



**Submission on the draft operating standards and technical design  
for Australian Clinical Quality Registries**

**June 2008**



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### ***Introduction***

The Consumers Health Forum of Australia Inc (CHF) is the national voice for health consumers. As an independent non-government organisation, CHF helps shape Australia's health system by representing and involving consumers in health policy and program development.

CHF has contributed to the debate on registries through several projects. In the 2006-08 E-health for Consumers Project<sup>1</sup>, CHF consulted with consumers about their expectations of how their health information should be collected, stored and shared electronically. CHF also conducted a consumer impact assessment on registries and other e-health systems.

In the CHF 2007-08 'Private health insurance reforms – consumers have a say' Project, CHF consulted with consumers on private health insurance reforms including prostheses reforms and the proposed technology monitoring through registries.

CHF also considered the role of registries in research through a collaboration between CHF and the National Health and Medical Research Council (NHMRC) in 2004. The Project aimed to pilot the principles endorsed by both organisations in their joint *Statement on Consumer and Community Participation in Health and Medical Research* (the Statement on Participation)<sup>2</sup>.

In this submission, CHF considers the Australian Clinical Quality Registries in the context of consumer expectations of how their personal health information should be collected for research and the important role that registries play in assisting consumers to make informed decisions.

This submission addresses key areas identified in the Guidelines for the establishment and management of national clinical registries (the Guidelines) prepared by the NHMRC and the draft technical and operating standards that impact on consumers including:

- Data collection
- The need for registries to assist informed decision making
- National registries and the national registry portal
- Consent
- Ethics and privacy, and
- Governance.

### ***Australian Clinical Quality Registries***

Clinical registries are databases that systematically collect health related information on individuals. They aim to improve patient care and outcomes through greater understanding of events, treatment and outcomes. The draft operating standards aim to ensure that clinical registries add value over data that already exists and provide timely feedback to clinicians while the draft technical design contains standards and architecture to help enhance the

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<sup>1</sup> The 2006-08 E-health for Consumers Project is funded by the Australian Government Department of Health and Ageing.

<sup>2</sup> <http://www.nhmrc.gov.au/publications/synopses/r22syn.htm>

efficiency, timeliness and interoperability of registries. The Australian Clinical Quality Registries will be piloted in September 2008.

### ***Data collection***

Health consumers support the use of registries and the gains in safety and quality that can be made from them. At the December 2007 CHF Consumer Representatives Workshop on New Health Technologies and Medical Devices, consumers called for more monitoring activities and mechanisms, including the creation of more registries similar to that of the National Joint Replacement Registry.

The Guidelines paper states that data is collected for registries through consumer interactions with the health system and questionnaires. When data is collected from interactions with the health system, its collection must not impact on the provision of health care. When the primary purpose of the health care interaction is for data collection, not the provision of health care, it must not be a burden or cost to consumers.

CHF notes that consumer questionnaires, such as those aimed at collecting long term outcomes of treatment (outcome measures) are not the best way of collecting health information. CHF recommends that the way that data is collected from consumers is evaluated in more detail.

It is extremely important that consumers, and the wider community, are made aware of the fact that their data may be collected in registries and how the data may be linked, shared and used. There must be strong communication strategies, such as a national campaign, to raise public awareness about data collection for registries. This communication strategy must also inform the community about what the data may be used for and the governance structures that support it.

CHF supports the eight principles related to data collection outlined in the Guidelines; however, it is not a conclusive list. The following three principles must be included:

1. Data collection must not impact on the primary purpose of the health care visit which is for the provision of health care
2. Data collection must not be a burden or cost, time or financial, to consumer, and
3. Consumers must be told that their health information may be collected and how it may be used.

CHF acknowledges that data collection for registries must remain largely paper based until Australia has a more integrated e-health system to support electronic collection. Furthermore, as consumers have had particular concerns with offshore holdings of de-identified data in the past, the data collections must not be held off-shore.

### ***Registries to assist informed decision making***

A key benefit of registries is that analysis of the data collected can assist informed decision making. CHF, however, is concerned that the important role of registries in assisting consumers to make informed decisions is not acknowledged. For example, the issue paper developed by the Commission focuses on the benefit and access for clinicians, not consumers:

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

clinicians, to lead to improvements in practice, and in medication and device usage.

CHF maintains that if registries are to provide tangible benefits to consumers, they must provide information to assist consumers to make informed decisions. To do this, consumers must be viewed as key stakeholders, registries must answer questions that consumers want answered and the information gained from registries must be user-friendly and accessible to consumers.

Registries should address consumer questions including:

- Information and transparency about clinical trials
- Who tests treatment and devices for safety, efficacy and suitability
- Thorough and appropriate monitoring
- Safety and skill levels of surgeons, medical staff and hospitals, and
- Outcomes of different treatment options.

CHF recommends that the Commission and NHMRC consult further with consumers about what questions consumers want answered through registries.

### ***National registry portal***

The Architecture Overview, developed by the National E-Health Transition Authority (NEHTA), outlines a national approach to registries with the aim of improving consistency. The national approach is supported by national infrastructure that:

- Assembles the many different registries together under a consistent portal for the convenience of individual providers, and
- Applies a standards based discipline to improve sustainability.

