

# What is a Registry?

Magda Melo, BScPharm, MSc

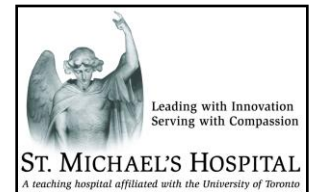
OEQRU, Applied Health Research Centre, Li Ka Shing  
Knowledge Institute of St. Michael's Hospital



Leading with Innovation  
Serving with Compassion

## ST. MICHAEL'S HOSPITAL

*A teaching hospital affiliated with the University of Toronto*



# Outline

- Defining Registry
- Purpose of Registries
- Planning a Registry
- Evaluating Registries: Basic Elements of Good Practice

# What is a registry?

*A “registry” both defined as the act of recording or registering, and as the record or entry itself.*

*A “patient registry” is an organized 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 one or more predetermined scientific, clinical, or policy purposes.*

# What is NOT a registry

- Database of patients' contact information that are used solely to identify patients with particular diseases in clinical practices, but is not used for evaluating outcomes.
- A database used in a clinical trial
- Clinical database used for the clinical management of patients is also NOT a registry
- Administrative databases - Secondary data sources (analyses of data collected for other purposes)

# A Registry...

- Designed to fulfill specific purposes
- Captures data elements with specific and consistent definitions
- Data collected in an uniform manner for every patient (types of data and frequency)
- Include types of data that clinicians would use for the diagnosis and management of patients
- At least one element of the registry data collection is active. Registries can be enriched by linkage with external databases (e.g., to determine deaths or other outcomes or to assess drug use or resource utilization)

# Patient Registry...Powerful Tool

- Observe course of disease
- Understand variations in treatment and outcomes
- Examine factors that influence prognosis and quality of life
- Describe care patterns (incl. appropriateness of care and disparities in the delivery of care)
- Assess effectiveness
- Monitor safety
- Change behaviour through feedback of data

# Purposes of Registries

1. Natural history of disease
2. Determine effectiveness
3. Measure or monitor safety and harm
4. Measure/Improve quality of care

Multiple purposes

# Planning a Registry

## Initial Steps:

1. Articulating the purpose(s)
2. Determining whether data being sought have already been collected elsewhere
3. Deciding whether a registry is the most appropriate means for addressing the research question
4. Identifying stakeholders
5. Defining the scope of the registry (planned representativeness of the target population and characteristics of data to be collected)
6. Assessing feasibility and likelihood of success



# Planning a Registry

## Next:

- Funding
- Advisors
- Teams
- Oversight
- Registry end

# Planning – 1. Establishing a Purpose

- Single
- Multi-purpose

Translates into:

- One
- Several specific objectives or questions

# Planning – 1. Establishing a Purpose

## Specific objectives help

- Define the structure and process of data collection
- Ensure that the registry effectively addresses the important questions through the appropriate outcome analyses
- Avoid collecting large amounts of data of limited value
- Identify a core data set

# Planning – 2. Other Sources of Data

**Do these data already exist? If so, are they accessible?**

- Relevant data extracted from electronic health records, or administrative health insurance claims data
- Adapting the registry or linking to other relevant data sources (incl. piggy-backing onto other registries)
- Data not accessible or not sufficiently collected → create registry

# Planning – 3. Stakeholders

## Stakeholders

- Primary stakeholders:
  - party that requires the data, creates and funds the registry
- Secondary stakeholder:
  - party that would benefit from the knowledge of the data (or would be impacted by the results) but that is not instrumental in establishing a registry

# Planning – 3. Stakeholders

## Examples of stakeholders

- Regulatory authorities
- Product manufacturers
- Health care service providers
- Payer or commissioning authorities
- Patients and/or advocacy groups
- Treating physician groups
- Universities or professional societies

# Planning – 4. Scope of Data

## Scope may be viewed in terms of:

- Size (number and complexity of data points or enrollment of investigators and patients)
- Setting (e.g. hospital, doctor's office, pharmacy, home)
- Duration

# Planning – 4. Scope of Data

**Scope may be viewed in terms of (cont.):**

- Geography (if global, then challenges – language, culture, time zone, regulatory)
- Financing
- Richness of clinical data
- Scientific rigour of certain outcomes:
  - Diagnostic confirmation via supporting documents from referrals and biopsies
  - Formal adjudication by a committee



# Planning – 5. Core Data Set

- Core data values (“need to know”)
  - Address central questions
- Non core data (“nice to know”): speculative fields to generate and explore hypotheses
- Balance against the risk of overburdening sites with capturing superfluous data collection

# Planning – 6. Patient Outcomes

- Primary and secondary endpoints identified early in the concept phase of the registry
- Guide the selection of the data set
- Establish methods to ascertain the principal outcomes, diagnostic requirements, level of data details, and level of data validation

# Planning – 7. Target Population

- Target population: population to which the findings of the registry are meant to apply
- Definition should be consistent with established guidelines and standards within the therapeutic area
- To consider:
  - How common is exposure or disease of interest?
  - Can eligible persons be readily identified?
  - Are other sources competing for the same patients?
  - Is care centralized or dispersed?
  - How mobile is the target population?
- Comparison (control) group internal or external to registry

