by external agencies
- 2) Review all data produced by the database: annual reports, articles submitted to journals, papers presented at meetings
- 3) Design and supervise research projects including those derived from the dataset and specific projects including longitudinal studies

Membership is yet to be determined but will comprise of clinicians, epidemiologists and statisticians. Reporting and Research Committee will be reporting to the Steering Committee who will be monitoring this process.

General recommendation - OP 38:

We agree that OP 38 is a requirement for Australian Clinical Quality Registries.

OP 39. Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care;

Site data managers will have full access to their own data and the facility to run site specific web reports (refer to OP26) for in house auditing purposes and reporting.

General recommendation – OP 39:

We agree that OP 39 is a requirement for Australian Clinical Quality Registries.

OP 40. Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings;

It is planned that two reports will be generated annually:

Public Report: The Public Report would provide an overview of the patients who have undergone cardiac procedures, age and gender distribution, risk factors, cardiac history, the types of procedures performed, morbidity and mortality across participating centres. The report will also include comparison between involving units for the key performance indicators identified by the craft groups. Consumer input will be sought on the format of the report content. The report will essentially be for a lay audience and will be made publicly available.

Comprehensive Clinician's Report: The Clinician's Report provides a more comprehensive assessment of the data than the Public Report and will be modelled on the Society of Cardiothoracic Surgeons of Great Britain and Ireland Annual Report. It gives the opportunity to look for emerging trends within the data, and to look for inter-relationships between variables.

Sample ACPR Public Report 2009 - 2010

This is the first report of the register. It describes the data of procedures performed between 1 July 2009 and 30 June 2010 at eleven Cardiac Units. These are located at:

State	Hospital	PCI	Surgery	Device
VIC	Cabrini Health			
SA	Flinders Medical Centre			
VIC	Geelong Hospital			
NSW	Lake Macquarie Private Hospital			
QLD	Mater Health Services, North Queensland			
VIC	St Vincent's Hospital			
VIC	The Alfred Hospital			
VIC	Epworth Healthcare			
SA	Royal Adelaide Hospital			

Demographics

Figure 1: Age distribution of patients having cardiac procedures during 2009 - 10



Table 1: Patients' demographics and risk factors for PCI and Surgery		
Total number of Patients included 2009 – 10: n=10,000		
Age (mean + SD)	65 + 10 years	
Gender - female	30%	
Risk Factors %		
Diabetes	26	
Peripheral Vascular Disease	11	
Cerebrovascular disease	10	
Cardiac History %		
Previous CABG	5	
Previous PCI	10	
Previous Valve	3	
Acute Coronary Syndrome (ACS)	40	
Admitted on the Day of Procedure %	33	



Figure 2: Total cardiac procedures in 2009 - 10

Figure 3: Crude 30-day survival rate by procedure in 2009 - 10





Figure 4: Crude 30-day survival rate by procedure, in relation to patient age in 2009 - 10

Figure 5: Crude 30-day mortality rate by procedure in 2009 – 10



Figure 6: KPIs for PCI in 2009 – 10



Figure 8: KPI for PCI, in relation to Door To Balloon Time in 2009 – 10



Figure 8: KPIs for Cardiac Surgery in 2009 – 10



Figure 9: Post procedural complications within 30 days following ICD /CRT

in 2009 – 10



Figure 10: Survival rate for cardiac surgery, in relation to the urgency of surgery in 2009 – 10



Figure 11: Resource utlisation by procedure in 2009 – 10



General recommendation - OP 40:

We agree that OP 40 is a requirement for Australian Clinical Quality Registries.

OP 41. Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance;

The Peer Review Procedure for the identification and management of outliers has been developed based on the ASCTS model (refer to pages 35 & 36 of this document). A Data Monitoring Committee will be appointed and meet on a quarterly basis to review reports produced by the Central Data Management Centre. In principle, where results of individual sites are inconsistent with the group standards or found outside the three standard deviations from the mean pooled estimate, unit's data will be reviewed and Head of Department will be notified to discuss the unit's plans for outlier remediation.

