Health Information Technology in Disease Registry

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Course Objectives

“The illiterates of The 21st century are not those who can’t write and read but those who are not able to learn, get rid of old learnings, and learn again”

Alvin Toffler

01

Registry Basics

Registry Basics

Registry Basics

- Why Have a Clinical Data Registry?
- Definition of registry
- Aim of registry
- Registry classification
- Advantages and disadvantages of registry data
- Impact of registries
- What data is collected in the registry?
- How is the registry data used?

Definition of registry

An organized system that collects, analyses, and disseminates the data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purposes.

In brief
a patient registry is

a collection
of standardized information
for one or more purposes

about a group of
patients who share a
condition or experience

Aim of registry

- به طور کلی اهداف رجیستری در دو دسته کلی اهداف مراقبتی و اهداف تحقیقاتی جای می‌گیرد:
- **اهداف مراقبتی**
- اهداف مراقبتی رجیستری شامل موارد زیر است:
- تعیین بروز و شیوع بیماری یا مواجهه خاص یا سایر پیامدهای بهداشتی
- بررسی روند تغییرات در طول زمان
- ارزیابی کیفیت خدمات و مراقبت بیماران

Aim of registry

- **اهداف تحقیقاتی**

- می‌توان از داده های رجیستری در جهت انجام تحقیقات استفاده کرد. ازجمله این تحقیقات می‌توان به آنالیز بقا، مطالعات کارآزمایی بالینی، مطالعات مورد – شاهد و کوهورت اشاره کرد. مطالعات کوهورت و مورد شاهد به شناسایی عوامل بیماری‌ها کمک می‌کنند.

Why create a Registry?

Why create a Registry?

