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Methods Corner

The science of clinical quality registries

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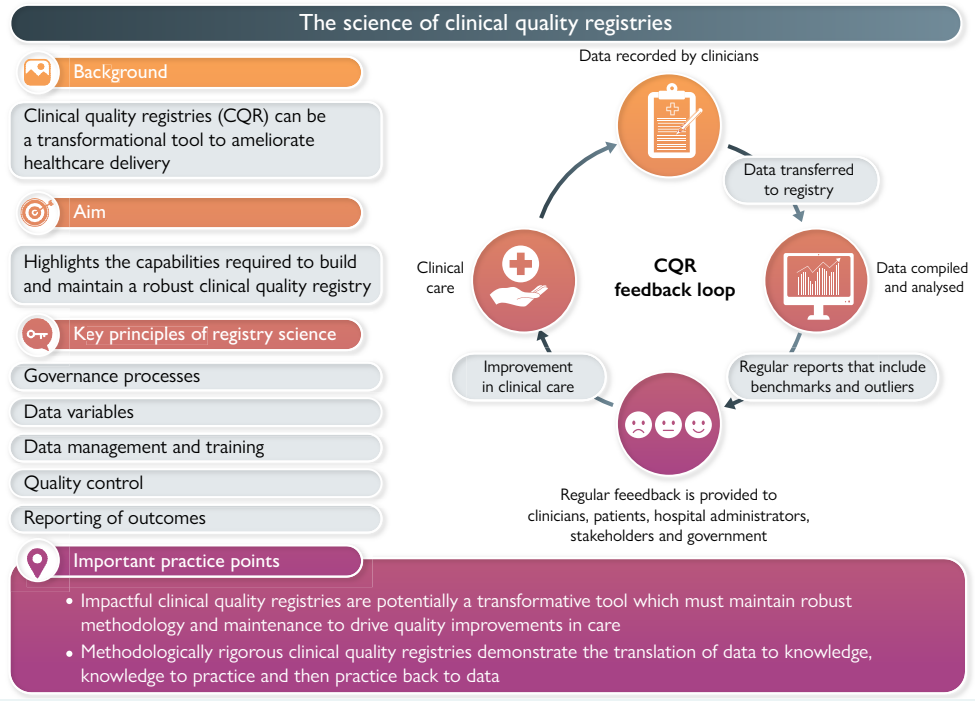
Clinical quality registries can be a transformational tool to improve healthcare delivery. Clinical registries with an incorporated quality emphasis identify evidence-practice gaps, inform quality improvement, and provide foundational research data to examine and improve health-related outcomes. For registries to create an impact it is essential that clinicians and researchers understand historical context, importance, advantages, and key criticisms. This methodological paper highlights the skills and capabilities required to build and maintain a robust clinical quality registry. This includes key measures to ensure data security, quality control, ongoing operational components, and benchmarking of care outcomes.

Graphical Abstract



Keywords Clinical quality registries • Registry science • Quality improvement • Implementation science • Learning health systems

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Learning objectives

- Define the key characteristics of impactful clinical quality registries.
- Understand and critique the advantages and disadvantages of clinical quality registries.
- Explore and understand the important concepts of a successful clinical quality registry and their role in future research methods.

Background

Clinical registries are defined as a systematically collected database of health-specific information that is managed by a research team and designed to monitor outcomes and care.[1] Clinical registries have had a significant role historically as they have been utilized worldwide to measure the health and well-being of populations.[2] An original definition by the World Health Organisation (WHO) in 1967 established the characteristics of a clinical registry as a disease-specific permanent record (register) able to be statistically tabulated and with follow-up over a period of time.[3] One of the world's first national patient register dates back to 1856; the National Leprosy Registry of Norway.[4] Historically, and without the advantage of modern-day algorithms, registries would operate as observational surveillance-based research of a participant cohort or disease. Registries continue as non-interventional systems although outputs from registries are increasingly used to inform clinicians and institutions about improving quality and safety.[5] As technological and medical advancements have progressed, current registries like the Australian and New Zealand Cardiothoracic Organ Transplant Registry and the National Cardiac Registry, are multifactorial in their application to treatment, decision making, and monitoring. These registries are used to enhance the quality of care within their specific data point of choice, monitor multiple different sites, and facilitate the recruitment of participants into research projects.[6]

