Diseases registry, Overview, Q.A/Q.c

Koorosh Etemad MD,MPH,PhD

Disease registry office, Deputy of Research and Technology

Shahid Beheshti University of Medical sciences

Contents:

- Overview of Registry
- Definition of Q.C
- Elements of Q.C
- Example of Q.C

- Registry
- Patient registry

A patient registry is an organized system that collect :

- uniform data (clinical and other)
- specified outcomes for a population defined by a particular disease,
- Condition
- Exposure
- predetermined scientific, clinical, or policy purposes.

Purposes of Registries

- Describing the **natural history** of disease
- Determining clinical and/or **cost-effectiveness**
- Assessing **safety** or **harm**
- Measuring or improving **quality of care**

Patient Registries and Policy Purposes

- The utility of registry data for decisionmaking is related to **three factors**:
- Stakeholders
- The primary scientific question
- The context

"adequate data in support of the decision at hand "

Kind of registries

- Product Registries
- Health Services Registries
- Disease or Condition Registries
- Combinations

Product Registries

- In the case of a product registry, the patient is exposed to a health care product, such as a drug or a device.
- *Pregnancy registries* represent a separate class of biopharmaceutical product registries that focus on possible exposures during pregnancy and the neonatal consequences

Health Services Registries

- Individual clinical encounters:
  - Office visits or hospitalizations
  - Procedures
  - Full episodes of care
- Patients undergoing a procedure:
  - Carotid endarterectomy
  - Appendectomy
  - Primary coronary intervention
  - Admitted to a hospital for a particular diagnosis (e.g., community-acquired pneumonia).

Disease or Condition Registries

Use the state of a particular disease or condition as the inclusion criterion such as :

- cystic fibrosis or Pompe disease, or a chronic illness such as heart failure, diabetes, or end-stage renal disease
- May have the disease or condition for a more limited period of time (e.g., infectious diseases, some cancers, obesity)

Combinations

- Complicating this classification approach is the reality that these categories can be overlapping in many registries.
- For example, a patient with ischemic heart disease may have an acute myocardial infarction and undergo a primary coronary intervention with placement of a drug-eluting stent and postintervention management with clopidogrel.

several other types of or uses for registries

- **geographically** based population registries (not based on a disease, condition, or exposure);
- registries created for **public health** reporting without tracking outcomes (e.g., **vaccine** registries);

Articulate the Registry's Purpose

- A registry may have a **singular** purpose or **several purposes**.
- **Avoid** collecting large amounts of data of **limited value**
- What **key questions** the registry needs to answer

- scientific, clinical, and health policy purposes
- can provide a real-world
  - clinical **practice**
  - patient **outcomes**
  - **safety**
  - comparative **effectiveness**

- Many registries are, or include, **high-quality** studies of **cohorts** designed to address a **specific problem** and **hypothesis**.
- **Randomised trials** are **not** always **feasible** and, in some **instances**, **observational** studies may provide **better evidence**, as is generally the case for **rare adverse effects**.

- for demonstrating the **real-world effects** of **treatments** outside of the research setting and potentially in **large subsets** of **affected** patients, and for **providing long-term**

- **Threshold** above which a **payer** is willing to pay for an **improvement** in patient **outcomes**.
- **Rare diseases**, when it can be difficult to gather clinical effectiveness data together with **quality-of-life** data
- Facility the process of **technology assessment** and improving patient care

Strategic Plan

- Almost are disease base
- Attention to:
  - cost
  - satisfaction
  - compliance
  - Adverse effect
  - Induced demand

Overview

- The data are collected in a **naturalistic manner**
- The registry is designed to fulfill **specific purposes**
- The **registry** captures data **elements** with specific and consistent data **definitions**.
- The data are collected in a **uniform manner** for **every patient**
- At least one element of registry data collection is active

Goals

- Understand **variations** in **treatment** and **outcomes**
- To examine factors that **influence prognosis** and **quality** of **life**
- To assess **effectiveness**
- To monitor **safety** and **harm**
- To measure **quality** of **care**

- Demonstrate the **performance** of a **product** in the real world
- Meet a **postmarketing** commitment or requirement
- **Develop hypotheses**, or identify patient populations that will be useful for product development, clinical trials design, and patient recruitment

Examples of these outcomes

Biomedical outcomes:

- Survival and disease-free survival
- Health-related quality of life
- Satisfaction with care
- Economic burden

Six guiding aims

- Safe
- Effective
- Efficient
- Patient-centered
- Timely
- Equitable

Examples of key or driving questions

- What is the natural course of a disease, and how does geographic location affect the course?
- Does a treatment lead to long-term benefits or harm, including delayed complications?
- How is disease progression affected by available therapies?
- What are significant predictors of poor outcomes?

Examples of key or driving questions

- What is the safety profile of a specific therapy?
- Is a specific product or therapy teratogenic?
- How do clinical practices vary, and what are the best predictors of treatment practices?
- Are there disparities in the delivery and/or outcomes of care?

Examples of key or driving questions

- What characteristics or practices enhance compliance and adherence?
- Do quality improvement programs affect patient outcomes, and, if so, how?
- What process and outcomes metrics should be incorporated to track quality of patient care?
- Should a particular procedure or product be a covered benefit in a particular population?

Examples of key or driving questions

- Was an intervention program or risk-management activity successful?
- What are the resources used/economic parameters of actual use in typical patients?

Role

- Data about disease presentation and outcomes on large numbers of patients rapidly, producing a real-world picture of:
  - disease
  - current treatment practices
  - outcomes

- Is it safe?
- Does it produce greater benefit than harm?
- Is it clinically effective?
- Does it produce the desired effect in real-world practice?
- Does the right patient receive the right therapy or service at the right time?
-

- Is it cost effective or efficient?
- Does it produce the wanted effect at a reasonable cost relative to other potential expenditures?
- Is it patient oriented, timely, and equitable?

