



Government of **Western Australia**
Department of **Health**

Rare Disease Patient Registries:

Guidelines for establishment, governance and operation

DRAFT FOR CONSULTATION

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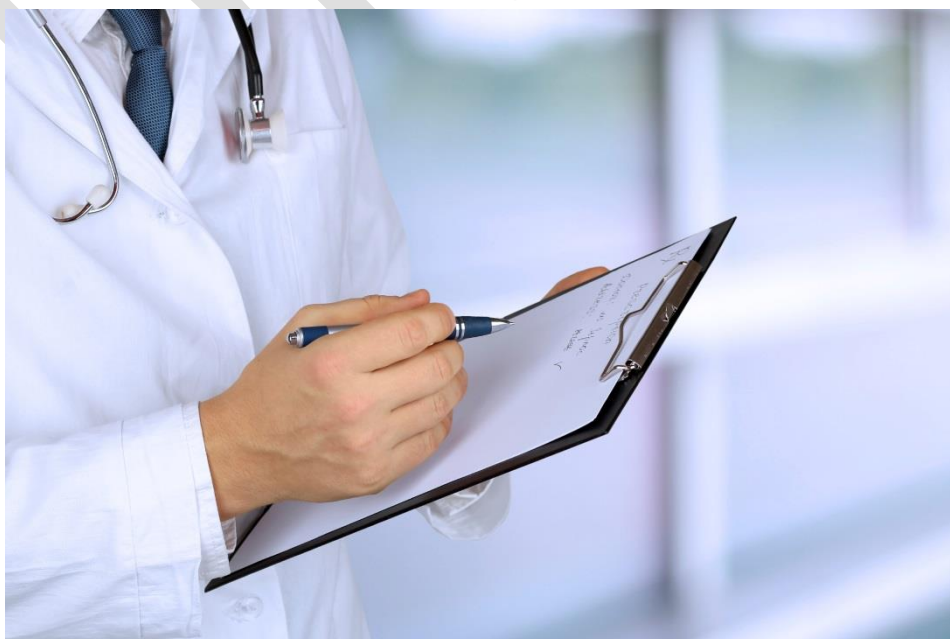
Context

The *Guidelines for the establishment, governance and operation of rare disease patient registries* (the Guidelines) have been developed to promote the consistent use of elements considered necessary for successful registry design and operation. This document may serve as a reference for interested stakeholders who are considering developing a rare disease patient registry and for other stakeholders engaged in shaping policy around patient registries.

The Office of Population Health Genomics, Government of Western Australia, has supported the development of rare disease patient registries in consultation with stakeholders, since 2010. The Guidelines bond the knowledge gained through the development of these registries to the learnings from stakeholder engagement. Furthermore, they respond to a gap in the current landscape, and build upon existing evidence to present a set of principles and general guidelines to support the WA health system to develop and implement rare disease patient registries.

The Guidelines are intended to assist researchers, health professionals, patient organisations and policy officers with explanation of the key principles to consider when establishing a rare disease patient registry. For the purpose of this document, a registry refers to a patient registry, defined in Section 1 of this document. The Guidelines are intentionally focused on rare disease patient registries that collect data from patients in the WA public health system. Statutory registries (e.g. WA Register of Developmental Anomalies) and other patient registries may have different requirements, and so are not included in the scope of the guidelines, however many of the principles herein may be relevant for establishing other disease-based patient registries.

The Guidelines are not intended for use by clinical quality registries (CQR). CQRs monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. CPRs are governed by principles, guidelines and standards outlined in the Framework for Australian clinical quality registries ¹.



Background

A patient registry is defined as “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)”². More simply, a patient registry is a collection of standardised health information about a group of participants who share a health situation. Patient registries can be used to increase knowledge on diseases, by pooling data for epidemiological research, clinical research, and real-life post-marketing observational studies³.

Patient registries vary in their purpose, methods of collection, information collected and use of the data. Types of patient registries include those designed for research and clinical trial readiness, disease screening, disease monitoring and prevention, post-marketing surveillance (pharmaceuticals), and clinical service administration. The information can be collected from the treating doctor, associated professionals such as laboratory staff, patient support organisations, registry administration staff and/or the participants themselves.