Current clinical registries widely vary in size, data capture, and scope, and have an increasing focus on quality and safety within the specific health setting of choice. Clinical registries can also operate in different geographies and have local, state, national and international level reach, and population samples.[7] Thus, the term 'clinical quality registry' (CQR) is growing in popularity in registry science as there are significant increases in registry data output to focus on and improve the quality of care.[6] With the significant capability for evolution alongside medical and technological advancements, registries hold an important and impactful role in future research development.[8] The potential to improve health care through registry data could have a significant real-time impact on outcomes for patients and communities. Modern-day registry data collected on a participant population can be leveraged to dictate and lead national health decisions and policy, help to develop multi-site national registries and pioneer international findings in health-specific fields.[9]

Registry science

Medical informatics and data development in today's research landscape is fuelling 'Registry Science'. More recently data capabilities and technologies are excelling which leaves opportunities for clinical registries to capitalize on these advancements and elevate their data abilities and outputs. Consequently, there is an increasing need for registry science and methods to be robust and well-established as the evolution of registries continues to flourish to the sophisticated generation of complex data sets. Therefore, the structure and development of a registry needs to be methodological and competently developed, as discussed in the following. The building and formation of a registry needs a pre-planned method and discussion on the data points of interest, clinical setting, governance, and data collection and storage.[8] Registry science key principles include the following: [8,10,11]

(1) *Governance processes*
(2) *Data variables*
(3) *Data management and training*
(4) *Quality control*
(5) *Reporting of outcomes*

While these principles are described in a linear format, registry development often occurs in parallel. Decisions made around the setting and outcomes will help to design the registry team, also funding, governance and steering committees will have direct instructions around quality control and data management and storage, as demonstrated in *Figure 1*. Understanding the scope and rigour regarding the objectives of the registry will direct the setting, duration, size, outcome measures/assessments, and data points.[10]

Registry governance

At the beginning stages consideration of key stakeholders (often healthcare providers, academic institutions, public health or regulatory authorities, and lead clinicians) is necessary as they have a significant role in implementation and funding.[8] Once these initial steps are determined the next stages of planning and set-up can be achieved. Different locations and contexts have respective governing bodies which manage the quality and safety of clinical registries.[12] Within this, each registry has its own governance team to ensure continual effective data collection and management. Different countries and geographical locations have respective Registers of registries as an accessible published platform on which published registries are available, for example, the Australian Register of Clinical Registries.[13]

Data variables

Articulating a registry's purpose and determining a clear goal assist in the design and development of registries. Common types of registries include condition or disease-specific registries, or drug/device/product-based registries. Included in the initial steps is an assessment of feasibility which is undertaken in most research methods to determine if the

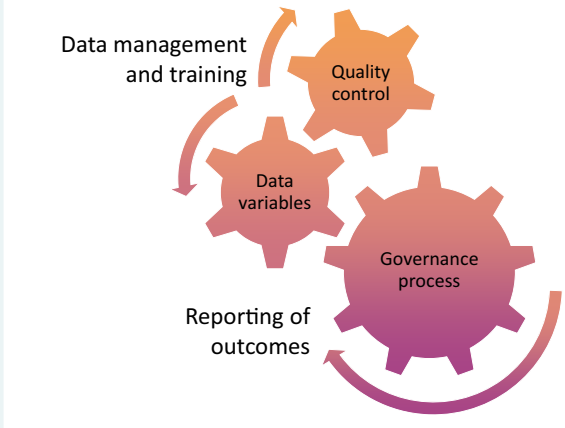

Figure 1 The interaction of the key principles of registry science.