Impact of Registries

01 Improve survival in lung cancer and colon cancer

02 Improve compliance with guidelines for diabetes care

03 Improve the success of smoking cessation counseling

04 Reduce use of antibiotics in ulcer treatment

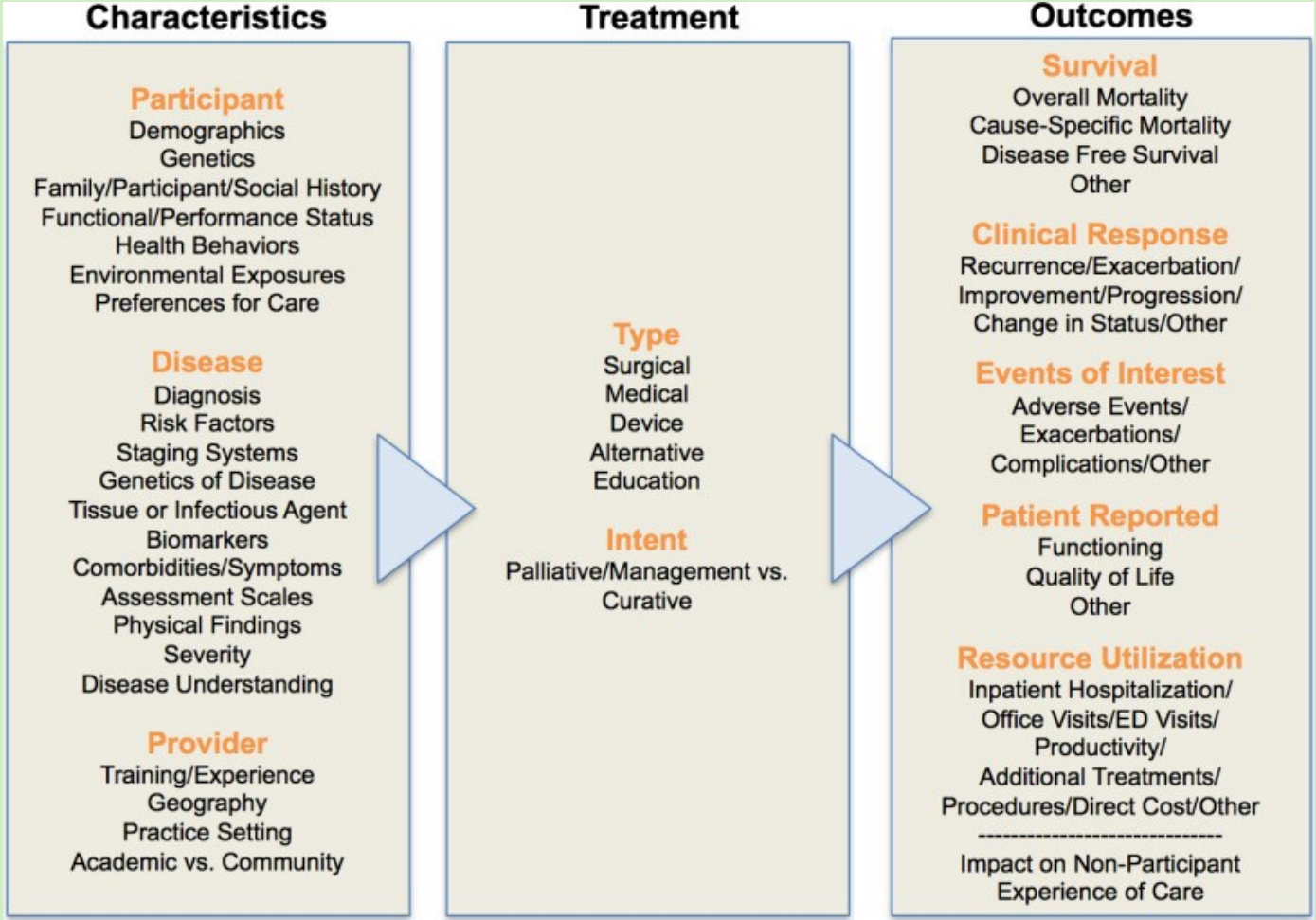
05 Reduce post-surgical infections


RESEARCH ARTICLE

Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review

Dewan Md Emdadul Hoque[1,2]*, Varuni Kumari[1], Masuma Hoque[1], Rasa Ruseckaite[1], Lorena Romero[1], Sue M. Evans[1]

What Data is Collected in the Registry?



Registry classification

Category	Diseases and conditions	Products	Services, events
Object type	chronic, acute communicable, rare diseases, disabilities, cause of death	medicines, devices, equipment	diagnostic, curative, preventive, discharges, births, abortions
Purposes / objectives (primary and secondary)	disease surveillance, control, natural course of disease	post-market surveillance	intervention evaluation, quality of care
	health outcomes (objective, patient reported)		
	effectiveness (clinical, comparative, financial)		
	safety and harm (HTA, vigilance)		
	intervention (planning, guidelines, reminders)		
Coverage (geographical and organizational)	health care unit (GP, hospital)		
	local (counties, districts, insurers, professional associations, NGOs)		
	national (MS, non-MS)		
	international (regional, EU, European region, global)		
Population definition	population (geographically based)[3]		
	population based (exposition dependent)[4]		
Observation unit	patient (user, client, insured party)		
	person with a characteristic of observation	person related device, equipment item	person related event (birth, death, service)

Disease or Condition Registries

Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure, or the same group of conditions such as disability.

Aims of Disease Registries

The aims of disease or condition registries are most often primarily descriptive, such as describing the typical clinical features of individuals with a disease, variations in phenotype, and the clinical progression of the disease over time (i.e. natural course of the disease)

The Value of Disease Registries

The value of disease registries is increasingly recognized as they are able to provide historically comparable data and long-term evaluation, potentially serving as an addition to randomized clinical trials, and thus providing insights about real-sites outcomes that could not be addressed in the limited controlled studies.

Product Registries

Product registries

include patients who have been exposed to biopharmaceutical products, medical devices or diagnostic/therapeutic equipment

Product Registries

Registries that aim to assess safety or harm associated with the use of various products (drugs) or devices need to anticipate and assess the need for adverse event (AE) detection, processing, and reporting.

Health Services Registries

Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization.

The focus of health service registries is on providing information used in the management of health services.

Hospital discharge data are a specific type of health service registry data.

- **انواع رجیستری برطبق محتوا**
- رجیستری بیماری یا عارضه خاص
- رجیستری مواجهه با یک عامل خاص
- رجیستری ثبت خدمات بهداشتی درمانی
- سایر پیامدهای بهداشتی
- **انواع رجیستری بر حسب گستره جغرافیایی**
- رجیستری بیمارستانی
- رجیستری مبتنی بر جمعیت

Data Imputing Formats

Manual

Data manually inputted onto paper or a computer database or spreadsheet or into a web based program