Patient registries can be developed to respond to a range of different needs. Often, they are established in response to calls from stakeholders including patients, patient advocacy groups, pharmaceutical companies and clinical groups and focus on a particular disease or cluster of disorders. In many situations, such as rare diseases where the prevalence is low, expanding the registry focus to a broader disease category or geographical area for collection is required to increase the value of the registry. This can also be achieved through the formation of multi-site, national and international patient registries⁴.

An example of a national group of rare disease patient registries crossing jurisdictional borders is the Australian Neuromuscular Disorders (NMD) Registry, consisting of three registries specific to rare neuromuscular disorders (Duchenne muscular dystrophy, spinal muscular atrophy, and myotonic dystrophy). Patients are enrolled in the appropriate NMD registry within the jurisdiction (state or territory) in which they reside and access to the data from each jurisdiction is restricted to the assigned jurisdictional curator. The existence of a national custodian oversees the national registry and enables linkage to interstate registries and the New Zealand NMD Registry containing similar disease-specific registries. The Australian and New Zealand NMD Registries further provide links to the international network of patient registries, TREAT-NMD, a global alliance for the NMD field. TREAT-NMD has tailored patient registries to the NMD they cater for and the geographical location in which they operate⁵. TREAT-NMD assists companies currently planning or running NMD trials by coordinating the collection and access of international patient data, and is involved in investigator-led research.

Rare disease patient registries are often a source of data for third parties; researchers investigating new treatments or companies planning clinical trials. Enabling researchers to access data from the registry may assist in the translation of research findings into best clinical practice. Opportunities to make better use of existing rare disease patient registries and facilitate the establishment and utility of new rare disease patient registries are being explored nationally and internationally. Of interest is the use of rare disease patient registries as a source of high-quality data for regulatory decision-making. This includes post-marketing surveillance studies and clinical trials that sponsors conduct after approval to gather additional information about a product's safety, efficacy, or optimal use. Furthermore, longitudinal patient data collected in rare disease patient registries is an important tool for studies on the natural history of disease.

Principles

The following outlines the principles that should guide the development of rare disease patient registries.

Establishment

- Principle 1 The registry should have a clearly articulated purpose that addresses a defined and recognised need.
- Principle 2 The scope of the registry should maximise the value of the data collected.
- Principle 3 Consultation should occur to determine the needs of registry participants and other stakeholders prior to establishment of the registry.
- Principle 4 The registry design should be flexible and strive for interoperability and harmonisation with other patient registries. Internationally recognised common data elements should be used where available.

Governance, management and oversight

- Principle 5 The registry should have a charter that clearly articulates the purpose and governance structure, including management and oversight roles and responsibilities. The charter should be publically available.
- Principle 6 A business plan should be developed to ensure the sustainability of the registry.
- Principle 7 All ethical and legal requirements should be met prior to recruiting participants to the registry. Where patient registries cross jurisdictional boundaries, efforts must be made to consider the differing legal environments at the outset of registry development.

Operation

- Principle 8 Participants should be involved, informed and empowered.
- Principle 9 Processes must be in place to support participant recruitment, including for non-coercive, informed and equitable consent.
- Principle 10 Data entered into the registry should be subject to quality control and quality assurance measures. Data should be protected and housed in a secure environment for the life of the registry.
- Principle 11 Clearly defined governance arrangements are required and policies and procedures documented that ensure appropriate operations and access to data.
- Principle 12 All staff with access to the registry should be provided with appropriate training in the administration and governance of the registry.

Closure

- Principle 13 The duration for which the registry data will be maintained and what circumstances may lead to the secure destruction of the data must be clearly defined.

Detailed guidance

The following builds upon the abovementioned principles, to provide detailed guidance for consideration when developing rare disease patient registries. Examples of a registry charter and patient information and consent forms are available by request from the Office of Population Health Genomics at genomics@health.wa.gov.au.