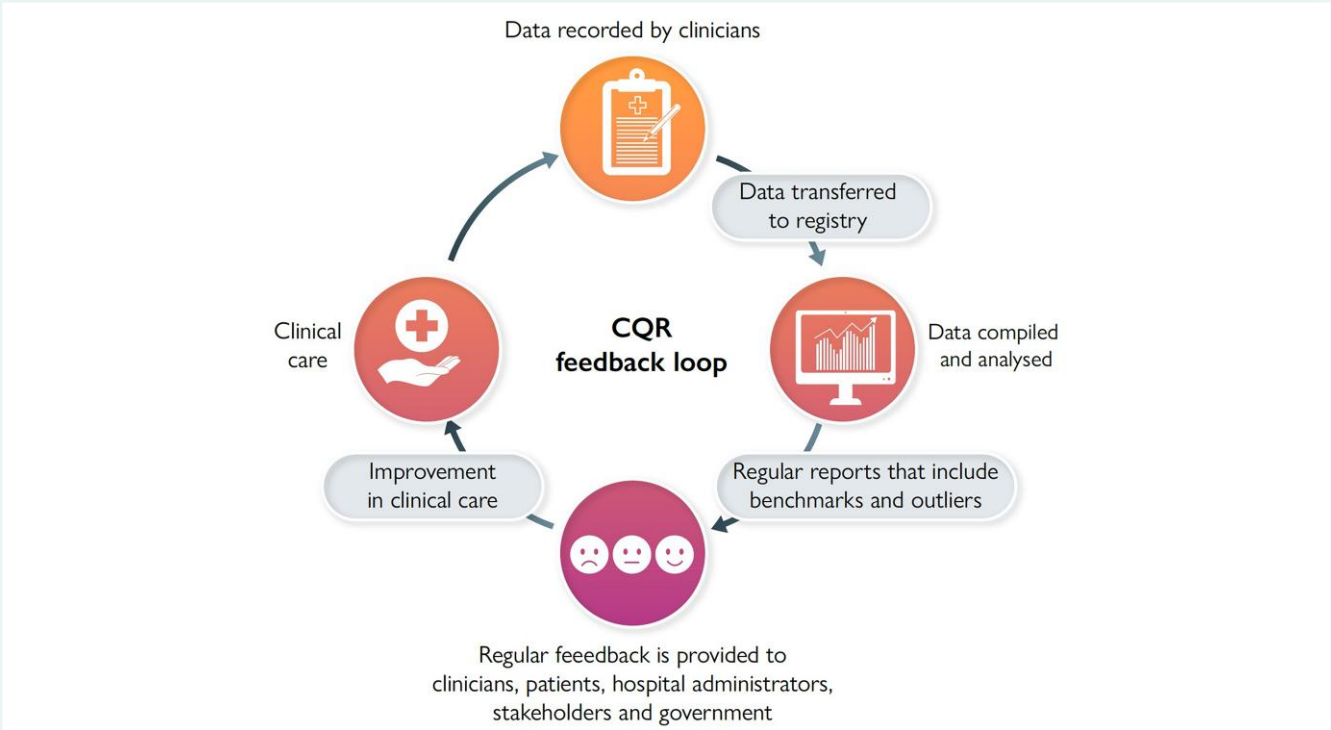

Figure 2 The cyclical process of a Clinical Quality Registry (with copyright permission from Australia New Zealand Trauma Registry, previously produced by the Australian Commission on Quality and Safety).

design and objectives meet the current needs of the population.[8] Deciding specific data variables with consideration of outputs of interest ensures registries are robust in design. Engagement of end-users (clinicians and consumers) in the design helps to ensure that it captures what it needs to without capturing too much—understanding that every data point has a cost. During conceptualization and design, a clear protocol for data collection is established to maintain data integrity. Consecutive prospective recruitment in clinical registries limit bias and likely result in a more representative sample of the specific population.[14] Therefore, defining the scope, participant population, variables of interest, implementation, and mobilization of a clinical registry in the early planning stages provides a clear direction for the clinical registry and a unified strategic goal.[15] This includes the quality of data collection, storage, and analysis as they directly dictate the overall quality of the findings and outcomes.

Data management and training

Hallmarks of quality are important mechanisms put in place to improve data management during design and planning. There are various softwares available that specialize in data control, management and security which create an environment that provides protection and is user friendly, for example, RedCap.[16] Data must be stored within a secured networked data drive and have procedures to protect against misuse of data. Data validity, reliability, and bias can be mitigated with documented procedures, informed personnel, and supervision. Ensuring uniform and systematic methods of data collection and assessments across sites and personnel are established and continued.[8] With this sees a clear protocol and description of data elements to remove errors and variability in assessment and data entry. Training helps to mitigate errors in data entry, transfer, or transformation accuracy. Successful clinical registries implement regular data cleaning and checking protocols to ensure security and accuracy in variables.[15] Throughout the development and continuation of the registry, there must be ongoing key personnel training and education. Procedures and registry documents, for example, a data dictionary, are important tools to ensure registry data are robust.