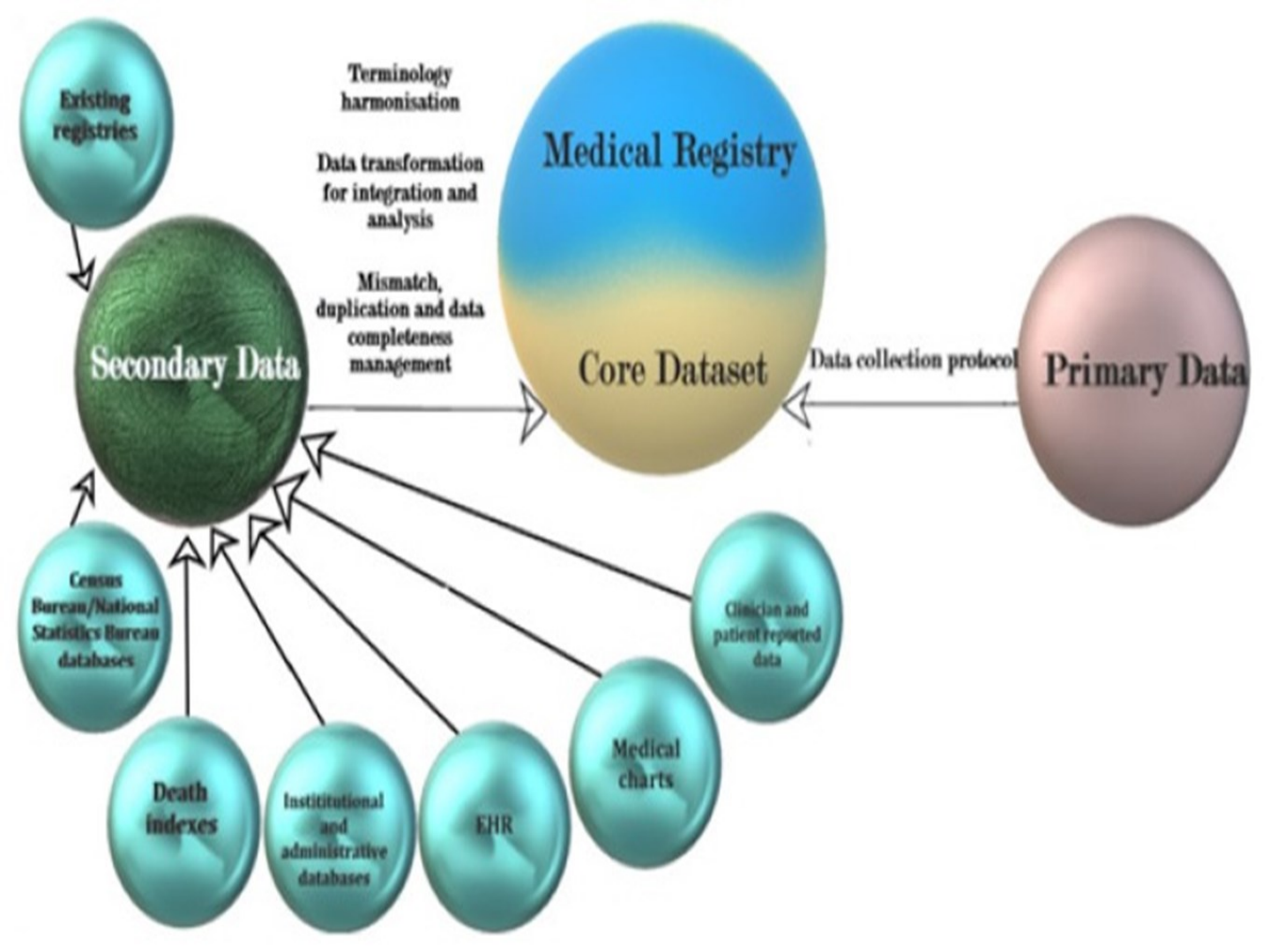
Automatic

Data automatically inputted into standalone software or web based site using client-server software and integrated with, for example, a laboratory result program using LOINC and HL7 standards

Automated and integrated

Data input, retrieval, tracking and graphing are all automatic and part of an electronic health record. This is the least common scenario currently but is felt to have great potential in disease management program.

Data Source


Existing registries
Terminology harmonisation
Data transformation for integration and analysis
Mismatch, duplication and data completeness management
Medical Registry
Core Dataset
Secondary Data
Data collection protocol
Primary Data
Census Bureau/National Statistics Bureau databases
Death indexes
Institutional and administrative databases
EHR
Medical charts
Clinician and patient reported data

شناسایی و ارزیابی منابع داده های مناسب باید در چارچوب هدف رجیستری و در دسترس بودن داده ها مورد علاقه انجام شود.

یک رجیستری واحد ممکن است چندین هدف داشته باشد و داده ها را از منابع مختلف دریافت و ترکیب شوند.

داده های اولیه: شامل داده هایی که به طور مستقیم برای اهداف رجیستری جمع آوری می شوند.

داده های ثانویه: شامل اطلاعات مهمی که می توانند از پایگاههای داده موجود به رجیستری منتقل شوند.

منابع داده اولیه

- شامل اطلاعات جمع آوری شده برای اهداف مستقیم رجیستری هستند.
- منابع داده اولیه معمولاً هنگامی استفاده می شود که:
  - داده های مورد علاقه در جای دیگری قابل دسترسی نباشند.
  - یا در صورت وجود، بعید به نظر می رسد دقت و اعتبار کافی برای تجزیه و تحلیل و استفاده را دارا باشند.
- جمع آوری داده های اولیه، احتمال کامل بودن، اعتبار و قابلیت اطمینان را افزایش می دهد، زیرا تیم رجیستری روش های اندازه گیری و جمع آوری داده ها را در اختیار دارد.

منابع داده ثانویه

- شامل داده هایی هستند که در ابتدا برای اهداف غیر از رجیستری مورد بررسی، جمع آوری شده اند(به عنوان مثال، پردازش مطالبات بیمه)
- داده هایی که به عنوان داده های اولیه برای یک رجیستری جمع آوری می شوند، در صورت لینک با یک رجیستری دیگر به عنوان اطلاعات ثانویه برای رجیستری دوم در نظر گرفته می شوند.