1 Establishment of rare disease patient registries

1.1 Defining the need and purpose

It is important to ensure there is a defined need for the registry prior to its establishment and operation. Clearly defining the purpose of the registry is an essential first step which will guide how the registry is designed². A single registry may have multiple purposes however these need to be prioritised, with the involvement of the appropriate stakeholders. Some examples of rare disease patient registry purposes include:

- identification of suitable candidates for clinical trials and/or research studies,
- monitoring the quality of health care within specific clinical domains, and
- post-marketing surveillance.

1.2 Registry scope

When identifying the purpose of the registry, consideration should be given to its scope, including:

- the condition or a group of conditions to be included,
- criteria for participant recruitment (for example, affected individuals only, or inclusion of unaffected family members), and
- the geographical catchment area (local, national or international).

There is the need to assess the current local, national and international landscape to identify patient registries established or in development for the same or similar purpose. Duplicating patient registries reduces the effectiveness and efficiency of each registry and can lead to

stakeholder fatigue. If a similar registry already exists, every effort should be made to coordinate with the existing registry, rather than duplicate datasets.

1.3 Considering the needs of stakeholders

Early engagement and consultation should occur to determine the needs of registry participants and other stakeholders. Gaining support from the stakeholders leads to better outcomes for both the participants and the other stakeholders and this can be gained through the establishment of a working group. The working group's role is to ensure that key stakeholders are on board and address the principles required to develop and operate the registry. A working group should include representation from key stakeholders expected to utilise, benefit from or influence the success of the registry.

Before establishing the registry, the working group should consult with diverse stakeholder groups and communities. As appropriate, this may include:

- patient support organisations,
- patient representatives,
- clinicians,
- molecular testing experts and/or pathology experts,
- researchers,
- ethicists,
- national and international registry networks,
- industry representatives, and
- general public.

Stakeholders should be consulted over a variety of topics with consideration of:

- the purpose and design of the proposed registry,
- the potential benefits to participants and stakeholders,
- the risks to participants and their families, and to other stakeholder groups, and how to manage these risks,
- when and how communication with participants will occur, including around consent and when their information is used, and
- opt-in or opt-out participation and consent (see Section 3.1.1).

1.4 Registry design

1.4.1 Infrastructure and software

When designing the registry, consideration should be given to maximising flexibility to enable future collaboration, especially in regards to compatibility with other patient registries and databases. Critical to the success of a patient registry is the technology used to develop the registry. Robust computing infrastructure is required, consisting of both hardware and software components. These components should facilitate interoperability with other patient registries and biobanks, and be secure to prevent unauthorised access to databases.

Databases and software tools have been developed and are in use by successful international registry networks and include standardised approaches for the collection, storage and analysis of data (for example, RD-Connect⁶). Many have been developed with open-source software and are freely available for use by others. CIPROS, a checklist with items for a patient registry software system, is one example that supports developers in assessing requirements on existing systems⁷.

The design of a registry should be continually reviewed and improved if necessary to support the longevity and sustainability of the registry⁸. The Australian Digital Health Agency⁹, created in 2016, is leading a national approach to support digital health reforms and any updates on standards and guidelines by the agency relevant to patient registries should be considered.

1.4.2 Types of data

The types of information collected and stored in the registry should be justified on the basis of the purpose and scope of the registry. The data should be representative of the targeted population and scientifically appropriate for its intended use. Types of data collected may include:

- personal identifying information such as name, date of birth and address,
- clinical information pertaining to the disease, such as affected organs, function tests and medication
- genetic information obtained through genetic testing, and
- other test results appropriate to the diagnosis and management of the disease.

Registries intended for post-marketing surveillance may also require the collection of data related to medication safety and quality.

1.4.3 Data elements

For the longevity and sustainability of the registry, careful consideration should be given to the data elements collected. Registry networks often contain mandatory datasets that specify the minimal data elements to be collected, to provide consistency and harmonisation between patient registries. When a mandatory dataset exists, consideration should also be given to whether the registry will collect information that is additional to the mandatory dataset, although, it is only appropriate to collect data that is necessary for the purposes of the registry. If there is currently no mandatory dataset that is agreed upon for the specified purpose of the registry, input from key opinion leaders and international patient registries should be sought to ensure the data elements collected are fit for purpose.