Quality control

As in all research development and processes, critical appraisal, and quality control is an important utility of consideration. As the growing trend for registries increases, more emphasis on quality control is needed to ensure outcomes and learnings from clinical registries are of sound nature. Without quality control, findings from registries around safety and effectiveness, and the benchmarking of care are not transferable or robust.[17] Understanding and identifying the registries' purpose from the outset to ensure all team members' and key stakeholders' goals are aligned is imperative to success. The responsibility of quality assurance within registries demands strong clinical leaders and falls on the research team and governing body. The process to ensure quality assurance will be dynamic to reflect the mode and methods of the registry format and data points but should be developed during the planning stages before study commencement.[10] Quality assurance can be maintained through data quality audits, designated individuals responsible for data quality and, ongoing assessment and training of competency of personnel. Best practice in appraising clinical registries includes transparency of data and is assessed as observational research utilizing STROBE (The Strengthening the Reporting of Observational Studies in Epidemiology) statement.[12,18]

Reporting of outcomes

For registry findings to have impact the reporting of results in a timely manner must be a priority. Ensuring opportune public reporting and,

Table 1 Advantages and criticisms of clinical quality registries

Advantages

- Measure and provide benchmarks of care and performance-based data for specific variables of interest.[5]
- Versatility in design as they can be patient, clinical area, surgery or condition-specific which means data variables are highly valid and trustworthy as they are collected in real-time.[8]
- Increase healthcare value and revenue as data feedback allows for adjustment of health practices and where specific services are needed.[1]
- Used to identify evidence-practice gaps, unwarranted clinical variation, and inform quality improvement initiatives.[2]
- A tool for clinicians to utilize as a mechanism to foster improvement in their own practice, enhance data-based literacy and provide a reflective platform to evaluate management.[19]
- Transparency in clinical registry research provides momentum and analysis of specific interventions simply and efficiently, and can increase clinician, consumer and hospital engagement.[10]
- Guided by governing body frameworks and policies specific to their location which combats differing national and international registry infrastructures.[15,20]
- Registration of registries helps to identify specific populations for potential participants for other research and highlights gaps in registry research.[13,21]
- Data linkage possibilities through joining of event, participant or condition-specific data with other independent data sources (e.g. Electronic Medical Records) helps to build a more detailed clinical picture,[22,23] e.g. Australian Stroke Clinical Registry linking data with Ambulance Data.[24]

Criticisms

- Limits in registry learnings to specific populations and interventions, with generalisability and comparability complex (e.g. metropolitan hospitals may see more complex patients).[17]
- Sharing of findings back to the end-users is inept.[2]
- Issues with public reporting and, internal to external data availability and transparency between institutions. Improvements in the data-delay feedback is necessary to employ effective practice change.[8]
- It is recommended that consumers are included in organisational governance and development, criticisms relate to the registry team failing to relay their findings back to consumers.[12,25]
- Institutional inertia makes data collection often complex, with clear protocols needed for ongoing data entry and maintenance.
- Not all clinical registries are cost-effective and some view registries as a largely costly research method exacerbated by the delay of implementation of findings.[23,26]
- Current regulations are in effect on registry capability to work nationally, interstate, and between health districts.
- Regulations for consent are governed by the requirements of the location in which they operate, there are extensive arguments for the impracticability of informed consent as registry research is observational-based and with small risks to participants.[27]
- Various models of consent (e.g. proxy, verbal, written and e-consent) all have effects on cost, recruitment and bias in registry research and thus the use of 'opt-out' or waiver of consent is preferred.[28,29]