منابع داده ثانویه

داده های منابع ثانویه می تواند به دو روش مورد استفاده قرار گیرد:

- داده ها ممکن است منتقل و به رجیستری وارد شده و بخشی از پایگاه داده رجیستری شوند.
- داده های ثانویه و داده های رجیستری به هم مرتبط شده برای ایجاد یک مجموعه داده جدید بزرگتر برای تجزیه و تحلیل.

منابع داده ثانویه

هنگامی که داده ها از منابع ثانویه مورد استفاده قرار می گیرند، توافقات باید:

- مالکیت داده های منبع را مشخص کرده و به طور واضح اجازه استفاده از داده توسط رجیستری گیرنده را بدهند.
- این قراردادها باید نقش های هر موسسه، مسئولیت های قانونی آن و هر گونه مسائل نظارتی را مشخص نماید.
- مهم است که این مسائل و توافقات قبل از انتقال داده انجام شوند به طوری که هیچ گونه ابهامات یا محدودیت های پیش بینی نشده در رجیستری گیرنده وجود نداشته باشد.

منابع داده ثانویه

برخی از رجیستری ها ممکن است مایل باشند داده ها را از بیش از یک کشور وارد کنند. در این موارد، مهم است که اطمینان حاصل شود که داده ها با روش مشابه در هر کشور جمع آوری می شوند یا برای هر تبدیل مورد نیاز برنامه ریزی انجام شده باشد.

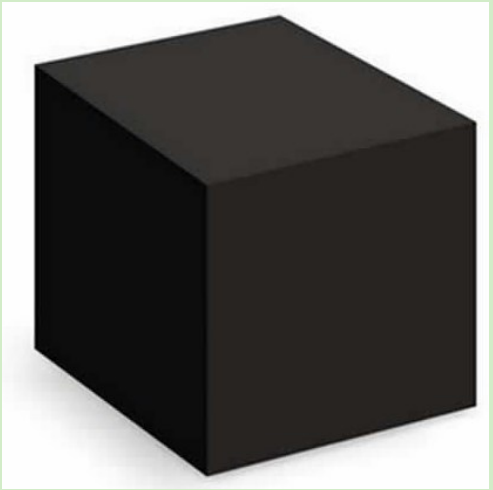
منابع داده ثانویه

به عنوان مثال:

- به احتمال زیاد واحدهای داده های ارتفاع و وزن جمع آوری شده از سایت ها در اروپا نسبت به داده های ارتفاع و وزن جمع آوری شده از سایت های ایالات متحده متفاوت خواهد بود.
- نتایج آزمون آزمایشگاهی نیز ممکن است از طریق واحدهای مختلف گزارش شوند.
- ممکن است انواع مختلفی از محصولات دارویی و تجهیزات پزشکی که برای استفاده در کشورهای شرکت کننده مورد تایید قرار می گیرند، متفاوت باشد.

How is the Registry Data Used?

How is the Registry Data Used?(cont.)



