



Australian Government
Department of Health and Ageing

Professor Chris Baggoley
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Australian Commission on Safety and Quality in Health Care
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Dear Professor Baggoley

Australian Clinical Quality Registries

Thank you for providing the Department of Health and Ageing (the Department) with the opportunity to comment on the following draft documents:

- Guidelines for the establishment and management of clinical registries;
- Architecture Overview – Clinical Registries; and
- Standards Map – Clinical Registries.

I note that you have also provided these documents to members of the Commission's Inter-Jurisdictional committee for comment.

As discussed with Niall Johnson last week, I apologise that our comments have been slightly delayed.

The Department supports in principle the overall direction of the Australian Clinical Quality Registries operating standards and technical design, which appear to be consistent with the directions of the national eHealth agenda and have the potential to enable effective secondary use of data collected at the point of care. I have attached further comments from the Department on the draft documents. Dr Bernie Towler, the Department's representative on the Australian Clinical Quality Registries working group has assisted in the provision of these comments.

I understand that the National Health and Medical Research Council is in the process of providing separate comments on these documents.

If you have any questions about this input please do not to hesitate to contact Abha Bedi, Director of the Performance, Safety and Quality Section on (02) 6289 8290.

Yours sincerely

Authorised for transmission

Alice Creelman
Assistant Secretary
Governance and Agency Relationships Branch
2 July 2008



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Comments on the Consultation Papers for the Draft Australian Clinical Quality Registries

Overarching Comments

These documents are progressing well and adequately address the issues that have been raised previously. However, there would be benefit in streamlining the documents into one document with chapters for the Architecture and Standards Map

Some of the 'systems' issues for interoperability can only be addressed in the longer term and even then are by no means certain. It will be important to consult with developers of contributing systems concerning registry and interface design.

A simple way for information to be submitted to the registry is important. While web services provide a good technology and represent the National E-Health Transition Authority's (NEHTA) preferred solution, they are not the only possibility and may not provide the simplest approach given the current state of software.

A body of work establishing a National Health Information Regulatory Framework (the NHIRF) is currently under way, but is not yet in the public domain and should not be made so through this process.

The Commission's focus should be on registries which are 'clinical quality registries', that is registries for which the principal purpose is quality of care.

Terminology in all documents

There is a semantic issue relating to the use of the terms 'register' and 'registry'. It is noted that the Centre for Research Excellence in Patient Safety (CRE-PS) document cites Last's D(i)ctionary of Epidemiology, but it is respectfully suggested that neither this document nor NEHTA's documents use these terms according to their respective definitions, but rather they almost exclusively use the term 'registry' in relation to the actual list of data. This is distinct from the correct definition of 'registry' which describes the system of ongoing registration of the data. In this respect it is noted that, in NEHTA's environmental scan, it only used 'registry' and 'registries', but not 'register' in the search terms, despite the fact that many national data collections (including almost all the large Commonwealth-funded ones) are called 'registers'.

Consideration should be given to standardising the correct use of these terms in the document: that is, that a 'register' is the actual list or database, and that a 'registry' is the system or organisation managing the register. Information is provided to a 'registry', for inclusion in a 'register'.

Clinical Registers and their relationship with Therapeutic Goods Administration (TGA)

It is suggested that more explicit discussion be included in the *Guidelines for the establishment and Management of Clinical Registries* (either in Section 2 *Preamble* or Section 5 *Role of Clinical Registries*) on the role of registers within the broader Australian post market surveillance

system. While the role of clinical registers is a very important one, they are one part of a wider system. It is suggested that the Guidelines discuss the overall role of post market surveillance and that, in broad terms, this involves both mandatory and voluntary reporting and tracking of the performance of health technologies, including systems for recall in the event of failures.