Advantages for active surveillance

- First, the current practice relies on a nonsystematic recognition
- Second, these events are generally reported without a denominator

Some of the specific variables

- Size
- Diuration
- Setting
- Geography
- Cost
- Richness of clinical data needed

Planning a Registry

- Variability in size, scope, and resource requirements for registries
- Registries may be large or small
- They may target rare or common conditions and exposures.
- They may require the collection of limited or extensive amounts of data

Planning a Registry

- Operate for short or long periods of time
- Funded generously or operate with limited financial support
- In addition, the scope and focus of a registry may be adapted over time
- Focus on or expand to different geographical regions
- Address new research questions

Data Elements for Registries -Identifying Domains

Requires explicit articulation of the goals

- On patient demographics
- Medical history
- Health status
- Any necessary patient identifiers
- The exposure domain describes the patient’s experience with the product, disease, device, procedure, or service of interest

Selecting Data Elements

- The most effective way to select data elements is to start with the study purpose and objective, and then decide what types of groupings, measurements, or calculations will be needed to analyze that objective
- The use of established data standards, when available, is essential so that registries can maximally contribute to evolving medical knowledge

- Data elements that can be collected once are often collected at the baseline visit.

Examples of possible baseline data elements

- Enrollee contact information
- Another individual who can be reached for followup (address, telephone, email)

Examples of possible baseline data elements
Enrollment data elements

- Patient identifiers
- Permission/consent
- Source of enrollment (e.g., provider, institution, phone number, address, contact information)
- Enrollment criteria
- Sociodemographic characteristics, Education and/or economic status, insurance, etc.
- Preferred language
- Place of birth
- Location of residence at enrollment
- Source of information
- Country, State, city, county, ZIP Code of residence

Examples of possible additional enrollee, provider, and environmental data elements

Pre-Enrollment History medical history

- Morbidities/conditions
  - Onset/duration
  - Severity
  - Treatment history
  - Medications
  - Adherence
  - Health care resource utilization
  - Diagnostic tests and results
- Procedures and outcomes
- Emergency room visits, hospitalizations (including length of stay), long-term care, or stays in skilled nursing facilities
- Genetic information
- Comorbidities

Examples of possible additional enrollee, provider, and environmental data elements -Pre-Enrollment History- Patient characteristics

- Functional status
- Health behaviors
- Social history
- Marital status
- Family history
- Work history
- Social support networks
- Economic status, income, living situation
- Sexual history
- Foreign travel, citizenship
- Legal characteristics (e.g., incarceration, legal status)
- Reproductive history
- Health literacy
- Individual understanding of medical conditions and the risks and benefits of interventions
- Social environment (e.g., community services)
- Enrollment in clinical trials (if patients enrolled in clinical trials are eligible for the registry

Patient Identifiers

- The patient’s name, date of birth, or some combination thereof) that are subject to legal and security considerations. When the planned analyses require linkage to other data (such as medical records),
- Patient identifiers may change during the course of the registry

Data Definitions

- Creating explicit data definitions for each variable to be collected is essential to the process of selecting data elements
- Include the ranges and acceptable values
- It is important to determine which data elements are required and which elements may be optional