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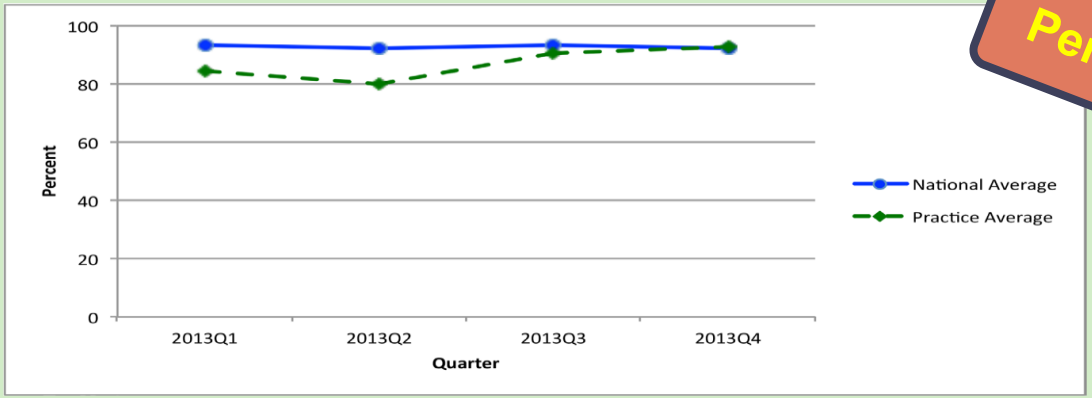
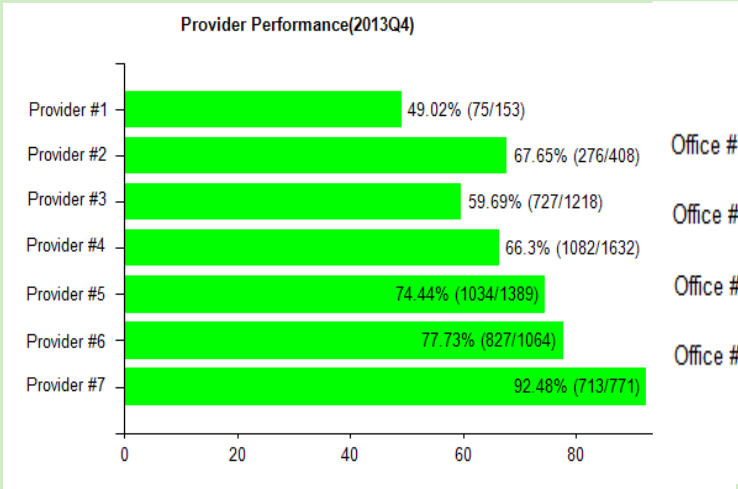
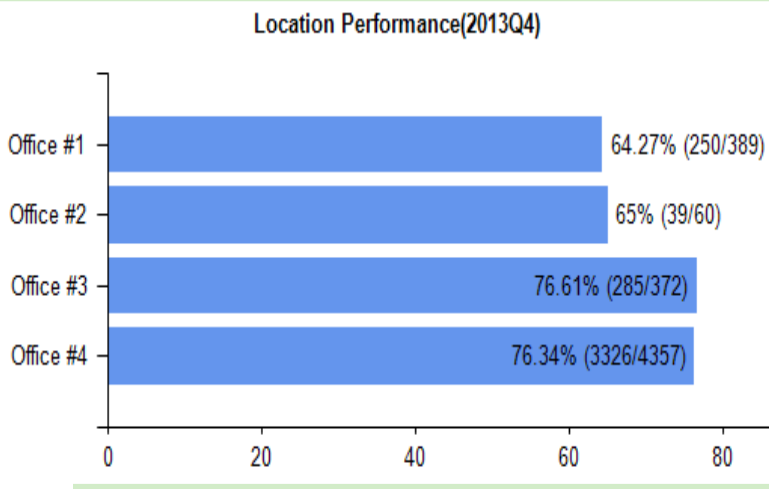
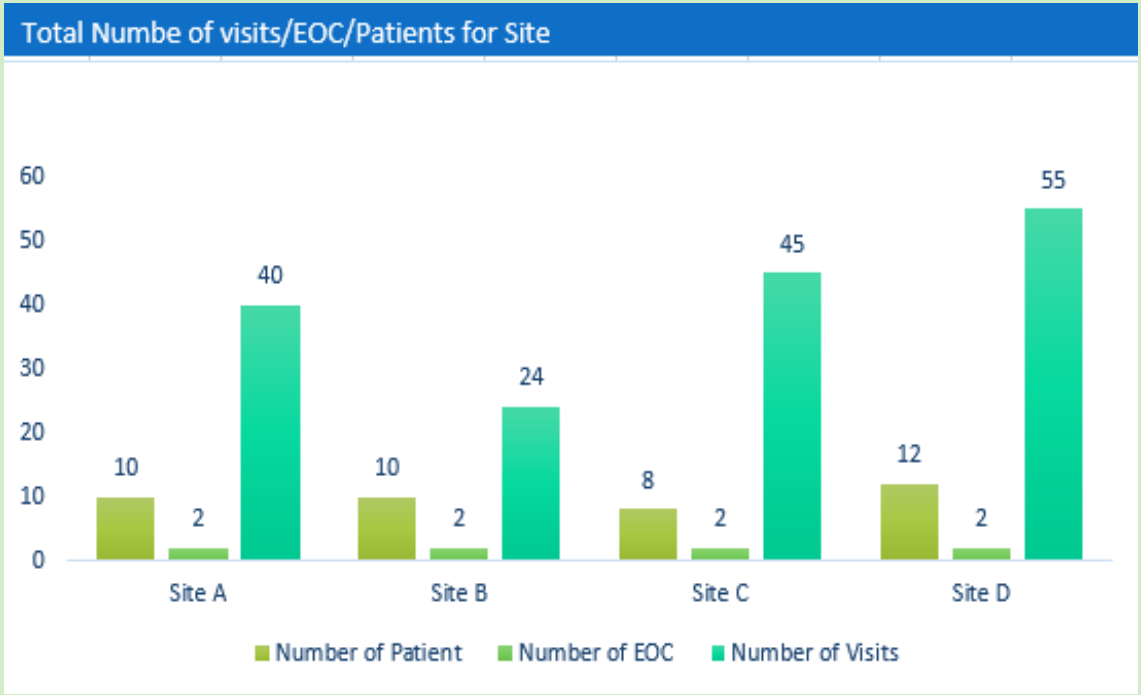