1.4.4 Collection of data

A registry can be set-up to collect data in several ways. Models for collecting data may include reporting by participants (self reported), health care professionals, or a combination of participant self-report and reporting by health care professionals. Consideration should be given to the types of information collected from participants and/or from other sources and take into account any disease specific or cultural issues which may hinder the ability to capture the required data⁸.

2 Governance, management and oversight

2.1 Governance

Governance is the term used to encompass the rules and processes, relationships, policies, and systems whereby authority within the organisation is exercised and maintained. The governance structure for the registry should be clearly outlined, including management and oversight roles and responsibilities. Patient registries should be administered in line with the principles of good corporate governance, including:

- a solid foundation for management and oversight,

- a governing body (for example, an advisory board) with an effective composition to adequately discharge its responsibilities,
- ethical and responsible decision making,
- integrity in financial reporting,
- timely and balanced disclosures,
- respecting the right of stakeholders,
- recognising and managing risk,
- reviewing membership of the governing body and its effectiveness, and
- recognising legal and other obligations to stakeholders.

2.1.1 Governing body

The registry should have a governing body in place that will ensure the registry is working towards its objectives⁸. Functions of the governing body include decision making in relation to:

- data access and use by researchers,
- database content and research objectives,
- financial and administrative issues,
- ethical and legal issues, and
- communication with stakeholders.

2.1.2 Custodianship

A custodian should be nominated at the time the registry is established. The custodian is responsible for ensuring the safe storage of registry data; authorisation of data collected, released and safely transferred; and implementation of policies and procedures.

The registry custodian should anticipate that the need to modify the policies and procedures over the lifespan will arise, and should ensure a process is in place for undertaking these modifications.

2.1.3 Charter

A registry charter is a statement that provides delineation of roles and responsibilities, outlines the purpose, defines the governance structure and identifies the members of the registry's governing body. The charter serves as a reference of authority for the future activities of the registry and must be agreed to by all members of the governing body.

The registry charter should clearly define the:

- role of the governing body including the registry custodian, its chairperson and secretariat,
- governing body membership requirements (experience),
- governing body method of appointment and period of membership,
- governing body meeting requirements (e.g. frequency, attendance, quorum of members),
- governing body reporting requirements (frequency, to whom and how),
- policies and procedures for operation of the registry, including recruitment of participants, informed consent and access to data, and
- procedures in the event of the demise of the registry, including seeking alternative arrangements for the housing of data and the length of time for data retention.

The charter should document the frequency of governing body meetings, meeting outcome reports and communication requirements to stakeholders, and be publically available.

An example of a registry charter is available from the Office of Population Health Genomics and can be requested by emailing genomics@health.wa.gov.au.

2.1.4 Registry coordinator

Patient registries that contain data collected over a number of sites or jurisdictions should consider management by a registry coordinator. The role of a coordinator is operational, to ensure cross-site coordination and over-arching data curation, including processes for data extraction. The coordinator and registry custodian(s) are typically the only positions to have access to data across sites and/or jurisdictions. The responsibilities of a registry coordinator (in relation to the responsibilities of the custodian) need to be clearly defined before the release of the registry for registrations.

2.2 Business plan

A business plan should be developed to help consider and plan for the sustainability of the registry. The business plan should set out the financial and scientific feasibility of the registry and include a financial model that the registry intends to adopt over its lifespan. Assumptions and risks identified with establishing the registry should be clearly documented. Furthermore, the business plan should be explicit and transparent about the nature and source of the registry's funding and include a business strategy in the event that funding for the registry is terminated or changes in nature.

A business plan may also provide details of ongoing software and hardware support and provision of sufficient personnel and resources to operate the registry effectively throughout its existence. Avenues to grow the registry once established should also be identified.

2.3 Ethical and legal requirements

Patient registries collect sensitive and valuable health data about participants. It is therefore important to comply with local regulations to ensure the safety and security of the data being collected⁸. Consultation with an appropriate local ethics committee, governing body and/or the institution where the data is housed is required to ensure suitable governance is in place for establishing and maintaining the registry. The type of recruitment, be it opt-in or opt-out (see Section 3.1.1), should be considered in consultation with the local ethics committee. Both opt-in and opt-out systems have challenges such as: uptake, representation for population research, and issues related to participants feeling a lack of control of their data.

