National Health Information Management Group
NHIMG

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Minimum Guidelines for Health Registers for Statistical and Research Purposes

information paper

Why these guidelines?

This paper responds to a need identified by the National Health Information Management Group (NHIMG) for a set of guidelines on the establishment, maintenance and coordination of health registers, and on their use for health information analysis and research. It provides guidance to government and other bodies who from time to time consider proposals to auspice, fund or provide some other form of assistance towards the establishment or operation of a health register, and to the proposers themselves. It aims to document good practice for the operation of a health register.

Some material in these guidelines has been drawn from a report *Health Registers – How, Why and for Whom?* prepared by the Royal Australasian College of Surgeons for the Department of Health and Aged Care in December 2000.

The document does not cover all issues that need to be addressed in establishing and operating a health register. In particular, the consent of data subjects and possible linkages with other registers are not addressed. These particular issues are being considered in other forums in connection with the Health*Connect* initiative and the December 2000 amendments to national privacy legislation.

The principal objective of the NHIMG is to define a set of guidelines that represent minimum standards for health registers operating at a national or State/Territory level. However, adoption of the guidelines for locally based and service-based registers is encouraged.

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Abbreviations

NHDC
National Health Data Committee

NHDD
National Health Data Dictionary

NHIMG
National Health Information Management Group

AIHW
AUSTRALIAN INSTITUTE OF HEALTH & WELFARE

What is a health register?

For the purposes of these guidelines, a health register is a collection of records containing data about aspects of the health of individual persons. The subjects will typically be patients or clients of a health service or health program, from which the data are collected. Health registers are characterised by being:

personal data	each record represents a person, not a set of aggregated data;
identified	each record in the register is identified to a particular subject;
population-based	the register aims to include a record of all persons within its defined scope; populations may be broadly or narrowly defined, e.g. Australia wide, regionally based or clients of a local service; and
ongoing	collection is not restricted to a particular period of time.

These characteristics distinguish health registers from other health data collections, e.g. health surveys. Health registers may be able to be constructed from administrative by-product data.

Rationale for a health register

Health registers are established for several purposes. Some focus on the magnitude of a health problem through the measurement of incidence or prevalence of specific diseases or conditions. Others document cases of defined health interventions, for clinical audit, performance measurement (e.g. patient outcomes) or development of clinical guidelines. Most will be intended to facilitate further research, for example through record linkage to other data sets or establishing a sample frame for more detailed study of a health problem or for clinical trials. Some, for instance donor registries, have an administrative purpose related to clinical care. These guidelines outline good practice for use of registers for information analysis and research.

Register types

Health registers reflect a multitude of health-related issues including acute health episodes, long-term diseases, intervention, diagnostic screening and immunisation. Examples of registers of various types operating in Australia are:

disease screening	State and Territory breast screening and pap smear registries
disease prevention	Australian Childhood Immunisation Register
acute health episode	Cardiac Arrest Register, Neonatal Intensive Care Register
chronic disease	State and Territory cancer registries, National Diabetes Register, Australian Cystic Fibrosis Data Registry
health intervention	Coronary Angioplasty Registry
vital events	National Death Index
genetic disease or events	West Australian Birth Defects Registry.

Good practice for health registers

CLEAR JUSTIFICATION OF PURPOSE, USE AND SCOPE

- The purpose of the register should be clearly defined. To justify the holding of personal health data the establishment of a register requires a clearly stated purpose related to program administration, service delivery or research. Objectives should relate to critical questions about the health issue of interest, such as:
  - How many people are affected?
  - What is the distribution of the health issue?
  - What is the impact of an intervention, i.e. outcomes?
  - What are the causes/influences on the health issue?
- The intended use of the register should be clearly stated. This should describe the audience to whom access would be provided and the types of analysis that are likely, the reporting mechanism and timing and the likely application, for instance:
  - informing policy making (e.g. extent of issue or cost estimates);
  - benchmarking (e.g. comparison with best practice guidelines);
  - monitoring (e.g. population-based performance indicators); and
  - research (e.g. a sampling frame for specialised survey work).
- The rationale for establishing a health register rather than drawing on existing aggregated or de-identified data sources, or conducting a one-off survey must be clearly established. The need to collect and hold data over the long term, maintaining follow-up if required, and the sustainability of a register in terms of resources and capacity to capture data of adequate quality are important considerations.
- Scope of the register. A health register should clearly define its registration subject (e.g. malignant neoplasms) and its population of interest. The registration subject should be readily recognised and measurable. A register should aim to record information about all persons within its scope in a defined population.

