



Australian Orthopaedic Association National Joint Replacement Registry

Response to *Call for Written Submissions on Draft Operating Standards and Technical Design for Australian Clinical Quality Registries*

Our response is based on the following documents:

1. *Guidelines for the establishment and management of clinical registries (Draft Version 2)*
2. *NEHTA Architecture Overview Clinical Registries Draft Version 2 - 8/05/2008*

Introduction

As the largest national procedural registry in Australia we have reviewed the documents provided with great interest. They were circulated to Registry staff for comment. Our staff includes clinicians, epidemiologists, statisticians, data managers, database designers and IT personnel. The purpose of this response is to highlight a number of specific areas which may need inclusion, development, modification or change.

General Assessment

Our view is that the draft documents provide a comprehensive guideline for Registry establishment and management. We believe that at times the Guidelines document is repetitive and perhaps overly prescriptive in some areas. It was also thought that there was some lack of understanding at the practical level of what was involved in the collection and management of high incidence national data sets. This was in part evident by the lack of reference to the collection of these particular data sets both within Australia and overseas in particular detailing approaches used to ensure effective data quality collection and management and the reason those approaches are used. We believe that some of these issues may have been clarified if the authors had consulted more widely.

It is probably worth noting that in the preparation of the Guidelines document there was no consultation by the authors with the National Joint Replacement Registry. There has been consultation in the preparation of the Architectural Overview and there has also been direct consultation between the National Joint Replacement Registry and the Commission prior to the release of these documents.

Specific points of discussion in a number of areas are mentioned below:-

1. Clear description of the role and purpose of a clinical registry

We believe it is important to be precise with this description as it sets the criteria for what is useful and what is not useful in a clinical registry. It is our view that an appropriately designed and targeted clinical registry is a powerful quality assurance activity tool that will bring about significant clinical improvement. It does this by providing community based comparative information on outcomes that can be used to identify best practice. A clear understanding of this enables rational decisions to be made on what should or should not be supported with respect to any proposed registry. It is important to identify the problem that needs to be fixed and how establishing a registry will achieve this objective. There is no point in supporting the development of a registry to collect information because it seems like a good idea. It has to be justified in terms of clear clinical benefit and cost effectiveness that can be obtained through the development of an individual registry.

2. Value of registry-derived clinical evidence

Internationally there is significant discussion on the relative values of registry derived clinical evidence particularly in relation to the undertaking of clinical studies. It is not clear where outcomes based on registry data lie in the hierarchy of clinical evidence but for a variety of reasons it is increasingly regarded as high on the scale. There has not been a clear discussion about the relative value of these data in this document and it is an issue worth considering.

3. Cost of registries

In the Executive Summary and throughout the Guidelines document there is reference to the "high" cost of registries, that is, "registries are expensive to establish and maintain". We believe that this comment is not justified and is not helpful. There is no definition of "expensive", and there has been no analysis of cost let alone an analysis of cost effectiveness. It would be our strong argument that appropriately designed registries that have a clear purpose and ability to achieve improved clinical outcomes are in fact a very cheap health care investment. Using the National Joint Replacement Registry as an example, the cost per procedure to the Registry is between 0.08% to 0.17% of the cost of the procedure itself (NJRR \$20 per procedure; joint replacement operation \$12,000 to \$25,000).

In recent years there has been a major reduction in the revision rate of joint replacement surgery in this country much of which is a consequence of change in practice directly attributable to the provision of information based on Registry data to clinicians. This reduction is equivalent to more than 2,000 fewer procedures per year than would have otherwise been anticipated. A conservative estimate of the cost saving is between \$40-50 M. Perhaps instead of making unsubstantiated comments related to expense there should be more specific justified comments as to why Australia cannot afford *not*

to have appropriately designed registries in relevant areas of health care. An important justification for the establishment of any registry is the benefit associated with improved outcomes both at a patient and health care cost level.

4. Wider perspective on registry benefits

Registries have the potential to produce benefits in many ways. Best practice can be identified, but also the registry's quality assurance tools can be integrated into the mechanisms involved in comprehensive quality health care delivery. The National Joint Replacement Registry is well integrated in device regulatory mechanisms and has brought about change in this area. It is also involved in supporting pricing policy (in both private and public sectors) for prostheses and associated advances in joint replacement technology, prosthesis selection by surgeons and bulk purchasers. The Registry has initiated and supported the development of clinical guidelines by the profession and is now very much involved in providing data necessary for planning future service delivery. These are just some examples of the potential wider advantages that registries may have not only within Australia but also overseas. It is an area that we believe could be expanded further.

5. Data collection

It is important to point out that paper-based data collection is not necessarily more prone to error than web or computer based systems using range and consistency checks. An allowable range for a systolic blood pressure for example needs to be quite wide – the range will not prevent an error occurring. Furthermore web-based data collection systems are not usually paperless systems, but are rather distributed data entry systems using paper as opposed to centralized data entry systems using paper.

We believe this section of the document should include a discussion on the potential merits of centralized data processing such as the economy for equipment and personnel, lack of duplication and the benefits of using 'expertise' - training, standard operating and security procedures. The report seems to focus on a distributed model for all data collection regardless of mode, with a stated advantage of 'typically reduce the costs involved'. Our strong suspicion is that overall costs may not be reduced, merely transferred.

The ideal form of data capture would be directly from hospital computer systems, but as has already been alluded to, whether the data required for a particular registry are available from this source or not (now and in the future) will have to be assessed on a case by case basis.

6. Inter-registry collaboration and database linkage.

The importance of these activities, which we strongly support and are involved in, has been mentioned in the report but the report gives no

significant examples of how this may work or how it has worked elsewhere. We submit that an excellent example is the amalgamation of the Swedish registries into National Competency centres. The centres are able to provide a comprehensive snapshot of a broad range of regional and institutional comparative health care outcomes. This may have important relevance considering the increasing focus on obtaining this type of data within Australia.

Examples of statements made in the Executive Summary that may require modification

Ensuring data is of a high quality – 18: states that *“Clinical registry data should be checked against source records in a sample of cases”*. Such a requirement in the case of a national device registry with > 65,000 procedures/year performed in approximately 300 hospitals nationwide has major resource and logistical implications if a truly representative sample were to be audited. It should not be an expectation that incomplete and inaccurate data can only be identified by checking against source data. Rigorous backend data cleaning and checking procedures combined with front-end logic checks with appropriate input from experienced clinicians can identify most data deficiencies. A request for additional information back to source hospitals when needed is also a good option to complete and/or check data.

Ensuring data is of a high quality – 19: this is a simplistic statement overstating the value of range and validity checks at the data entry stage and makes sweeping assumptions about the data management process. A stronger recommendation would incorporate other data management processes to facilitate the collection of high quality data. The AOA NJRR for example, which collects data from hospitals Australia wide, has a process that works very well given the state of computer systems in these hospitals and which involves limited front-end data checking and extensive back-end data checking. Once again the best way to do things will be and should be dictated by the context in which the registry is set and a “one size fits all” approach is not appropriate.

Custodianship – 23: Reporting policies should be available for all interested parties, but data access needs some qualification over and above ‘interested’ parties.

Ethics, and privacy – 25: This particular point needs to be expanded in relation to the discussion in the body of the report (**Consent pages 65-66**). In its current form, *‘Consent must be obtained from participants or their next of kin prior to the collection of registry data’* could be easily misunderstood or misinterpreted if a full reading of the report is not undertaken. Page 65 provides a discussion on problems including selection bias imposed on registries if an individualized consenting process is required, and recommends the use of an ‘opt-off’ consenting process. It would be beneficial to explicitly state this in the Executive Summary.