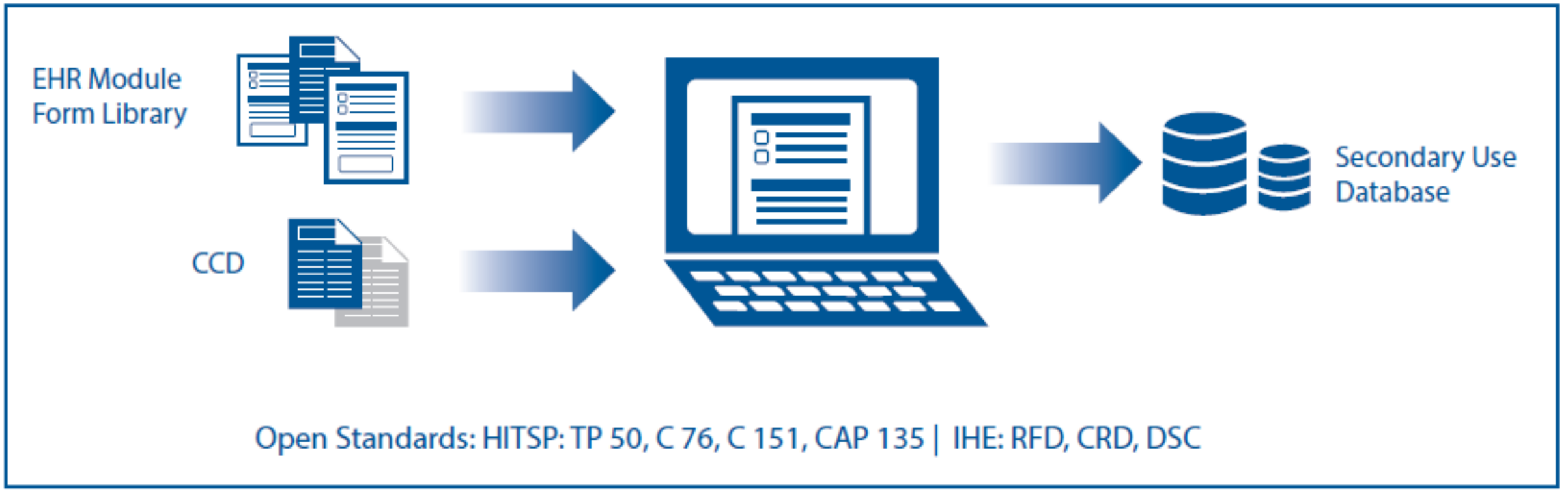
Patient-Reported Outcomes

- valid, reliable, responsive, interpretable, and translatable

Registry Data Map

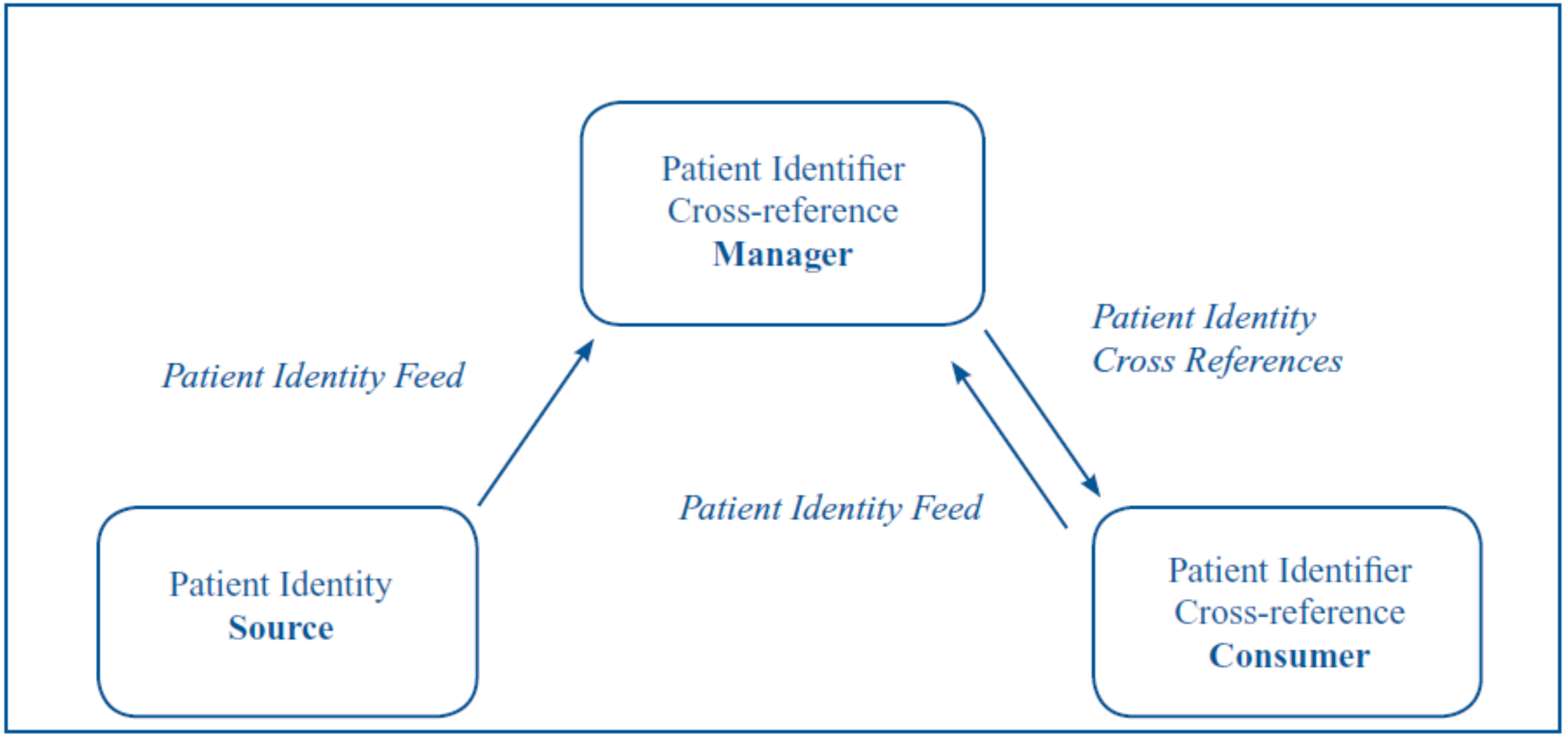
- The data map identifies all sources of data and explains how the sources of data will be integrated.
- Data maps are useful to defend the validity and/or reliability of the data, and they are typically an integral part of the data management plan

Figure 15–2. Retrieve form for data capture diagram



CAP = Capability; CCD = Continuity of Care Document; CRD = Clinical Research Data Capture; DSC = Drug Safety Content; EHR = Electronic Health Record; HITSP = Healthcare Information Technology Standards Panel; IHE = Integrating the Healthcare Enterprise; RFD = Retrieve Form for Data Capture; TP = Transaction Package.

Figure 17–1. Basic process flow with patient identifier cross-referencing



Use of Patient-Reported Outcomes in Registries

- Survival
- Quality of life

The key to successfully navigating this process is to clearly define the following aspects of the registry

- Population of interest
- Outcomes of interest
- Intended users of the registry
- The purpose(s) of the registry

Data Sources for Registries

- Primary data collection
- Existing databases

- Pharmacy database
- Disease and treatment information, such as details of the coronary anatomy and percutaneous coronary intervention from a catheterization
- Information system,
  - Electronic medical record,
  - Medical claims databases

Types of Data

- *Patient identifiers*
- *Patient selection criteria*
- *Treatments and tests—*
- *Confounders*
- *Outcomes*
- *Cost/resource utilization—*
- *Patient identifiers*
- *Disease/condition*
- *Treatment/therapy*
- *Laboratory/procedures*
- *Health care provider characteristics—*
- *Hospital/clinic/health plan—*
- *Insurance*

Data Sources

- Classified as primary or secondary

- Primary data sources are typically used when the data of interest are not available elsewhere or, if available, are unlikely to be of sufficient accuracy and reliability for the planned analyses and uses. Primary data collection increases the probability of completeness, validity, and reliability

- Secondary data sources are comprised of data originally collected for purposes other than the registry under consideration

Data from secondary sources may be used in two ways:

1. The data may be transferred and imported into the registry, becoming part of the registry database,
2. The secondary data and the registry data may be linked to create a new, larger data set for analysis

For secondary data useage

Questions to ask include:

- Is data collection passive or active?
- Are standard definitions or codes used in reporting data?
- Are standard measurement criteria or instruments used (e.g., diagnoses, symptoms, quality of life)?
- The existence and completeness of claims data, for example, will depend on insurance company coverage policies

Data Source

- Patient-reported data
- Clinician-reported data
- Medical chart abstraction
- Electronic health records (EHRs)
- Institutional or organizational databases
- Administrative databases
- Death indexes
- Census Bureau databases
- Existing registries
- Encounter-level databases

- SIB
- Death registry
- SEPAS
- HIM
- HIS
- Insurance
- …

Quality Assurance and Control

- ***Quality Assurance*:** Activities to ensure quality of data before data collection.
- ***Quality Control*:** Activities to monitor and maintain quality of data during the conduct of the study.