TECHNICAL SPECIFICATIONS

Measurement and definition

- A register should have clearly defined data elements that are required to measure the registration subject and to facilitate the register operation. A register should also identify the measurement process appropriate for these data items and its application to the registration subject (e.g. pathology test, self-report questionnaire). Specific collection instruments and measurement tools should be clear and unambiguous, field tested before implementation and kept under review. Where administrative sources are used for case ascertainment, changes may be required to make them suitable as a register source (e.g. to provide for consent) and ongoing vigilance is necessary to ensure that register data are not compromised by system or process changes.
- A subset of register data elements might be defined as the minimum requirement for the register operation (a minimum data set). This should not prevent the collection of a wider set of data elements on the registration subject where resources permit and the purpose justifies. For example, collection of information on factors that influence the health status of the registration subject (e.g. smoking and cancer) may be undertaken. However, data elements of dubious quality or coverage, or where a strong argument for their collection cannot be made, should not be included.

- The definition of such data elements (metadata) should be well documented and readily accessible.
  - The descriptions for each data element should ensure that there is no ambiguity in the definition so that no variation in concept, collection or format exists between organisations and individuals collecting or reporting on the data (e.g. registrants, clinicians, data managers).
  - To promote uniformity across health registers and other data sets and to facilitate combination or comparison of data, health registers should adopt generic data elements that are defined in the *National Health Data Dictionary* (NHDD). For health registers that meet these guidelines and are national in scope, register-specific metadata should be deposited into the NHDD. The NHIMG through its National Health Data Committee (NHDC), whose secretariat is located at the Australian Institute of Health and Welfare, publishes annual updates of the NHDD for the NHIMG and can provide advice on whether it is desirable and practicable for a particular health register to be included. It can advise also on the standards used for the documentation of metadata in the NHDD.

Coverage—geographical and temporal

- A register should operate at a specified geographical level (e.g. national, State/Territory level) or on a smaller scale (e.g. health service area, hospital catchment area). These areas should be aligned with known at-risk populations (e.g. estimated resident population, number of people serviced) to facilitate risk assessment (e.g. prevalence rates). The scale of the register should reflect the rarity of the health issue to be measured (i.e. the rarer the event the wider the geographic and temporal parameters). This rarity factor should also be considered in statistical reporting from the register.
- The collection of data for the register should start on a specified date to facilitate the comparison of time trends and to allow an assessment of data completeness.

DATA QUALITY

- In the establishment and management of a register, continued effort to maintain the quality of data is of paramount importance. Factors that should be monitored in quality control procedures include:
  - completeness (the proportion of cases in scope that are captured by the register);
  - validity (accuracy of case ascertainment); and
  - timeliness.
- Stringent procedures should be developed that maintain a high quality of data. These processes can vary from simple ongoing checks (e.g. range edits, intuitive checks and the checking of standards) to more detailed analysis of data or more formal audits between register data and source data.

AUSPICES AND SUPPORT

Community and government support

- It is important that a heath register have prior support from registration subjects, consumer groups that may support these subjects (e.g. Cancer Council) and government agencies that have responsibility for the area of interest (whether they provide funding or not). Researchers who will undertake analysis of such data should also be consulted to meet their needs where possible. These individuals or groups may be referred to as stakeholders.

Formal agreements and approvals

- Health registers are usually auspiced by an organisation—private or government-based. Many of these auspicing organisations are bound by formal agreements relating to the collection of health information (e.g. National Health Information Agreement) or may abide by the principles of these formal agreements. The establishment of any register should ensure that conditions set out in these agreements are met.
- When public funding is provided for a register, it is essential that the data be available to all researchers with a scientifically valid requirement for its use. To facilitate this, the funding parties should have access to the unit record data, subject to the constraints on access to identifiable data. A formal agreement (contract) should set out the conditions of operation including data collection, management and outcomes, data access arrangements, evaluation and review provisions, and performance indicators.
- The agreement must also specify legislation or formal agreements between the registry and other third parties where they are applicable (e.g. privacy legislation).
- Approval for the operation of a register (either in concept or operational arrangements) by the local institutional ethics committee for the host institution is essential. As well, approval under several additional arrangements may be necessary:
  - State/Territory or national ethics committees;
  - State/Territory or national Privacy Commissioner support;
  - Ministerial approval.
- Some health registers may operate on a voluntary arrangement and have no obvious formal approval process. However, adoption of the principles set out in this document is encouraged.