Approvals for the registry may be required from more than one governing body, for example, when participants are recruited from multiple sites or across jurisdictional boundaries. Hence, it is important to check with local governing bodies as to the requirements early in the course of registry development. When considering multi-site or across jurisdiction recruitment, the *International Charter of principles for sharing bio-specimens and data*¹⁰ serves as a point of reference to address effective and transparent data and bio-specimen sharing.

Often, patient registries are electronically linked to a biobank or bio-repository that stores tissue, blood or other samples from the participants. In the case where a registry is to be linked to a biobank, separate approvals are required for the registry and biobank. No data should be collected from participants until all the necessary approvals are in place.

3 Operation of rare disease patient registries

3.1 Recruitment and participation

Participants are an integral component to a registry and should be involved, informed and empowered where possible. Recruitment should be undertaken in a non-coercive and informed manner. Registry participants should be informed of their rights including the right to withdraw at any time and for any reason, and should not be paid for their participation or receive any direct benefit from participating.

3.1.1 Consent

There are two main forms of participation with associated consent processes; Opt-in or Opt-out. Opt-in participation requires the participant to affirmatively give permission for the collection and use of their data. That is, the participant will actively seek enrolment and provide explicit consent and, if for any reason wishes to, can revoke that decision at any time and withdraw. Registration without the participant requiring explicit consent is referred to as Opt-out. Chapter 2.3 *Qualifying or waiving conditions for consent* of the *National Statement on Ethical Conduct in Human Research 2007*¹¹, and the *Ethical Considerations in Quality Assurance and Evaluation Activities*¹², provide guidance on alternative approaches to explicit consent for research, and for quality assurance activities, respectively.

One of the challenges in obtaining participant consent with Opt-in participation is ensuring that all the information and background material necessary to make a fully informed decision to participate is provided to the participant. The information should be presented in a way that the participant will understand what his/her participation and signature mean. Additional information beyond what can be presented in the written consent form may also be beneficial.

For participants under the age of 18 years (or the legal adult age of the jurisdiction involved), consent should be sought from the legal guardian or parent. When a minor participant becomes 18, consent should be obtained directly from them for continued participation. For participants unable to provide consent, their legal guardian or parent can provide consent on their behalf.

The Registry may seek to establish consent only at the time of participant registration. Static consent does not provide avenues for participants to change their consent over time. In a dynamic consent model, patients can electronically control consent and thereby adjust the level of their participation and the use of their data through time. A dynamic consent model may require additional electronic management of the registry but provides a transparent, flexible, and user-friendly means to inform and maintain trust in the registry¹³.

If the registry will be electronically linked to a biobank, separate consent for donating samples to the biobank must be sought.

An example of a patient information and consent document is available from the Office of Population Health Genomics and can be requested by emailing genomics@health.wa.gov.au.

3.1.2 Patient information

Information about the registry and the participant's involvement should be provided at the time of recruitment and be made publically available. Participant information should clearly articulate the purpose of the registry and the benefits and potential risks to the participants and stakeholders anticipated from enrolment. Information should be regularly reviewed and updated when necessary to maintain accuracy and clarity of participation.

3.2 Data access

3.2.1 Access to data for clinical trials

If the registry collects identifiable patient data for the purposes of readily contacting those who, based on their demographic, clinical or genetic data, meet the eligibility criteria for a specific clinical trial, then the identifiable data will not be provided to third parties, disclosed, reported or published for any reason.

The Coordinator will contact the [site] coordinator, who in turn, will ask the nominated clinician to contact the registrant to discuss the opportunity to participate in the trial. Access to personal information is restricted to those treating the patient, the clinical site coordinator and the national curator of the registry. Data will not be accessible across Registry sites to anyone other than the Coordinator.

Access to patient identifying information is restricted to the treating clinician who enters the data, the coordinator of the site of registration and the Coordinator. Third parties will not be given direct access to patients' identifiable data under any condition.