Types of errors in the registries

1. Errors in coding.
2. Errors in data entry, transfer, or transformation.
3. Errors in interpretation.
4. ....

Quality assurance activities

1. Quality assurance of data.
2. Quality assurance of registry procedures.
3. Quality assurance of computerized systems.

Quality Assurance

- Overall study protocol
- Operation manuals
- Instruments & procedures
- Training and certifying staff
- Pretest and pilot study

Measuring Quality

- Quality must be evaluated in the context of the data elements themselves and the methods used to generate evidence
- the essential elements

- quality scale;
- Each scale emphasizes distinctive dimensions of Some scales use a summary score,
- The weakness of most summary scoring approaches is that they ignore whether the items exert a bias toward the null

Quality component analysis

- This approach uses two domains:
- Research quality, which pertains to the scientific process (in this instance, the design and framework of registry operations) used to generate the registry data,
- Evidence quality, which relates to the findings derived from the registry and processes used, including data collection, site and patient recruitment, followup, data curation, safety reporting, etc., in the context of a given study purpose.

Quality Domains

- Quality domains address research methods and evidence separately

- For research methods, the quality domains are design, processes and procedures which should be considered in planning, design, selection of data elements and data sources, and ethics, privacy, and governance.

Registry Design-GOALS

Essential Elements of Good Practice

- Develop goals, objectives and/or research questions (main and supporting, as needed)

Enhancements

- Formalize the study plan as a research protocol.
- It may be helpful for external stakeholders to have input to ensure clinical relevance and feasibility

Registry Design-TARGET POPULATION

Essential Elements of Good Practice

- Describe the target population
- For registries that are intended to study effectiveness and safety, it is often desirable to study typical patients

Enhancements

- Where feasible, it is desirable to study diverse patients (few exclusion criteria) to facilitate analyses of subgroups.
- For studies of effectiveness and safety, use concurrent comparators,

Registry Design -OBSERVATION PERIOD

Essential Elements of Good Practice

- Describe the follow up time

Enhancements

- Consider whether longer-term follow up can be achieved through linkage with external data sources,

Registry Design -SIZE

Essential Elements of Good Practice

- Determine the desired number of patients and observation time required to detect an effect

Enhancements

- For studies of effectiveness and safety, use formal statistical calculations to estimate the number of patients or patient-years of observation

Registry Design-DATA

Essential Elements of Good Practice

- Determine which variables are critical to the registry purpose and which are desirable but not critical
- Use existing common data elements or other data standards, where appropriate, in the registry.
- Evaluate whether data in existing sources are of sufficient quality

Enhancements

- Use open standard approaches to interoperability
- Consider the collection of information to permit linkage with external databases
- Use the literature to inform the choice of data elements.

Registry Design -EXPOSURE

Essential Elements of Good Practice

- Determine appropriate exposure assessments
- For studies of a specific product(s), collect sufficient information to identify the product of interest, e.g., drug or biologic brand name or generic, code, device product and its universal device identifier (UDI), etc., as appropriate and feasible.

Enhancements

- Collect information on start and stop dates of treatments of interest and dose (if relevant) or other means to discriminate between high and low exposure.

Registry Design-OUTCOMES

Essential Elements of Good Practice

- Define patient outcomes clearly, especially for conditions or outcomes that may not have uniformly established criteria
- Use validated scales and tests when such tools exist for the purpose needed

Enhancements

- Endpoints that can be confirmed by an unbiased observer, such as death and test results,

Registry Design -EFFECT MODIFIERS & CONFOUNDERS

Essential Elements of Good Practice

- Identify important factors or characteristics that may influence response (effect modifiers or potential confounding factors), :
- other important exposures (treatment), medical history, other risk factors including personal habits, and qualifying (or protective) factors.

Enhancements

Registry Design - SAFETY

Essential Elements of Good Practice

- Consider what safety events, if any, need to be reported to satisfy regulatory requirements
- Develop appropriate reporting plans.

Enhancements

- Maintain appropriate documentation, such as an audit track,

Registry Design-ANALYSIS PLAN

Essential Elements of Good Practice

- Create a high-level data analysis plan to address the key objectives or research questions
- Determine how missing data will be handled for key variables.
- Describe how composite variables will be created.

Enhancements

- Develop formal analysis plans

Framework-ETHICS & DATA PROTECTION

Essential Elements of Good Practice

- Evaluate the issues of protection of human
- Obtain review and approval by any required oversight committees
- Identify appropriate personnel and facilities, including those for secure data storage.

Enhancements

- Appropriate methods for collecting and storing such protected health information.
- Integrity of the data, computerized and hard copy.

Framework -GOVERNANCE

Essential Elements of Good Practice

- Develop a clear, written plan for registry governance that specifies how registry decisions will be made and describes the roles of any external advisors.
- Define the role of any external sponsor, including data access, use, and rights to review, participate or approve any publications.

Enhancements

- Consider using an advisory committee(s)
- consider how decisions or recommendations will be agreed

Framework-TRANSPARENCY

Essential Elements of Good Practice

- Consider if, when, and how to allow third parties access to data, if feasible, and the process for any such data access.
- Plan how study results will be communicated on completion and whether the results will be made public,
- Consider posting information on a public registry of patient registries

Enhancements

- Specify publication policies

Framework-CHANGE PROCESS

Essential Elements of Good Practice

- Establish a process for documenting any modifications to the research plan,

Enhancements

- Develop plans for periodic review of analytic plans
- Develop a plan for stopping or transitioning the registry, including any archiving or transferring of data and notifying participants, as appropriate.

Methods: Data Collection, Curation, and Documentation -DATA COLLECTION

Essential Elements of Good Practice

- Use an efficient, reliable, and affordable means to collect data consistently of sufficient quality to meet the registry's purpose. Prioritize simplicity and accuracy to the extent feasible.
- Consider using tools for automated data extraction from existing records

Enhancements

Methods: Data Collection, Curation, and Documentation -SITE AND PATIENT RECRUITMENT AND FOLLOWUP

Essential Elements of Good Practice

- Methods for data collection should be documented.
- operational definitions of outcomes and other data elements.
- Develop standard instructions for use in training data collectors.
- create a process for identifying and reporting serious events that is consistent with regulatory requirements.
- For studies using existing data sources, use uniform and systematic methods

Enhancements

- use standardized data dictionaries, such as the International Classification of Diseases, and use coding that is consistent
- Methods used for data transformations should be recorded.
- For studies linking to or integrating existing data sources, document the process for record linkage and whether probabilistic or deterministic matching was used.

