Quality assurance

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Challenges in validating quality of care data in a schizophrenia registry: experience from the Danish National Indicator Project

Registration in the Danish Regional Nonmelanoma Skin Cancer Dermatology Database: completeness of registration and accuracy of key variables

Acute myeloid leukemia in the real world: why population-based registries are needed

Clinimetrics corner: the many faces of selection bias

Eric J. Hegedus, Jennifer Moody
Duke University, USA
EPIRARE: Survey on RDR Quality-I

- GENERAL CHARACTERISTICS OF THE REGISTER (5 questions)
- AIMS AND SCOPE OF THE REGISTER (4 questions)
- COLLECTED DATA (6 questions)
- REGISTER’S SOURCES (3 questions)
- QUALITY OF DATA (9 questions)
- ETHICAL AND LEGAL ISSUES (4 questions)
- INFORMED CONSENT (4 questions)
- GOVERNANCE (2 questions)
- COMMUNICATION (2 questions)
- ACCESS TO DATA AND SECURITY (6 questions)
- REGISTER’S SUSTAINABILITY (5 questions)
- NEEDS AND EXPECTATIONS (6 questions)
Case definition: Inclusion/exclusion criteria

- Q0013 Case definition available for the RD of interest (87.7%)
- Q0014 Standardised inclusion/exclusion criteria (78.6%)
Quality Assessment

- Q0025 Registry checked for reliability (48,6%)
- Q0026 Registry checked for agreement (46,4%)
- Q0027 Registry checked for internal validity (58,2%)
- Q0028 Quality test/surveys periodically performed (43,6%)
- Q0029 Methods to avoid duplication of the registered cases (87,7%)
Summary

• The quality of survey was high
• Good level of quality among RDR participants in that survey
  – Case definition; inclusion/exclusion Criteria Data are periodically updated
  – Standardized data entry processes
  – Control of mistakes
  – Instructions and training
What is a registry?

- Organized information system
- Observational study design
- Collect uniform data
- Evaluate specified outcomes
- Population defined
- Predetermined purposes
  - Scientific
  - Clinical
  - Policy

Registry vs database
The term "quality" refers to the degree of excellence, as in, "a quality product". Yet, one could also define this term as *fitness for the purpose*.

**Other terms related/surnames**
- Quality Assurance (QA)
- Quality Control (QC)
- Quality Indicators (QInd)
- Quality Assessment (QAss)
- Quality Results (QR)

**Quality and Health Care Systems**
Quality assessment framework

• **Data quality**
  – Features and characteristics of a data set, that bear on its ability to satisfy the needs that result from the intended use of the data.

• **Quality Assurance (QA)**
  – Activities undertaken before data collection to ensure that the data are of the highest possible quality at the time of collection.

• **Quality Control (QC)**
  – Activities undertaken during and after data collection aimed at identifying and correcting sources of data errors.

• **Quality Assessment (Qass)**
  – Process of quality evaluation of the consolidated database.

• **Quality Results (QR)**
  – Value or set of values resulting from applying a data quality measures.

• **Quality Indicators (QInd)**
  – List of quality measurements.
RD Registry Procedures

- Study aims and hypothesis with their background and bases
- Definition of the target population, settings and study population
- Study design
- Case definition and inclusion/exclusion criteria
- List of set of variables including sources and definitions
- Standardized data report form
- Pilot study phase description (not always is needed)
- Data collection methods
- Data interpretation/abstraction
- Data codification
- Data stored
- Data analysis
- Ethical issues
- Study limitations and bias analysis
- Standardized data reporting, including discussion of results and their relationships with other published studies
Key points

● Inclusion/exclusion criteria
  (use of case definitions, definition of conditions to admit disease- or treatment-specific data)

● Coding and classification

● Monitoring of data collection procedures
Type of errors

1) Problems in case selection and case ascertainment; duplicates, mistakes in the interpretation and diagnosis

2) Errors in coding, data entry, data transformation, accuracy

3) Data consistency across sites and over time

4) Intentional errors.
Quality & Research

• Internal validity
• Sensitivity
• Intramethod reliability
  – Test–retest reliability
  – Interrater reliability
• Intermethod reliability
• External validity
  – Consistency
  – Coherence
Types of Validity

External population

Target population

Actual population

Study population (sample)

\[ \theta^0 \]

\[ \theta \]

\[ \hat{\theta} \]

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\[ \hat{\theta} \]

Statistical inference

Internal validity

External validity
Types of biases

a – high precision (low variance) but biased;
b – low precision (high variance) but no overall bias;
c – low precision (high variance) and biased;
d – high precision (low variance) and no bias
Dissemination & Publication

- **STROBE** - Strengthening the Reporting of Observational Studies in Epidemiology
- **STROBE-ME** - STrengthening the Reporting of OBservational studies in Epidemiology
- **STREGA** - STrengthening the REporting of Genetic Association Studies
- **GRIPS** - Strengthening the reporting of genetic risk prediction studies
- **CONSORT** - Consolidated Standards of Reporting Trials
- **PRISMA** - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- **MOOSE** - Meta-analysis Of Observational Studies in Epidemiology
- **STARD** - Standards for Reporting of Diagnostic Accuracy
- **REMARK** - REporting recommendations for tumor MARKer prognostic studies
- **GRACE** - Good Research for Comparative Effectiveness
- **GRRAS** - Guidelines for Reporting Reliability and Agreement Studies
GUIDELINES FOR QUALITY OF RD REGISTRIES

- Addressing systematisation of quality procedures
- The development of a quality assurance plan
  - Quality control measures
  - Data security and confidentiality
  - Follow-up
  - Timeliness
  - Reporting
  - Coordination
- Manual of Procedures

- Policy rules and governance
- IT tools document
- Security document
- Ethic rules
- List of procedures for each topic
- Manual training
- Instructions for database users

- Data dictionary
- Data Report Form
- Catalogues
- Classifications
- Personnel functions and tasks
- Checklists
- Nested research study protocols
- Quality assessment
Quality and platform registries

• Governance and Quality
  – Registry platform Holders, who would provide information regarding their registries.
  – Registry platform Users, who would search and find information regarding registries included in the platform
  – Registry Platform Reviewers, who would ensure the listed registry information was accurate, consistent, and of high quality
  – Registry Platform Administrators, who would handle the maintenance and operation of the platform, and support the needs of the preceding roles

• Coordinating mechanisms
  – import data from patient registries and databases using the Common Data Elements previously agreed
  – use the collected information to find subsets of patients who may be potential candidates to participate either clinical trial or observational studies.
  – participating registries will retain their data ownership and control and they may collect additional data beyond the CDEs core
  – researchers can also use the information to report about the latest research findings to those families already registered

• Ethics and Quality
Quality Indicators

• Indicators
  – Process indicators
  – Monitoring indicators
  – Outcome indicators

• Quality assurance (user satisfaction assessment) of tools and services, including promotion of registration and networking
  – Identify improvement opportunities.
  – Tools and Resources Quality