

Registry Operating Standards

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Research Excellence
in Patient Safety



Federal Election 2007

Taking leadership — tackling Australia's health challenges

The health policy of the Labor Party

Nicola Roxon

Operating Standards

- Increasing pressure to measure the performance of the health system
- Registries are a potentially important source of data.
- For registries to reach their full potential:
 - They need to operate at a national level;
 - There needs to be full confidence in the quality of the data;
 - Checks and balances are required to ensure that they are ethical and well governed.
- This Operating Standard will:
 - Provide guidance in the design, implementation, analysis and evaluation of the quality of registries.

MJA 2007





Operating Standards- Chapters

- **Chapter 1: Introduction**

- What is a Registry? / Attributes of Registries / Purpose of Registries/ Types of Registries

- **Chapter 2: Registry information outputs**

- Benchmarking / Assessment of compliance with best practice / Outcome prediction / Preventive measures / Cost benefit assessment/ Publication reporting





Operating Standards- Chapters

- **Chapter 3: Data collection**
 - Identifying quality indicators/performance measures to be collected / Using existing data / Defining new data elements / Technical requirements for data collection / Data storage and security / Data analysis
- **Chapter 4: Ensuring data quality**
 - Completeness of recruitment, Assessing data quality / Independence of assessment of outcome / Timeliness of data collection / Security





Operating Standards- Chapters

- **Chapter 5: Ethics and Privacy**

- Legal considerations / Patient consent / Primary and secondary use of data / Reporting considerations / adverse events reporting / Product recall

- **Chapter 6: Organisation and Governance**

- Registry structure (Steering Committee / Management Committee_ / Registry governance (Data ownership / reporting and managing poor clinician/hospital performance / Reporting and Managing positive outcomes





Operating Standards- Chapters

- **Chapter 7: Resources and Funds**
 - Physical resources / Human resources / Financial resources
- **Chapter 8: Evaluating Registries**
 - Techniques for evaluating registries (frequency and process of evaluation) / Considerations regarding the ending of registries





Operating Standards

- **For discussion today**
 - Definition of a registry
 - Attributes of registries
 - Purpose of registries
 - Types of registries





Definition of a registry

- Patient registry
 - An organised system that uses *observational study* methods to collect *uniform data* (clinical and other) to evaluate specified *outcomes* for a population defined by a particular *disease, condition, or exposure*, and that serves a predetermined *scientific, clinical or policy purpose(s)*.
- Is this the same as a clinical quality registry?

Gliklich R, Dreyer Ne. Registries for Evaluating Patient Outcomes: A User's Guide Prepared by Outcome DEcIDE Center [Outcome Science, Inc. dba Outcome] under Contract No. HHSA290200500351TO1). Rockville, MD: Agency for Healthcare Research and Quality, 2007; Publication No. 07-EHC001-





Attributes of registries

- **Registries collect a core set of information about aspects of health of individuals**
 - Data spine
 - Limited procedures /treatments
- **Registries are observational, non-experimental databases**
 - They do not conduct research
 - Not like guidelines. Decision made by clinician prior to data entry





Attributes of registries

- **Registries collect data to serve a predetermined scientific, clinical or policy purpose**
 - Purpose of the registry made clear at outset.
 - Registry purpose should not change as this will impact on data within it
- **Registries actively collect data in a systematic and planned fashion;**
 - At least one element of registry data collection is active
- **Registries must have adequate data points to enable meaningful risk adjustment to occur**





Attributes of registries

- **Registries collect epidemiologically sound data**
 - Data elements should only be collected if they are of good quality, have good coverage, there is strong rationale for their inclusion and data are reproducible.
- **Registries evaluate patient outcomes**
 - An outcome is “an end result of a particular health care practice or intervention”
 - Therefore some registries would not be considered Clinical Quality or Patient registries
 - e.g. Incidence registries such as National Diabetes Registry, National Cancer registry





Purpose of registries

- Registries describe the natural history of a disease
 - e.g. Motor neuron disease, ?Spleen?
- Registries ascertain the incidence and prevalence of diseases and conditions in populations and monitor trends and survival rates over time
 - e.g. Trauma, others?





Purpose of registries

- **Registries monitor safety and quality of products and treatments**
 - E.g. Clozapine, Bosentan, Joint replacement, Haemostasis, Others??
- **Registries determine clinical and/or cost effectiveness of treatment (including drugs, devices and procedures) across a population.**
 - e.g. ANZDATA, Trauma, Others??





Purpose of registries

- Registries provide an infrastructure on which intervention studies can be established with relative ease.





Types of registries

- **Disease screening**
 - Bowel cancer, cervical cancer, breast cancer, phenylketonuria
- **Disease prevention**
 - Immunisation
- **Health Services**
 - Infection, Cardiac surgery, Trauma
- **Disease specific**
 - CJD, Motor neuron
- **Product**
 - Drug, Device





Other notes

- It is anticipated that members of the Registry Interest Group be acknowledged in the Operating Standards
- Is the group happy to play a role of endorsing the Standards?
- Prior to next meeting:
 - Circulate Chapters 1-5 for discussion at the meeting
 - Collate feedback from this group