# Planning – 8. Funding

- Cost of registry determined by the scope of the registry and rigour of data collection and audit required
- Projected life of the registry and/or its long-term sustainability
- Potential sources of funding:
  - Government
  - Product manufacturers
  - Foundation funding
  - Private funding
  - Professional societies
  - Professional society/pharmaceutical industry
  - Health plan providers
  - Multiple sponsors

# Planning – 9. Registry Team

- Subject matter (clinical experts)
- Registry science (epidemiologists and biostatisticians)
- Data collection and database management
- Legal/patient privacy
- Quality Assurance
- Project Management

# Planning – 10. Governance & Oversight

## Functions that may be considered

- Executive or steering (financial, administrative, legal/ethical, and scientific decisions. Direction of the registry)
- Scientific (database content, clinical research, epidemiology and biostatistics)
- Liaison (large registries)
- Adjudication (review and confirm outcomes)
- Data Safety Monitoring Board (DSMB)
- Data access, use, and publications

# Planning – 11. End of Registry

- Sponsors and participants should have an understanding of the proposed lifespan of the registry
- Who owns the data and where data are going to be stored
- Transitions to continue the registry functions after the original funding sources have expired

# Evaluating Quality: Quality Domains

- Research
  - Planning
  - Design
  - Data elements and data sources
  - Ethics, privacy and governance
  
- Evidence
  - Registry participants
  - Data elements and data sources
  - Data quality assurance
  - Analysis
  - Reporting



# Research Quality: Basic Elements of Good Practice

## Planning:

- Registry plan documents
  - Goals
  - Design
  - Target population
  - Methods for data collection and data review
  - High-level analysis plan
  - Plan for communication of study results
- Appropriate personnel and facilities are available
- Process established to document subsequent modification

# Research Quality: Basic Elements of Good Practice

## Design:

- Literature has been reviewed to guide appropriate data collection
- Target population and plan to recruit patients is described
- Eligibility (inclusion/exclusion criteria) defined
- Size and follow up time required to detect an effect is specified

# Research Quality: Basic Elements of Good Practice

## Data elements and data sources:

- Outcomes are clinically meaningful
- Operational definitions of outcomes are clearly defined
- Important exposures, risk factors, and protective factors are collected to the extent feasible
- Individuals responsible for integrity of data and data collectors are identified and received the necessary training
- Data and coding dictionary is maintained
- Quality assurance plan to address data editing and verification as appropriate



# Research Quality: Basic Elements of Good Practice

## Ethics, Privacy, and Governance:

- Protection of human subjects (incl. privacy, informed consent, data security, and study ethics) carefully considered in accordance with local, national, and international regulations
- Registry has received review by an oversight committee (REB, IRB, privacy committee)

# Evidence Quality: Basic Elements of Good Practice

- Registry participants:
  - Similar to target population?
  - Eligibility confirmed upon pt enrollment?
  - For safety studies, are personnel appropriately trained to ask about complaints and adverse events and to know how information should be reported?
  - Has completeness of information on eligible pts been evaluated and described?

# Evidence Quality: Basic Elements of Good Practice

- Data elements and data sources:
  - Relevant key exposures, risk factors, and protective factors
  - Pts outcomes are clinically relevant and clearly defined
  - Follow-up period is sufficient to capture the main outcome of interest

# Evidence Quality: Basic Elements of Good Practice

- Data quality assurance
  - Data are reasonably complete
  - Efforts made to assure that appropriate pts have been systematically enrolled and followed in an unbiased a manner possible
  - Efforts have been made to minimize losses to follow-up
  - Data checks are employed using range and consistency checks

# Evidence Quality: Basic Elements of Good Practice

- Analysis:
  - Accepted analytic techniques are used; these may be augmented by new or novel approaches
  - Role and impact of missing data and potential confounding factors have been explored



# Evidence Quality: Basic Elements of Good Practice

- Reporting:
  - methods
  - target population and selection of study subjects
  - compliance with applicable regulatory rules and regulations
  - data collection methods
  - any transformation of variables and/or construction of composite endpoints
  - statistical methods for analysis
  - and any circumstance that may have affected the quality or integrity of the data



# Evidence Quality: Basic Elements of Good Practice

- Reporting (cont.):
  - Results reported for all the main objectives
  - Follow up time described so that readers can assess the impact of the observation period on the conclusions drawn
  - Includes a clear statement of any conclusions drawn from analysis of the registry's primary and secondary objectives and any implications of study results, as appropriate
  - All authors have had a meaningful role in the design, conduct, analysis, or interpretation of results

# Bibliography

- Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes; A User's Guide. (Prepared by Outcome DEcIDE Centre [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS A29020050035ITO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality.
- Goldberg J., Gelfand H.M., & Levy P.S. (1980). "Registry Evaluation Methods: A review and case study." Epidemiologic Reviews 2: 210-220.

# Questions?

## Thank you for listening!