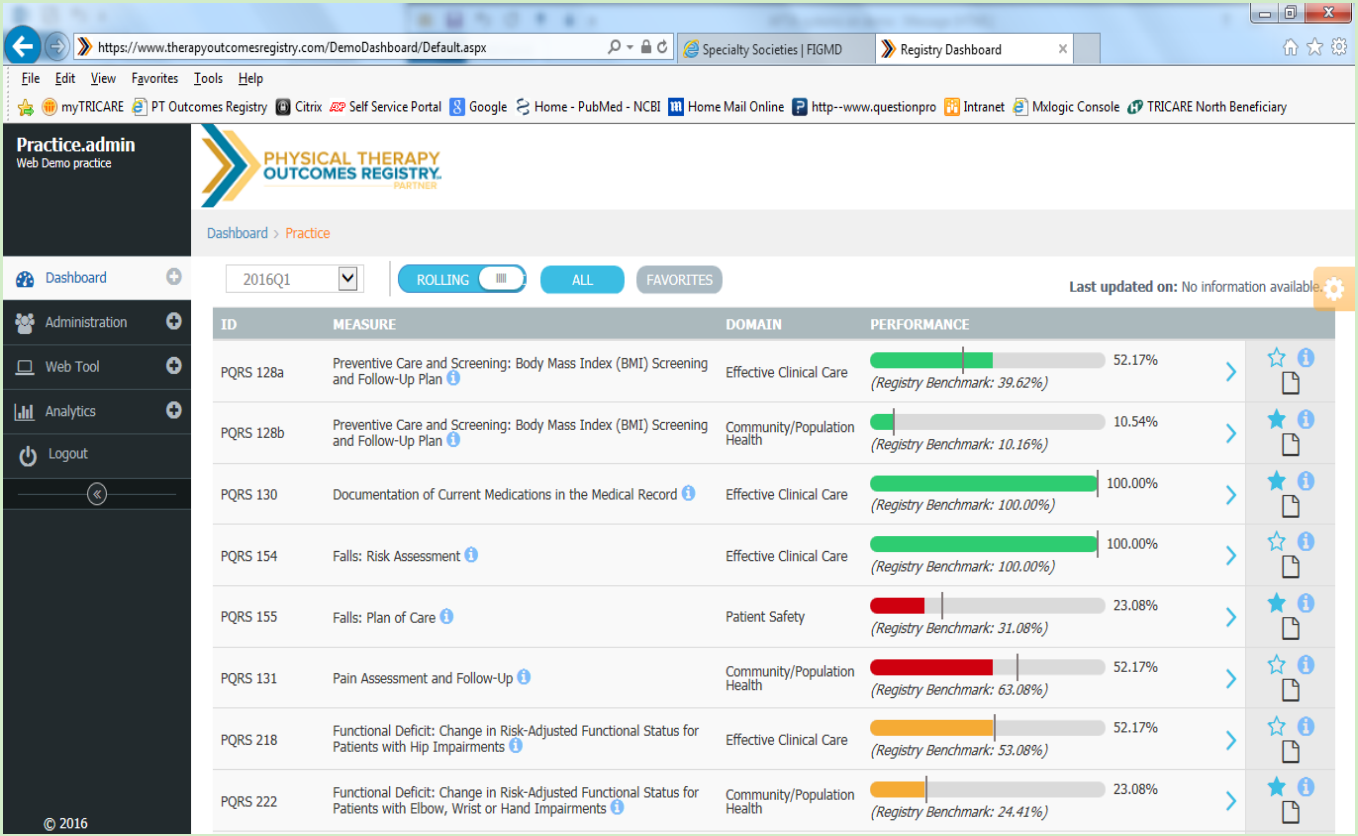




Identifying Variations in Practice



Quality Measure Benchmarking



Determining Clinical Practice Patterns

Ensure utilization of guidelines

- Quality measures that focus on clinical activities included in the CPGs (must do's or must avoid)