Methods: Data Collection, Curation, and Documentation-QUALITY ASSURANCE

Essential Elements of Good Practice

- Develop a data handling and analysis plan that describes any quality assurance and data curation activities that will be implemented.
- Data checks should use range and consistency
- Methods should be described for data curation, e.g., quality control procedures to enhance internal validity, review of consistency and comparability

Enhancements

- Quality assurance (QA) may include review or monitoring of a sample of data and/or data review
- For primary data collection, a sample of data collected should be compared with patient records
- If the registry chooses to implement a system of periodic monitoring for quality assurance,
- Establish processes and standards for creating analytic data files and maintaining such files to support publications and presentations,

Methods: Data Collection, Curation, and Documentation -OVERALL REPORTING

Essential Elements of Good Practice

- Registry reports or publications should describe the methods, including target population and selection of sites and study subjects, compliance
- Follow up time should be described to enable assessment of the impact of the observation period on the conclusions drawn
-

Enhancements

- Completeness of information on eligible patients should be evaluated and described for key variables of interest for the main exposures and/or outcomes of primary interest

Reporting-ANALYTICS

Essential Elements of Good Practice

- the main objectives, including estimates of effect for each (where relevant) and confidence intervals where feasible.
- For safety studies, the risks and/or benefits of products, devices, or processes
- The role and impact of missing data and potential confounding factors should be considered.
-

Enhancements

- transformation of variables and/or construction of composite endpoints and how missing data were handled Appropriate analytic approaches should be used to address confounding.
- Sensitivity analyses
- Selection bias should be evaluated
- characteristics of the actual population match those of the target population, and to whom the results apply.

Reporting-COMPARISONS

Essential Elements of Good Practice

- For comparative studies, comparators reflect medical practice

Enhancements

- External validity should be described by showing how registry participants compare to known characteristics of the target population

اسامی تیم کنترل کیفی دانشگاه علوم پزشکی شهید بهشتی

- خانم دکتر برزین (مسئول اصلی برنامه ثبت جراحی چاقی)
- خانم دکتر نعمت الهی (عضو تیم کمیته راهبردی برنامه ثبت اورولوژی ترمیمی)
- خانم دکتر کامفر (عضو تیم کمیته راهبردی برنامه های ثبت مرکز تحقیقات بیماری های خونی)
- خانم معینی (عضو تیم کمیته راهبردی برنامه ثبت تنگی نای)
- خانم سیفی (عضو تیم کمیته راهبردی مرکز تحقیقات عفونی اطفال)
- آقای حاجی پور (عضو تیم کمیته راهبردی پژوهشکده سلامت نوزادان)
- آقای دکتر هاشمی (عضو هیئت علمی گروه اپیدمیولوژی)
- خانم دکتر صباغی (عضو تیم کمیته راهبردی پژوهشکده چشم)
- آقای دکتر پناهی (عضو هیئت علمی گروه اپیدمیولوژی)
- خانم فلاح (کارشناس ثبت بیماری های دانشگاه)
- دکتر اعتماد (مسئول ثبت بیماری های دانشگاه، عضو هیئت علمی گروه اپیدمیولوژی)

ردیف	نام متغیر	نوع متغیر	نقش متغیر	تعریف عملی متغیر	نحوه و واحد اندازه‌گیری
۱	درصد اهداف قابل دستیابی	مستقل	کمی پیوسته	بررسی مطابقت اهداف با متغیرهای برنامه ثبت به منظور تعیین درصد اهداف قابل دستیابی	چک لیست– نمره
۲	درصد متغیرهای اضافی ثبت	مستقل	کمی پیوسته	بررسی مطابقت اهداف با متغیرهای برنامه ثبت به منظور تعیین درصد متغیرهای اضافی	چک لیست– نمره
۳	داشتن data dictionary	مستقل	کیفی اسمی	بررسی وجود فرمتی مشخص برای نام گذاری داده ها، تعریف و نحوه اندازه گیری آن ها	چک لیست– بلی، خیر
۴	وجود صورتجلسات بحث گروهی	مستقل	کیفی اسمی	بررسی وجود صورتجلسات بحث گروهی با حضور متخصصین مرتبط با برنامه ثبت جهت تدوین حداقل متغیرهای ضروری	چک لیست– بلی، خیر
۵	Routine data monitoring	مستقل	کیفی اسمی	مانیتورینگ دائم در نحوه ثبت اطلاعات	چک لیست– بلی، خیر
۶	درصد کامل بودن متغیرهای ثبت	مستقل	کمی پیوسته	انتخاب ۲۰ بیمار به صورت تصادفی از روی Data Bank به منظور بررسی درصد ثبت کامل تمام متغیرها و انتخاب ۴ متغیر به صورت تصادفی به منظور بررسی اینکه هر متغیر برای چند درصد افراد تکمیل شده است (در ثبت اولیه و پیگیری)	چک لیست– نمره
۷	وجود ثبات در تعداد متغیرها	مستقل	کیفی اسمی	بررسی مطابقت تعداد متغیرهای پرسشنامه موجود در پروپوزال، پرسشنامه فعلی و Data Bank	چک لیست– بلی، خیر