Table 2 Local, national, and international clinical quality registries

LEVEL	REGISTRY
Local	*Western Sydney Clinical Frailty Registry*[30] https://www.sciencedirect.com/science/article/pii/S1322769622001494 This prospective clinical cohort study set out to explore the condition of frailty and management within the community. The registry aims to obtain a cross-sectional view and clinical profile of older people with frailty admitted to the Blacktown Hospital and Mount Druitt Rehabilitation and Aged Care Service between 2020-2025.
National	*Australian Stroke Registry* https://auscr.com.au The Australian Stroke Registry collects hospital-based data Australia wide relating to acute stroke care. Aiming to improve and promote best practice of stroke care throughout Australia.
International	*Garfield- AF Registry* https://af.garfieldregistry.org The Global Anticoagulant Registry in the field is an observational study of newly diagnosed atrial fibrillation (AF) and their management over time. Aiming to inform worldwide strategies and improve patient outcomes of stroke prevention in AF.

internal to external data availability and transparency during design and implementation is an important component of registry science.[2] Combating the data-delay feedback is a defining feature of a successful clinical quality registry as it ensures findings help to fuel effective practice change.[8] As described in *Figure 2*, the Clinical Quality Registry feedback loop demonstrates the translation of data to knowledge, knowledge to practice and then practice back to data. By this process, patient outcomes and health can be succinctly and positively improved through the reporting of registry findings.[5]

Registry advantages and key criticisms

Clinical registries ultimately act as an interactive database on their data item of choice and collect, collate, and display this data for healthcare stakeholders. Current key criticisms of registries pertain to their methods, generalizability, and utility of application on the data collected to drive tangible improvements in health outcomes. Described in *Table 1* are key registry advantages and current criticisms around the science of clinical quality registries.

Examples

Table 2 outlines current clinical registries operating at different levels. Follow the links for further information on registry aims and processes.

Looking to the future

Within the dynamic climate of healthcare, the place for registries as a transformative tool becomes evident. The potential to rapidly aggregate patient data with machine learning to create the benchmarking of treatment practices has incredible capabilities for the overall health and well-being of individuals and an immense improvement in the provision of care within institutions. Other research methods have the potential to leverage the power of clinical registries as useful participant pools and utilize the resources that they harvest.[10] Registries also work to provide a research base for tracking progress and clinical status over prolonged periods. Therefore, the future of registry-based studies leverages the data and infrastructure of a previously established population-specific registry. Examples include registry-based randomized clinical trials, observational studies, or quality improvement projects based on registry outputs.[31] There are opportunities to implement models of audit and feedback, utilizing a learning health system as one example, to develop a system that learns from itself (the registry) and informs clinician practices in real-time.

The learning health system is modelled to drive quality improvement and compliments the strengths of clinical quality registries. Various models of care can be applied to registry data and be an efficient and cost-effective method to sustain data collection and analysis over predetermined follow-ups. Ensuring sustainable registry funding is as a priority for the future ensures standards of design, implementation and execution that uphold the desired quality and safety key stakeholders envision.[6] The call for ongoing funding into clinical quality registries; from health services, government grants, or device manufacturers, helps to meets the continual investment and interest of clinicians and patients.[1] Financial investment and other peripheral costs of maintenance, while not the sole facilitator to a successful clinical quality registry, is necessary to sustainability of registries.[32]

With registries as vehicles for capacity building and improvement in healthcare expenditure, there is growing collaboration and acceptance of the role of clinical registries in health research. This increasing interest leaves possibilities for further development in data linkages to other 'machine learning' or 'big-data' platforms and more in-depth analysis and presentation of data outputs. Leading to the provision of special reports on trends in healthcare utilization, quality and safety which can be accessed by policymakers and key stakeholders and used to dictate nationwide healthcare changes. Extensive collaboration between digital technologies and institutions to promote network-wide learning and development is within the not-too-distant future.[23,33]

Conclusion

Impactful clinical quality registries are potentially a transformative tool which must maintain robust methodology and maintenance to drive quality improvements in care. The five registry science key principles, namely governance processes; data variables; data management and training; quality control; and reporting of outcomes allow for the development of successful registry research. As the evolution of registries advances, nurses are key successful implementers well placed to make significant changes to improve patient outcomes at point of care. Methodologically rigourous clinical quality registries demonstrate the translation of data to knowledge, knowledge to practice, and then practice back to data.

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Data availability

No new data were generated—review only.

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