CHF supports the recommendation to create nationally consistent registries; however, it maintains there must be national governance framework to support this. CHF also supports the national registry portal and directory of registries. Consumers can benefit from the national directory of registries if they have access to the directory and the directory links to key findings that can assist consumers make informed decisions.

### ***Consent***

The Guidelines paper outlines two consent models. The first is an opt-in model that has low participation rates and therefore produces biased information. The second model involves approval from Institutional Ethics Committees (IEC) to collect clinical registry data without the consent of the individuals involved. This model results in high participation rates.

Information is provided to participants in the IEC model through a leaflet explaining the purpose and procedures of the registry including how their information will be used and identified.

CHF believes that high participation in registries is fundamental to quality data and improvements in safety and quality of health care. Furthermore, consumers are very concerned about clinical work that is based on inadequate information or offshore trials and supports improvements to this information.

Consumers are generally positive about their information being used for research or safety and quality improvement but only if they know at the time, not after the research has been conducted. As a result, it is extremely important that consumers are aware that their information may be used for research. CHF maintains that the information provided to consumers about

the registry and their information being included must be improved. This is regardless of the type of registry and consent model.

One way to improve information provision to consumers is to provide/direct consumers to the information in the registries when they first present or are diagnosed with a condition. This could be through the national directory of registry. This will have a twofold effect. Firstly, it will ensure that consumers are aware that their information is being included in a registry and secondly, it will provide consumers with information to assist their decision making.

### ***Ethics and privacy***

CHF supports the use of the Unique Health care Identifier (UHI) as an identifier for registries, but is concerned that de-identified data may be re-identifiable.

CHF notes that ethics committees do not provide consumers with confidence. This is because consumers are not represented in the committees and the committees do not have accountability to the community. To assist in data collections meeting consumer expectations, consumers should be involved in decision making bodies about how data will be used and managed.

### ***Governance***

Strong, consistent governance processes underpin consumer confidence and trust in registries. The Guidelines paper states that in order to demonstrate good corporate and clinical governance, clinical registries must:

- be run efficiently
- meet their fiscal responsibilities
- operate within legal constraints, particularly in regard to data security and confidentiality
- meet corporate and clinical goals related to the registry purpose
- monitor outcomes and deals appropriately with clinical issues arising from data analysis
- be appropriately managed by people who have clearly identified roles and responsibilities. This includes having documented and standardised practices and procedures for data collection, lodgement, storage and data management
- have established data access policies and procedures, for both registry staff and third parties, and
- have processes for demonstrating engagement and commitment of all relevant stakeholders.

CHF maintains that although the points identified above are important to the management of registries, strong governance is dependent on the governance body being independent of the day-to-day management of registries and being transparent and accountable.

Consumers must be involved in the governance processes<sup>3</sup>. CHF supports the view outlined in the paper that consumers must be part of the governance structure and that the body responsible for governance should be a legal entity that is accountable if it does not meet its obligations.

Consumers expect to have easy access to an independent complaints system and strong penalties if their information is misused or inappropriately accessed. Furthermore, audit and

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<sup>3</sup> See the CHF Consumers and E-health Project Principles paper for more information about governance for electronic health records on the CHF website at [http://www.chf.org.au/Docs/Downloads/273b\\_ehealthprinciples.pdf](http://www.chf.org.au/Docs/Downloads/273b_ehealthprinciples.pdf)

monitoring systems must also be in place to protect against privacy breaches; CHF is pleased that the Guidelines paper states audit trails will exist.

**Conclusion**

Registries play an important role in improving health care through greater understanding of events, treatment and outcomes. Consumers are supportive of registries and the health care improvements that can be made as long as registries have strong governance processes in place.

Consumers expect that they will be informed about collection of their personal health information for registries and that that their information will be transferred securely and that strong governance process will be in place.

When implementing Australian Clinical Quality Registers it is important to remember that consumers are key stakeholders of registries and that registries must answer the questions consumers want answered and provide consumers with information to assist them make informed decisions about their health care.

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## **Background information**

The Consumers Health Forum of Australia Inc (CHF) is the national voice for health consumers. As an independent non-government organisation, CHF helps shape Australia's health system by representing and involving consumers in health policy and program development.

Health consumers have a unique and important perspective on health as the users and beneficiaries of health care and, ultimately, those who pay for it. CHF takes consumers' views to government and policy makers, providing an important balance to the views of health care professionals, service providers and industry to achieve a health system that reflects the needs of all stakeholders.

CHF member organisations reach millions of Australian health consumers across a wide range of health interests and health system experiences. Health policy is developed through wide consultation with members, ensuring a broad, representative, health consumer perspective.

Current priorities include safety and quality in health care, safe and appropriate use of medicines and health care for people with chronic conditions. CHF also facilitates the appointment of consumer representatives on over 200 national health-related committees.

CHF believes all consumers should receive affordable, safe, good quality health care at the time they need it. The best outcomes are achieved when consumers are involved in decisions about and management of their own health care. Consumers should receive health care information when they need it in a form they can understand, particularly about using medicines.

Established in 1987, CHF receives funding from the Australian Government Department of Health and Ageing and membership fees. It seeks external funding for priority projects.

With its ability to access a variety of health consumer networks and extensive knowledge of consumer issues, CHF is a respected and influential contributor to the Australian health debate.

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