۸	وجود پیوستگی در تعداد متغیرها	مستقل	کیفی اسمی	بررسی مطابقت تعداد متغیرهای قابل جمع آوری در پرسشنامه موجود در پروپوزال، پرسشنامه فعلی و Data Bank	چک لیست– بلی، خیر
۹	وجود ثبات و پیوستگی در نام گذاری متغیرها	مستقل	کیفی اسمی	بررسی ۴ متغیر از پرسشنامه موجود در پروپوزال، پرسشنامه فعلی و Data Bank	چک لیست– بلی، خیر
۱۰	وجود ثبات در اندازه گیری متغیرها	مستقل	کیفی اسمی	بررسی ۴ متغیر از پرسشنامه موجود در پروپوزال، پرسشنامه فعلی و Data Bank	چک لیست– بلی، خیر
۱۱	وجود اعتبار داخلی	مستقل	کیفی اسمی	بررسی وجود معیارهایی برای جلوگیری از ثبت موارد تکراری	چک لیست– بلی، خیر
۱۲	درصد موارد تکراری ثبت شده	مستقل	کمی پیوسته	بررسی تمام موارد ثبت شده در Data Bank به منظور یافتن درصد موارد تکراری	چک لیست– نمره
۱۳	وجود کدگذاری استاندارد بین المللی در ثبت متغیرها	مستقل	کیفی اسمی	بررسی مطابقت نام گذاری ۴ متغیر ثبت با استانداردهای بین المللی بر مبنای مستندات موجود	چک لیست– بلی، خیر
۱۴	درصد پوشش موارد ثبت شده	مستقل	کمی پیوسته	بررسی مطابقت تعداد موارد ثبت شده در مدارک پزشکی و Data Bank در بازه زمانی معین به منظور تعیین درصد پوشش موارد ثبت شده	چک لیست– نمره
۱۵	تناسب ترکیب ساختار مدیریتی ثبت با اهداف ثبت	مستقل	کیفی اسمی	بررسی ترکیب ساختار مدیریتی ثبت با توجه به اهداف برنامه ثبت	چک لیست– بلی، خیر
۱۶	وجود برنامه عملیاتی	مستقل	کیفی اسمی	بررسی وجود برنامه عملیاتی	چک لیست– بلی، خیر
۱۷	همخوانی برنامه عملیاتی با اهداف ثبت	مستقل	کیفی اسمی	بررسی مطابقت تعداد موارد ثبت شده در پروپوزال و برنامه عملیاتی	چک لیست– بلی، خیر
۱۸	برگزاری کلاس آموزشی	مستقل	کیفی اسمی	بررسی برگزار شدن کلاس آموزشی	چک لیست– بلی، خیر

۱۹	درصد گواهی های آموزشی صادرشده	مستقل	کمی پیوسته	تعیین درصد گواهی آموزشی صادر شده برای مسئول اصلی ثبت، مدیر اجرایی، اعضای کمیته راهبردی و افراد دخیل در ثبت داده ها، آنالیز و گزارش	چک لیست– نمره
۲۰	وجود پروتکل اجرایی برنامه ثبت	مستقل	کیفی اسمی	بررسی وجود پروتکل اجرایی برنامه ثبت	چک لیست– بلی، خیر
۲۱	وجود دستورالعمل رعایت اصول اخلاقی و محرمانگی اطلاعات	مستقل	کیفی اسمی	بررسی وجود دستورالعمل رعایت اصول اخلاقی و محرمانگی اطلاعات	چک لیست– بلی، خیر
۲۲	وجود صورتجلسه کمیته راهبردی	مستقل	کیفی اسمی	بررسی وجود صورتجلسه کمیته راهبردی	چک لیست– بلی، خیر
۲۳	درصد حضور اعضای کمیته راهبردی در جلسات	مستقل	کمی پیوسته	بررسی صورتجلسه کمیته راهبردی به منظور تعیین درصد حضور تمام اعضا و مراکز همکار در جلسه	چک لیست– نمره
۲۴	درصد پیگیری های انجام شده	مستقل	کمی پیوسته	بررسی ۲۰ بیمار به صورت تصادفی به منظور مشخص شدن درصد پیگیری های انجام شده	چک لیست– نمره
۲۵	همخوانی حجم نمونه ثبت شده و پیش بینی شده	مستقل	کیفی اسمی	بررسی مطابقت تعداد موارد ثبت شده در پروپوزال و **Data Bank**	چک لیست– بلی، خیر
۲۶	وجود تفاهم نامه های منعقدشده	مستقل	کیفی اسمی	بررسی وجود تفاهم نامه	چک لیست– بلی، خیر
۲۷	تعداد تفاهم نامه های منعقدشده	مستقل	کمی گسسته	بررسی تعداد تفاهم نامه های داخلی و خارجی	چک لیست– تعداد
۲۸	وجود نرم افزار	مستقل	کیفی اسمی	بررسی وجود نرم افزاری با قابلیت های لازم در یک نظام مراقبت	چک لیست– بلی، خیر
۲۹	وجود اعتبار داخلی در نرم افزار	مستقل	کیفی اسمی	بررسی نرم افزار از نظر دارا بودن اعتبار داخلی	چک لیست– بلی، خیر
۳۰	Interpretation errors	مستقل	کیفی اسمی	خطا در تفسیر داده ها	چک لیست– بلی، خیر
۳۱	Documentation errors	مستقل	کیفی اسمی	خطا در ذخیره سازی اطلاعات	چک لیست– بلی، خیر
۳۲	Data transcription (typing error)	مستقل	کیفی اسمی	خطا در انتقال داه ها روی سرور (خطای تایپ)	چک لیست– بلی، خیر

۳۳	همخوانی گزارشات منتشرشده با اطلاعات موجود	مستقل	کیفی اسمی	بررسی مطابقت گزارشات منتشرشده با اطلاعات موجود (مدارک پزشکی، Data Bank، گزارشات منتشر شده)	چک لیست- بلی، خیر
۳۴	تعداد گزارشات ارسالی	مستقل	کمی گسسته	تعداد گزارشات سالانه دریافتی	چک لیست- تعداد
۳۵	وجود پروتکل کنترل کیفی	مستقل	کیفی اسمی	بررسی وجود پروتکل کنترل کیفی	چک لیست- بلی، خیر
۳۶	وجود گزارشات کنترل کیفی	مستقل	کیفی اسمی	بررسی وجود گزارشات و مستندات کنترل کیفی	چک لیست- بلی، خیر
۳۷	وجود پروتکل دسترسی به داده های ثبت	مستقل	کیفی اسمی	بررسی وجود پروتکل سطوح دسترسی هر کاربر به داده های ثبت	چک لیست- بلی، خیر
۳۸	کنترل کیفیت	وابسته	کمی پیوسته	فرآیند چگونگی ثبت اطلاعات در برنامه ثبت بر مبنای ارزش گزاری کیفیت داده ها	چک لیست- نمره

Development and evaluation of a customized checklist to assess the quality control of disease registry systems of Tehran, the capital of Iran in 2021

Maryam Barzin[1†], Hamideh Sabbaghi[2,3†], Sharareh Kamfar[4], Atena Seifi[5], Mahmoud Hajipour[6], Fatemeh Hadavand Siri[7], Elham Mir-Moeini[8], Anis Gharajeh[6], Nasrin Ferdosifard[7], Mohammadhossein Panahi[9], Seyed Saeed Hashemi Nazari[10], Fatemeh Fallah Atatalab[6*] and Koorosh Etemad[9,11*]

Methods

The present study had a mixed-method design and was conducted in two consecutive qualitative and quantitative phases. In the qualitative phase, a checklist was developed to assess the QC of 49 active DRSs established by the research centers, hospitals, and educational departments affiliated with the Shahid Beheshti University of Medical Sciences (SBMU). In these DRSs, the data were launched using unique and standard software, and crude data were transferred from actively supervised registries approved by SBMU. Registries with no recorded data were excluded.