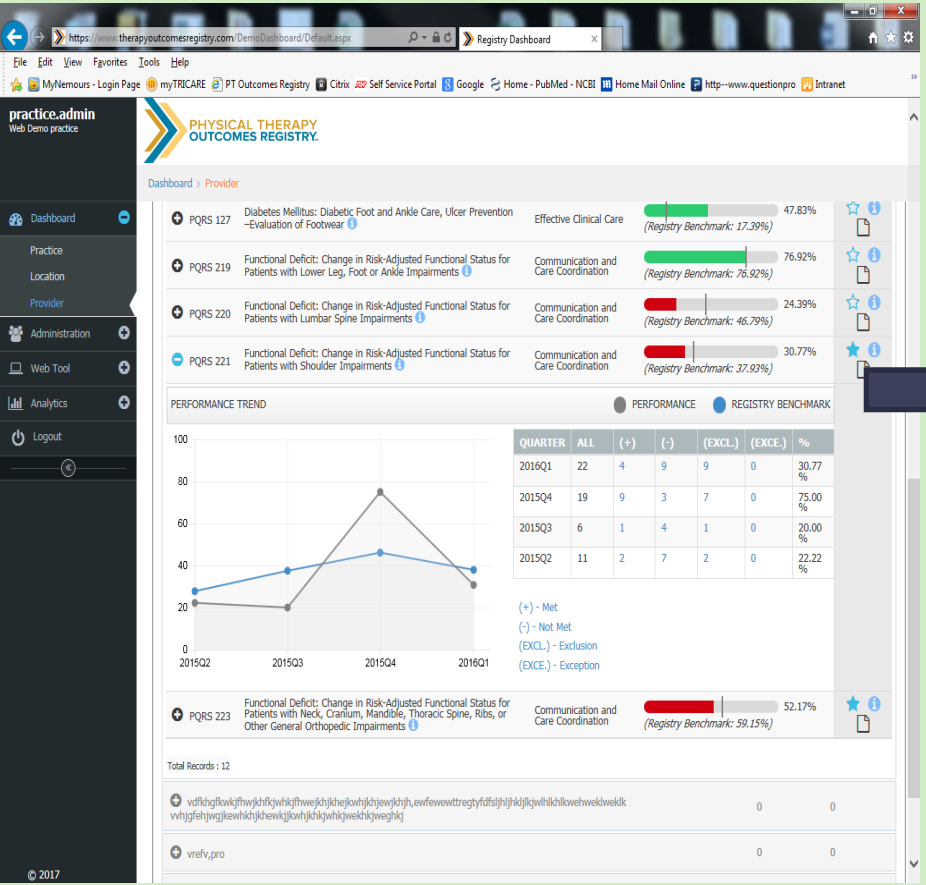
Analyze outcomes for population

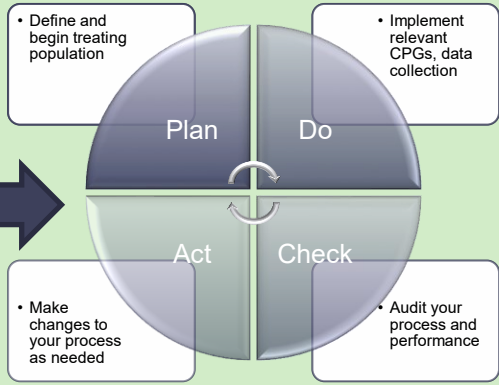
- Determine how adherence to CPG impacts patient outcomes

Inform CPG changes

- In addition to scientific publications, clinical data will help to evolves future CPGs

Performance Improvement and Feedback





Advantages and disadvantages of registry data

Registry Advantages

- Flowsheet is a powerful tool to monitor clinical data and track trends
- Provides a dashboard of who needs what
- Provides total population data reporting with no chart abstraction
- Generates revenue (it shows when services are needed)
- Provides outreach information at fingertips
- Improves team-based care
- Smaller software package than EHRs