The TGA has two primary interests in the operation of Registers:

- As TGA moves to more active postmarket monitoring of product performance and safety, active and regular 'mining' of data held in registers can give early warning signs of significant adverse event occurrences or poor medical implant longevity - such as now occurs with Office of Devices, Blood and Tissues (ODBT) and the National Joint Replacement Registry (NJRR) operated by the Australian Orthopaedic Association (AOA).
- For many years the TGA has been working with organisations such as AIHW, Medicare, the former Australian Council (now Commission) for Safety and Quality in Health Care and more recently with NEHTA on development of a Register for locating patients with an implantable device, in the event that remedial or recall action is necessary.

Both of these are strong incentives for the development of clinical registers and warrant mention in section 5 of the report - Role of Clinical Registries. Consideration should also be given in Section 14 of the report - Information output - to mention of regular liaison with the TGA as the regulator of therapeutic goods, where appropriate, and where analysis of data held within the register is useful in the monitoring of performance/efficacy and regulatory decision making.

The Guidelines, although mentioning one 'device focused' register - the NJRR operated by the AOA - concentrates more on 'procedural' or 'treatment' registers. As a consequence there is discussion on data elements to identify the patient, the procedure, the clinician, and key clinical information.

There is also mention of the Australian Medicines Terminology (AMT) (page 31), which is an extension of SNOMED CT and is used to describe medicines and related concepts. There is no mention however of key identification elements associated with a medical device such as a prosthetic hip or knee implant, or where such information may be held in a standardised form.

It is suggested that the Guidelines should include advice to the effect that where a registry is being established, and one of its key outcomes is benchmarking and monitoring device performance (such as the NJRR operated by the AOA), standardised data should be used to identify the device (manufacturer name and model number), and device specific information (batch/serial number of the device used in the specific procedure). The most reliable source for standardised device identifiers will be the National Product Catalogue currently under development by NEHTA, while the device specific information will be provided either on the device, or more generally the sterile packaging of the device.

While the AMT has a role in identification of a medication, it is suggested the reference to AMT be replaced with a reference to the NEHTA National Product Catalogue (NPC). Although there is an equivalent international standard for device - the Global Medical Device Nomenclature System (GMDN) - like the AMT it is only a generic descriptor of the device, eg *prosthesis, hip, internal, total* and does not identify the device manufacturer. Similarly, while the AMT identifies the medicine generically (eg paracetamol), the NPC identifies it more specifically (eg PANADOL in its specific dosage form of tablet, capsule or liquid, manufactured by Glaxo Smith Kline P/L).

Similarly, in the two NEHTA documents, reference is made to identification of the patient, the clinician, the procedure, etc including the AMT as a dataset for identification of medicines. No reference is mentioned relating to standardised identification of medical devices, where appropriate. Comments made earlier relating to citing of the NPC as the preferred dataset for medication and device identification should also be considered in the context of these two documents.

Comments on the *Guidelines for the establishment and management of clinical registries*

Funding wording

The current wording in some parts of the Operating Standards could be seen as critical of funding bodies. Suggestions of changes are as follows:

- Page 5 – second last paragraph change ‘inadequate funding’ to ‘lack of clarity around the appropriate levels of funding that are needed to operate registries’.
- Page 8 – point 20 change ‘sufficient resources should be provided’ to ‘would need appropriate funding’.
- Page 9 – point 29 change ‘should receive adequate funding’ to ‘would need appropriate funding’.
- Page 78 – in the Summary box first arrow change ‘should receive adequate funding’ to ‘need to receive adequate funding’.

We understand Dr Stephen Duckett from Queensland suggested that funding of 'quality and safety' registries would be restricted to those registries that have a demonstrable improvement on health outcomes of patients. These criteria would be helpful in prioritising funding for registries for those funding bodies that are primarily interested in 'quality and safety' registries. However, these criteria would not limit the funding bodies such as the Department of Health and Ageing from choosing to fund registries outside of this scope.