Title of the registry program:				
The main registry corresponding:			Executive director of registry:	
Registry type: Regional national international			Date of approval in the University Research Council:	
Registry workplace:			The number of cooperator centers:	
Visit date: Enter and exit time:			Names of the evaluation team	
Row	Score	Question	Responses	
1	20	Does the collection of health consequences/problems match the scientific and practical definition provided in the proposal?	Yes No	
2	25	What percentage of the goals of the registry the program has the required variables?	The number of goals that have the required variables: The total number of goals: Percent:	
3	15	What percentage of variables are additional?	The number of additional variables: Total number of variables: Percentage:	
4	30	Does it have a data dictionary?	Yes No	
5	10	Are the minutes of group discussion available to determine the minimum necessary registry variables?	Yes No	
6	50 30 20	In what percentage of recorded cases is the data of all variables fully recorded?	Initial registry 30	The number of complete cases: Total number of registered cases: Percentage:
			Follow up 20	The number of complete cases: Total number of registered cases: Percentage:

7	50 30 20	What percentage of each variable is completed?	Initial registry 30	Number of completed cases: Total number of registered cases: Percentage:
			Follow up 20	Number of completed cases Total number of registered cases: Percentage:
8	25	Is there internal credit for recording duplicates?	Yes	No
9	40 15 10 10 5	Are the registry variables defined and recorded based on international standard coding systems?	Diagnosis	Yes No
			Complaints and symptoms of the disease	Yes No
			Complaints and symptoms of the disease	Yes No
			Medicinal	Yes No
10	10	To what extent is the composition of the registry management structure in line with the goals of the program?	1 2	3 4 5
11	30	Is there an operational plan?	Yes	No
		15	Does the registry action plan consistent with the intended objectives? Yes No	
		15	What percentage of the operational plan goals have been achieved? Percent:	
12	10	Has a training class been held? Subject to the issuance of an educational certificate	Yes	No

13	30	Is the executive protocol of the registry program available?	Yes No
14	20	Are the standards used in the Executive Protocol for collecting main variables in line with international standards?	Yes No
15	10	Are there any guidelines for ethics and confidentiality of information?	Yes No
16	10	Is the Strategic Committee meeting held at least once a year	Yes No What percentage of the members of the Strategic Registry Committee were present at the meetings? The number of members present: Total number of members: Percentage:
17	20	What percentage of routine follow-ups are done for each person?	The number of follow-ups: The number of follow-ups required: Percentage:
18	25	Is the number of registered samples based on the predicted sample size in the population and the specified time?	1 2 3 4 5
19	30	Does it have an agreement?	Yes No
	30	Number of memoranda of understanding concluded between partner centers	National:10 International:20
20	90	Is there software with the necessary capabilities in a surveillance system?	Yes No
		10	Is it possible to validate the data when
			registering? Yes No

		5	Is it possible to display questions based on the answers to previous questions? Yes No
		5	Is it possible to display answer choices based on the answers to previous questions? Yes No
		5	Does the software have data quality assessment tools? Yes No
		5	Is it possible to control access levels at the questionnaire level? Yes No
		5	Is it possible to control access levels in operations? Yes No
		5	Is it possible for the project manager to monitor the data collection process? Yes No
		5	Are authentication and licensing following existing secure procedures? Yes No
		10	Is it possible to make a backup? Yes No
		10	Is sensitive information encrypted? Yes No
		5	Are the operation statement and change history recorded in the system? Yes No
		10	Is it possible to report and download data? Yes No

		5	Are the operation statement and change history recorded in the system? Yes No
		10	Is it possible to report and download data? Yes No
		5	Does the software have the ability to be flexible and dynamic? Yes No
		5	Does the software have the necessary infrastructure to exchange with other health systems? Yes No
21	50	Do the published reports match the available information?	Yes No
22	10	What percentage of the required reports have been sent to the University Disease Registry Unit	The number of reports received: The number of reports required: Percentage:
23	10	Is there a protocol for different users to access the registry data?	Yes No