General recommendation - OP 41:

We agree that OP 41 is a requirement for Australian Clinical Quality Registries.

Resources and Funds

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

This principle is of utmost importance and is perhaps the least certain for registries in the current financial climate, including the ACPR. The current funding has been used to develop and test a platform that would ultimately be suitable for a national roll-out; however, ongoing funding has not yet been identified. Registries by their nature and function require sustainable funding to ensure they fulfil the key role of being secure long-term data repositories. The work undertaken as part of this pilot project has included an extensive review and assessment of national and international registry funding programs with the development of a "BUSINESS CASE FOR FUNDING NATIONAL CLINICAL REGISTRIES". This document will be provided as a deliverable of this final report and will also be used by an external consultant engaged by the ACPR to scope out its implementation and acceptance by the stakeholders considered to be the funders of registries in the future. This work is ongoing.

In order to fulfil OP's 8, 9, 10, 11, 13, 14, 19, 20, 21, 24 and 26 registries must grapple with the multitude of different technology platforms and capabilities across the healthcare landscape in Australia. Until the NEHTA technical standards have been rolled out and implemented across Australia, the cost of registry data collection, processing and administering registers will remain high and difficult to control. There is desire and need that collection of data for quality reporting purposes becomes more embedded in the everyday tasks of healthcare workers, this would definitely lower the cost of data collection but this is going to require time and effort on the part of hospitals, their administrators and funders.

The current challenge for a new registry that can clearly fulfil operating principles 1 - 41 is that at present there is no funding set aside that can be accessed to undertake the activity.

The capacity to sustainably and reliably fund quality clinical registries needs to be a reality, not just a concept. Significant funding must be set aside by the government to monitor the safety and quality of the healthcare provided to the Australian population in a defined and systematic manner and this funding must be clear and transparent.

Recommendations:

General recommendation - OP 41:

- We agree that OP 41 is a requirement for Australian Clinical Quality Registries, however the following points must be considered:
- 1. Consideration be given to the establishment of a number of designated registry centres in order to increase efficiencies in the processes of collecting, managing and reporting of clinical quality data
- 2. These designated centres should be academically focussed with a strong clinical, epidemiological, biostatistical and IT support structure
- 3. These centres should actively engage in NHMRC Partnerships Program and Enabling Centre funding applications for value adding to the clinical quality reporting requirements associated with registry reporting.

Summary of Assessment of Operating Principles of Australian Clinical Quality Registries (ACQR)

OP	Attributes	Achieved by ACPR	Comments
1	ACQR are developed with a clear and precisely defined purpose	Yes	
2	ACQR core data collection focused on the collection of the essential elements to serve the main purpose	Yes	
3	Data collected by ACQR should be confined to items which are epidemiologically sound	Yes	
4	Systematic and identical approaches to data collection used at all contributing sites	Yes	
5	Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained.	Yes	30 day outcomes assessed as part of this pilot. An expanded registry activity would additionally aim to collect one year follow up data from patients
6	Must consider the burden and cost of data collection together with the likelihood of loss to follow-up.	Yes	Lost to follow up rates will be known once sufficient data collected and time elapsed
7	Complete registry data are collected from the eligible population.	Not yet known	Insufficient data collected as yet

OP	Data Collection	Achieved by ACPR	Comments
8	ACQR's must not impact on provision of care and not be a burden or incur cost to consumers	Assumed	
9	Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors.	Yes	
10	Data should be uniformly and easily accessible from the primary data source.	Pending	Review and assessment of these processes is underway. Anecdotal reporting from data managers indicate varying degrees of data completeness and requirement to retrieve records / obtain missing data
11	ACQR's should use standard definitions, terminologies and specifications used to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases.	Yes	
12	Data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry.	Yes	
13	Use data from existing data sources, including administrative data, where they are of a satisfactory quality.	No	Work to upgrade the current surgical and PCI collections to encompass the core data elements will be undertaken.
14	Have the capacity to enhance their value through linkage to other disease and procedure registers or other databases.	Pending	This work is underway