Data elements (pages 37 to 43)

The Department believes strongly that the issue of ‘identifiable’ versus ‘re-identifiable’ information should include the requirement that a ‘linkage key’ be used so that identifying information can be removed before transmission to a third party.

Ethics and privacy (pages 63 to 67)

This section would benefit from greater clarity. Also, it seems that ‘ethics’ and ‘privacy’ could be dealt with separately in the guidelines. While there are obvious areas of overlap between privacy considerations and ethics committees’ roles and functions, they are separate and distinct aspects of practices in clinical registries. The first paragraph on page 60 sits oddly as an introduction to ‘Ethics and privacy’. Also, the first sentence on page 64 does not match the material discussed on the remainder of the page. As a general comment, the material on pages 63 and 64 does not flow well.

There is a reference (page 64) that most major hospital committees do not consider that ‘existing legislation provides an adequate mandate for’ the collection of clinical registry data without the consent of the individuals involved. It may be that this is a reflection of the legislative

requirement in National Privacy Principle (NPP) 2.1(d) which permits use or disclosure of health information where (among other things) ‘it is impracticable ... to seek the individual’s consent’ (NPP 2.1(d)(i)). Hospital committees are not always disclosing patient information to clinical registries because they lack patient consent. However, in some circumstances there are good reasons for them to release this information. It is not clear whether this is directly linked to observations about the need for participation of the ‘highest possible proportion of patients’ without which ‘it is questionable whether the expense of establishing a register is worthwhile’ (page 24). If this is, in fact, a consequence of the legislative restriction, it might be helpful to spell this out in the guidelines.

The sentence immediately following (on page 64) deals with the content of National Health and Medical Research Council (NHMRC) ‘current advice to institutions’ about the non-requirement for ‘independent ethical review’ for registry data provided that both compliance with NPP 2.1 (whether via consent under NPP 2.1(b) or secondary purpose under NPP 2.1(a)) and the activity does not involve burden or harm. The source of this NHMRC ‘current advice to institutions’ is some sort of paper or publication (footnote 71), the legal or regulatory status of which is not clear. The Privacy Commissioner has approved guidelines issued by the CEO of the NHMRC under section 95A of the Privacy Act 1988. It would seem preferable to rely on the section 95A guidelines as authority for NHMRC guidance.

Reference is made (page 63) to both the Information Privacy Principles (IPPs) which apply to Commonwealth agencies and the National Privacy Principles (NPPs) which apply to private sector organisations. Registries in private hospitals are subject to the NPPs and it is not apparent that the IPPs are relevant in the context of the draft guidelines. Public hospitals in the States and Territories will generally be subject to the provisions of the relevant State and Territory privacy legislation. It should be ascertained whether the guidelines need to contain a reference to State and Territory public hospital clinical registries.

The section also contains a recommendation about consent and procedures designed to ‘overcome’ problems associated with low participation rates referred to above. The recommendation is effectively an ‘opt out’ mechanism (rather than an ‘opt in’ mechanism) designed to maximise participation. That approach is acceptable provided that it is clear in the information leaflet (or whatever information means is used) what the purpose of collection is and that participation is encouraged but is optional. An outcome that imposes no additional consent requirements is preferred in order not to compromise existing data registry collection.

Other Comments

It is recommended that the Commonwealth’s role in providing quality assurance confidentiality under Part VC of the *Health Insurance Act 1973* be included in the discussion of qualified privilege at 13.3 (pg 66) of the Guidelines. This legislation complements legislation in place in all Australian States and the ACT. The NT does not currently have any local legislation of this type.

To include the Commonwealth’s involvement in qualified privilege it is suggested the following be added to the third paragraph under 13.3:

The criteria for protection and its extent vary between the different States and Territories making it important that clinical registries check on the protection available in their jurisdiction. Further, if a quality assurance activity spans more than one State or Territory, has a national impact, or involves a new methodology or subject matter, protection under Commonwealth quality assurance confidentiality legislation may be more appropriate. Using NSW as a representative ...