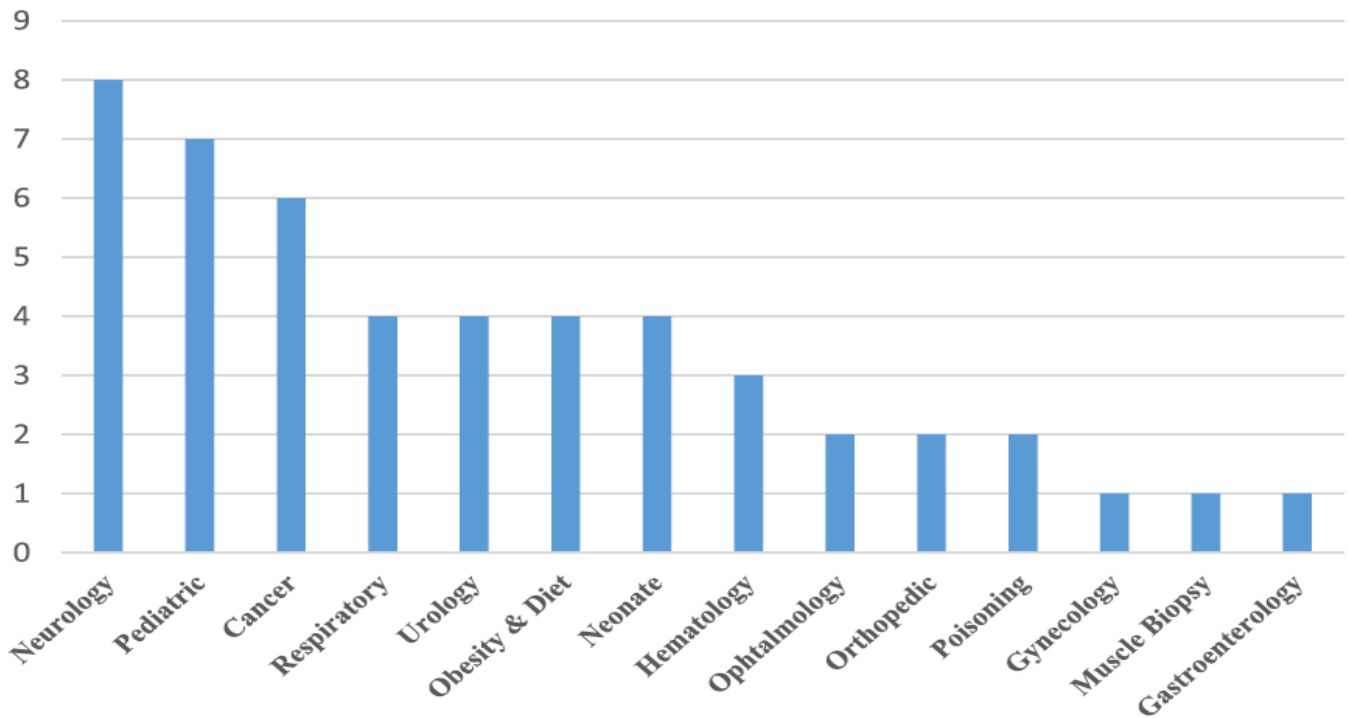


Fig. 1 Registries established by Shahid Beheshti University of Medical Sciences, Iran, in different health fields

Table 3 Total score and rank obtained of disease registry programs of Shahid Beheshti University of Medical Sciences in 2021

Serial No	Registry program title	Total score	Score of 100	Ranking
#42	Data registry of Hematopoietic Stem Cell Transplantation in pediatrics group (0–18 years old)	625	96.1	1
#22	A national registry system for patients undergoing reconstructive urologic procedures	625	96.1	1
#43	Regional Registry of Pediatric Immune Thrombocytopenic Purpura	615	94.6	2
#44	Registry of thromboembolism events in pediatrics group (up to15 years)	605	93.1	3
#40	Registry system for evaluation of the malnutritional status of children and adolescents hospitalized in Iran (1 month to 18 years)	605	93.1	3
#36	Pediatric Liver Failure (pALF) Registration System in Iran	605	93.1	3
#41	Registration of patients in Tehran Obesity Treatment Center	605	93.1	3
#2	Iranian Registry of Patients with Spinal Muscular Atrophy (SMA)	605	93.1	3
#10	Breast cancer clinical registry in Iran	600	92.3	4
#39	Registry system for evaluation of childhood Obesity in Iran	590	90.1	5
#20	Recurrent Urinary Tract Infection in Children	585	90.0	6
#12	Monitoring of intra-oral potentially malignant disorders	585	90.0	6

Original Article

Journal of INTERNAL MEDICINE

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doi: 10.1111/joim.12303

Review of 103 Swedish Healthcare Quality Registries

L. Emilsson[1,2,3], B. Lindahl[4], M. Köster[5], M. Lambe[6,7] & J. F. Ludvigsson[6,8]

From the [1]Primary Care Research Unit, Vårdcentralen Värmland's Nysäter, Värmland County; [2]School of Health and Medical Sciences, Örebro University, Örebro, Sweden; [3]Department of Health Management and Health Economy, Institute of Health and Society, University of Oslo, Oslo, Norway; [4]Department of Medical Sciences, Cardiology, and Uppsala Clinical Research Center, University of Uppsala, Uppsala; [5]National Board of Health and Welfare; [6]Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm; [7]Regional Cancer Centre, Uppsala; and [8]Department of Paediatrics, Örebro University Hospital, Örebro, Sweden

Abstract. Emilsson L, Lindahl B, Köster M, Lambe M, Ludvigsson JF (Vårdcentralen Värmlands Nysäter, Värmland County; School of Health and Medical Sciences, Örebro University, Sweden; Institute of Health and Society, University of Oslo, Norway; University of Uppsala, Uppsala; National Board of Health and Welfare, Stockholm; Karolinska Institutet, Stockholm; Regional Cancer Centre, Uppsala; and Örebro, Sweden). Review of 103 Swedish Healthcare Quality Registries. *J Intern Med* 2015; **277**: 94–136.

Background and objectives. In the past two decades, an increasing number of nationwide, Swedish Healthcare Quality Registries (QRs) focusing on specific disorders have been initiated, mostly by physicians. Here, we describe the purpose, organization, variables, coverage and completeness of 103 Swedish QRs.

Methods. From March to September 2013, we examined the 2012 applications of 103 QRs to the Swedish Association of Local Authorities and Regions (SALAR) and also studied the annual reports from the same QRs. After initial data abstraction, the coordinator of each QR was contacted at least twice between June and October 2013 and asked to confirm the accuracy of the data retrieved from the applications and reports.

Results. About 60% of the QRs covered ≥80% of their target population (completeness). Data recorded in Swedish QRs include aspects of disease management (diagnosis, clinical characteristics, treatment and lead times). In addition, some QRs retrieve data on self-reported quality of life (EQ5D, SF-36 and disease-specific measures), lifestyle (smoking) and general health status (World Health Organization performance status, body mass index and blood pressure).

Conclusion. Detailed clinical data available in Swedish QRs complement information from government-administered registries and provide an important source not only for assessment and development of quality of care but also for research.

Keywords: adult, child, life quality, morbidity, register, registry.

با تشکر

واحد ثبت بیماری ها

دانشگاه علوم پزشکی شهید بهشتی

Website
dregistry.sbmu.ac.ir

Email
dregistry@sbmu.ac.ir