OP	Data Elements	Achieved by ACPR	Comments
15	ACQR's should collect individually identifiable patient or subject information.	Yes	
16	Where patterns or processes of care have an established link to outcomes and process measures are simple, reliable and reproducible, they should be considered for collection by ACQR's.	Yes	
17	Where possible, outcomes should be assessed using objective measures.	Yes	

OP	Risk Adjustments	Achieved by	Comments
		ACPR	
18	Collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by using appropriate statistical adjustments.		
	PCI & Device	Pending	The appropriateness of the elements to adequately risk adjust is yet to be validated as sufficient data has yet been collected
	SURGERY	Yes	For cardiac surgery we have developed a local risk adjustment model that discriminates and calibrates well for the Australian population. Additional work to develop similar models for valves is ongoing with ASCTS

OP	Data Security	Achieved by	Comments
		ACPR	
19	Utilise secure access controls and secure electronic	Refer to Techni	cal Standards Assessment
	transfer and electronic messaging systems.	document	
20	The collection, storage and transmission of clinical		
	registry data must be in line with relevant		
	legislation and guidelines.		
21	Institutional policy principles set out in Part B:		
	Technical standards should be met.		

OP	Ensuring Data Quality	Achieved by ACPR	Comments
22	Report as a quality measure the percentage of eligible patients recruited to the registry.	Pending	Will be ascertained in due course
23	Have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected.	Pending	Will be ascertained in due course
24	Data checks/audits routinely performed against source records.	Pending	Insufficient time within the pilot to undertake auditing, however, it is fully anticipated that in the expanded ongoing ACPR annual auditing will be routine
25	Incorporate in-built data management processes such as data range and validity checks.	Yes	
26	Reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur.	Pending	Will be ascertained in due course

OP	Organisation and Governance	Achieved by ACPR	Comments
27	ACQR's must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry.	Yes	
28	Establish policies to manage a range of contingencies arising from the analysis of data from the registry to ensure that quality of care issues are effectively addressed and escalated appropriately.	Yes	Not yet tested as part of the pilot due to insufficient data and time, however, we expect the planned policies will be activated and further refined in time

OP	Data Custodianship	Achieved by ACPR	Comments
29	Custodianship of clinical register data needs to be made explicit in Contracts and/or Funding Agreements.	Yes	
30	Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data.	Yes	Policy developed, although not yet actioned
31	Third parties wishing to access data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re- identifiable data or contact with patients is sought.	Yes	Policy developed, although not yet actioned

OP	Ethics and Privacy	Achieved by ACPR	Comments
32	Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry.	Ongoing	IEC applications submitted in NSW, QLD, VIC, ACT and SA
33	Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the <i>National Statement on Ethical</i> <i>Conduct in Human Research</i> and the <i>Australian Code</i> <i>for the Responsible Conduct of Research</i> .	Yes	
34	Participants or the next of kin made aware of the collection of registered data and given the opportunity not to participate at no cost to the participant.	Yes	Approved waiver should also be considered appropriate in certain circumstances
35	Where projects are undertaken using register data, IEC approval must be sought unless the project falls within the scope of an institution's quality assurance activity.	Yes	Policy developed, although not yet actioned

OP	Information Output	Achieved by ACPR	Comments
36	Data from Australian Clinical Quality Registries should be used to evaluate quality of care by	Planned	
	identifying gaps in best practice and benchmarking performance.		
37	Must report without delay on risk-adjusted outcome analyses to institutions and clinicians.	Planned	
38	Australian Clinical Quality Registries should verify data collected using a formalised peer review process prior to publishing findings.	Planned	
39	Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care.	Planned	
40	Produce a publicly-accessible aggregated annual report detailing clinical and corporate findings.	Planned	
41	Have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance.	Planned	
OP	Resources	Achieved by	Comments
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		ACPK	
42	ACQR's should be appropriately funded to allow	No	Sustainable ongoing
	data collection, reporting and the institution of		funding has not been
	strong quality control procedures.		identified for the ACPR
			although registry activity
			will be continued
			beyond the pilot (but
			without reimbursement
			for data collection to
			pilot sites). This may
			cause sites to cease the
			data collection activity