SECURITY ISSUES

Information security

- To ensure that a health register operates in an environment that secures the information that it holds, providing confidentiality protection to its subjects and confidence to those supplying data, several conditions should be met in its establishment.
  - Legislation—where possible, legislation can be invoked to control data collection, management, reporting and access;
  - Storage—registers need to be in a secure repository. Protection from subpoena or other unintended release needs to be carefully considered. A balance between reasonable access for researchers and the security requirements of people included on the register must be struck;
  - Approval—the approval of the local ethics committee is essential. In addition, approval by a State or national ethics committee or Privacy Commissioner of a register may reinforce the application of acceptable standards for register operations;
  - Physical security—wherever data are held, data access should be restricted to persons with defined authority; this restriction should apply to all mechanisms of registry operations:
    - — paper-based files (e.g. questionnaires, administrative forms);
    - — computer data systems (e.g. file access, backup copies);
    - — information transmission (e.g. facsimile, email, post)—encryption should be used when transmitting identified or identifiable records electronically.
  - Operator security—it is important that those persons involved in the management of the register are made aware of and trained in the application of privacy legislation/regulation.

REGISTER VIABILITY

Register viability and sustainability

- Registers should only be established where this method of data collection is feasible and is the most efficient for answering the specific health questions (see above regarding justification of purpose, use and scope).
- A register should not duplicate other data collections.
- A register should be viewed as a long-term data development. Therefore a clear case for ongoing sustainability should exist, which takes into account financial viability, ongoing suitability and appropriateness of the data collection, and likely availability of caseload. The case for sustainability, as in any data collection, should be assessed periodically against specified performance criteria.
- A development plan for the registry should be formulated with those supporting its existence. This should set out key objectives for the registry development in terms of operations, coverage, scope and use.

Resources

- For sustainability, and to justify the collection and holding of identified health data, it is important to ensure that the register is adequately resourced to meet its objectives. Resources may be in the form of:
  - Staffing, encompassing skills in data processing, coding, programming and database and information technology management and analysis. This should include provision for initial and ongoing resources including training and, where appropriate, field visits.
  - Information technology resources—registers require adequate processing capacity and database infrastructure. The needs here will depend on the type, complexity and size of the register.
  - Specific skills or technology—registers often need particular skills or technology on an ad hoc basis. These skills may be exchanged with other organisations or purchased (e.g. data linkage, tissue sample storage).

MANAGEMENT

Development plan

- A register should underpin its activities with a development plan that sets out its key objectives in terms of operations, coverage, scope and use. Other specific aspects of a development plan should include:
  - funding
  - reviews of operations (internal and external)
  - staff development.
- In managing the register it is important to assess its performance against the register's objectives. This can be done with an internal and/or external review process. These review points, and their structure, should be determined by the register's advisory or funding bodies. They may be set at particular points in a reporting or data collection cycle or across a funding cycle. The scope of the review may change according to the stage of development of the register (e.g. operations protocol in the early stages, quality assurance in more mature stages).

Flexibility

- Registers should be flexible and adaptive but still maintain their integrity (e.g. over time), security (e.g. confidentiality provisions) and appropriateness (e.g. recognising alternative data collection systems). This flexibility should be applied to all facets of the register:
  - Scope or coverage—where the health issue has been initially divided for the purposes of the register new parts may be added as required (e.g. Type 1 and Type 2 diabetes); where a health issue spreads beyond the initially established boundaries the register might consider similarly expanding its geographical coverage (e.g. an infectious disease) or seek retrospective coverage;
  - Adapting data collection mechanisms—this may entail a response to gaps in the data collection identified as a result of a data audit or routine data edit checks, or a shift in the mechanism by which the data are collected (e.g. moving from paper-based collection to electronic health records);
  - Including data items and modifying definitions—the possible inclusion of new data items that reflect improved knowledge of the health issue (e.g. new treatment protocols); revision of current data item definitions (e.g. indigenous status); revision of coding and classification systems (e.g. International Classification of Diseases); and
  - Using alternative data output mechanisms (e.g. paper-based reports to interactive web-based interrogation of databases).

Operating rules

- Operating rules of the data collection should be developed, documented and readily available on request. Some operating requirements may be specified by legislation or through formal agreements between the registry and other third parties. Where State, Territory or Commonwealth legislation exists (e.g. data protection legislation and privacy laws) these must be complied with and reflected within the operating rules.
- Documentation should include details on at least the following:
  - data compilation
  - changes to data collection (operational procedures)
  - amendments to collected data
  - physical and electronic security arrangements
  - quality control of data
  - confidentiality
  - access to data
  - release of data
  - charges for access or release of data
  - reporting from the register
  - responsibilities
  - management and accountability structure.