3.2.2 Access to data for research or feasibility of clinical trials

Application for access to the registry data for research and clinical trial feasibility enquiries may be received from third parties and internal (governing body) staff and may be made via submission to the governing body. All applications must have prior approval by a [jurisdiction] ethics committee and the study objectives be aligned with the registry objectives.

The governing body will regulate the relationship of the registry with all parties. Access to de-identified patient information by third parties is subject to recommendation by the governing body and approval of the registry custodian.

Access to de-identified patient information by Registry staff does not require recommendation by the governing body; authorisation by the registry custodian is sufficient. In the event that a request for data is received from the Registry custodian, approval must be sought from the governing body in the absence of the custodian.

3.2.3 Access agreement

Following approval to access Registry data, an Access Agreement is required between the third party and the governing body, with copies to be held by the Custodian and circulated to the members of the governing body. An Access Agreement is not required for approved Registry custodian access.

The agreement between the registry and the third party must ensure that access to confidential health information by the third party is limited to the use specified, that appropriate safeguards are in place to protect information on the termination of the contract.

The access agreement will include:

- procedures for the storage, use and destruction of the provided data,
- acknowledgement that data derived from the registry may be used for registering medicinal products through the appropriate authorities,
- access by research and academic institutions will be provided [free of charge or cost],
- any publications must acknowledge support by the registry,

- access by commercial companies may be charged a service fee agreed to by the company and the governing body, and
- all parties agree with the ethical principle of benefit sharing, which requires that benefits resulting from any scientific research and its applications should be shared especially with the persons and groups that have taken part in the research.

The governing body will regulate the sharing of information with patients, clinical and genetic service providers in relation to:

- provision of de-identified aggregate data to third parties,
- details of trials and research projects recruiting through the registry,
- information on other Registry and external related activities, and
- any other way to return benefit in accordance with the ethical principal of benefit sharing.

3.2.4 Data transfer to authorised parties

Transfer of Registry data to approved third parties will be conducted by secure electronic data transfer.

3.2.5 Quality control and assurance

Effective quality systems, quality control and quality assurance measures, can contribute enormously to the success of the registry. Quality control refers to the standard of quality of the data collected and stored in the registry. Quality assurance refers to the set of processes applied to ensure the quality of the data collected and stored is of that standard. The registry protocols should outline the methods of collection, input, cleaning and storage of data to maintain the quality. All data entered and stored in the registry should be subject to proper quality control and assurance measures for the life of the registry.

3.2.6 Security

Data should be collected in a manner that protects the privacy of the participant and confidentiality of their data in line with relevant jurisdictional data security requirement. The registry data must be protected and housed in a secure environment for the life of the registry. The governance and management of the registry should occur in such a way as to prevent any inappropriate or unauthorised access to participants' data.

3.3 Policies and procedures

The registry custodian should ensure there are clear, detailed, publicly available policies and procedures in place guiding operations of the registry. This includes, but is not limited to, policies and procedures relating to access to all samples and data and outlining how data requests will be received, who is eligible, and what information is released.

The policies and procedures should clearly define:

- who is responsible for providing oversight of applications,
- the types of requests for access to data that will be accepted,
- management of internal (governing body) and external applications, including research groups and pharmaceutical companies,
- how data will be disclosed,
- the level of data to be disclosed (identified or only de-identified information), and
- whether a written agreement (access agreement) is required with the requesting party.

3.4 Training

All staff, including new and voluntary staff members, must be provided appropriate training in all aspects of the registry operation and governance prior to commencement. A review of training requirements should occur when policies and/or procedures are amended.

4 Closure of a rare disease patient registry

The registry charter should outline the duration for which the registry data will be maintained. This may vary between patient registries according to the scope and purpose, and potential uses of the data. Conditions may apply for specific data that form part of an application for market authorisation of a medical product or device.

Consideration should be given to a situation when the registry is required to cease operations. This may occur for several reasons, for example, from a lack of funding or resources, or by legal order. In the event that the registry can no longer operate, every effort should be made to securely rehouse or store the data whilst seeking alternative arrangements. Closure of the registry should be communicated to the stakeholders, including direct communication to the participants, and the appropriate ethics committee/s.

The Charter should detail under what circumstances data will be destroyed and the processes required to ensure that secure destruction of data is completed.

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