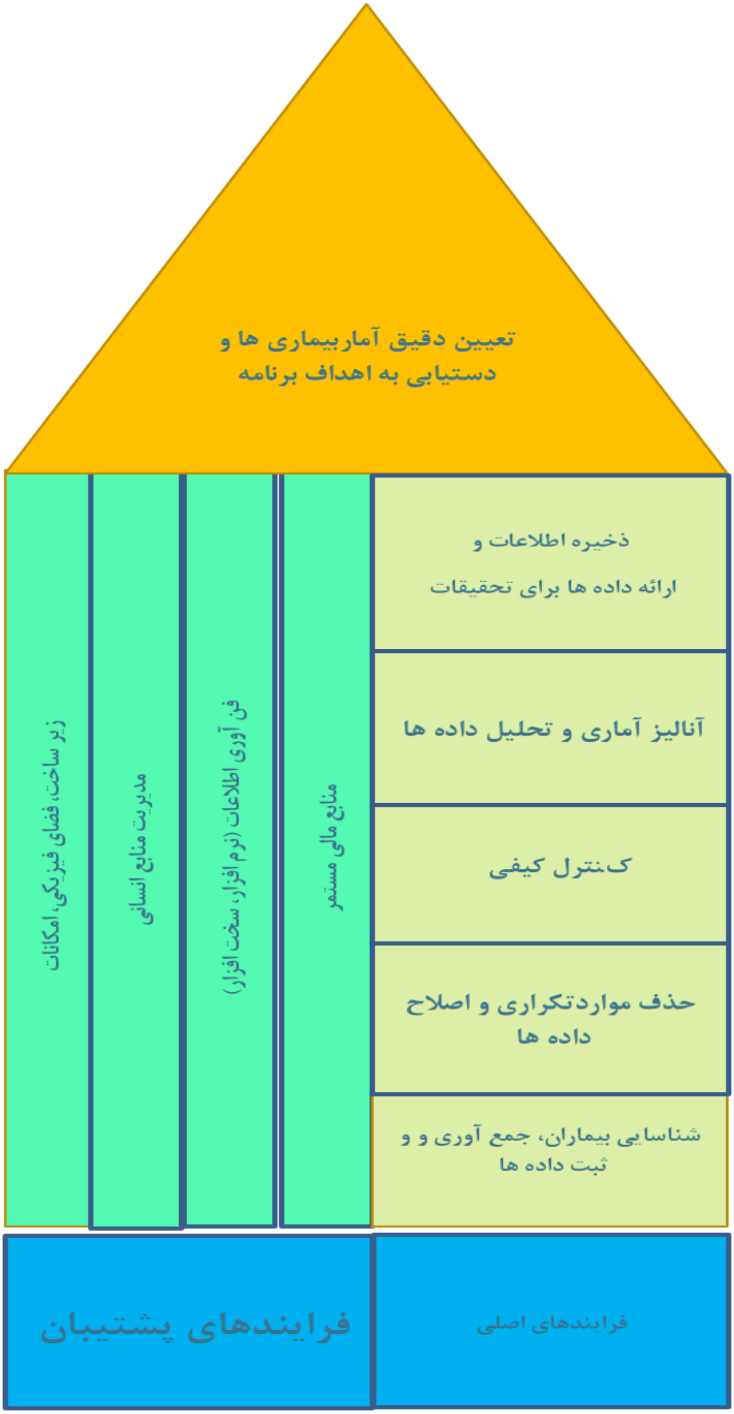
Registry Disadvantages

- Disease-specific, not longitudinal
- Does not include information necessary for billing
- Requires hardware, software, and maintenance
- Requires data entry and data maintenance
- Parallel documentation system (i.e., some information has to be entered in two systems)
- Can't stand alone, must have an additional documentation system.

02

Planning a Registry

Planning a Registry


تعیین دقیق آماربیماری ها و
دستیابی به اهداف برنامه
ذخیره اطلاعات و
ارائه داده ها برای تحقیقات
آنالیز آماری و تحلیل داده ها
کنترل کیفی
حذف مواردتکراری و اصلاح
داده ها
شناسایی بیماران، جمع آوری و و
ثبت داده ها
منابع مالی مستمر
فن آوری اطلاعات (نرم افزار، سخت افزار)
مدیریت منابع انسانی
زیر ساخت، فضای فیزیکی، امکانات
فرایندهای اصلی
فرایندهای پشتیبان

Defining the Purpose, Objectives and Outputs of the Registry

Purpose

The first step is to clearly define the overarching aim(s) or purpose(s) for which the registry is being established. This may emerge from a clinical need, a post-marketing requirement, or an interest of patients or clinicians, but the purpose(s) should be capable of being realised through the prospective, non-interventional, scientific approach that a registry should adhere to.

Defining the Purpose, Objectives and Outputs of the Registry

Objectives

To facilitate the generation of a valid scientific question, the registry's purpose(s) should be divided into specific objectives, which together will achieve that overarching purpose(s) of the registry.

Defining the Purpose, Objectives and Outputs of the Registry

Output

Ultimately, a registry's findings are only valuable if the data they generate can be translated into information capable of improving health outcomes. This is more likely to occur if outputs are considered at an early stage.

Data Considerations

The success of a registry will ultimately be judged on its ability to meet the goals it was created for.

This requires the collection and analysis of sufficiently high quality, targeted data specified by research hypotheses and the dissemination of the results of these analyses.

Data Quality

- Data and Information types

Data or information may be considered primary or secondary

Data Quality

- Data Quality Dimensions

"The delivery of safe and effective healthcare depends on access to, and use of information that is accurate, valid, reliable, timely, relevant, legible and complete"

Table 4.1: Data quality dimensions

Data quality dimension	Description
1 Accuracy	How well information in or derived from the data reflects the reality it was designed to measure (11). It is usually characterized in terms of error in statistical estimates. It may also be described in terms of the major sources of error that potentially cause inaccuracy (e.g., coverage, sampling, non-response, response) (12). ✓ How good are the data? ✓ What is done with the data?
2 Completeness	Extent to which all necessary data that could have registered have actually been registered (6). It is usually described as a measure of the amount of available data from data collection compared to the amount that was expected to be obtained (e.g. coverage) (13). ✓ Are all the appropriate data present?
3 Interpretability and Accessibility	Ease with which data may be understood and accessed (11). This includes the ease with which the existence of information can be ascertained, the suitability of the form or medium through which the information can be accessed, whether data are accompanied with appropriate metadata and whether information on their quality is also available (including limitation in use etc.) (12). ✓ How readily accessible are the data? ✓ How well documented are the data? ✓ How easy is it to understand the data?
4 Relevance	The degree to which data meet the current and potential needs of users. The purpose is to assess how well data collection can adapt to change and whether it is perceived to be valuable (11). ✓ Can user needs be anticipated and planned for? ✓ How valuable are the data?

5 Timeliness	Refers primarily to how current or up to date the data are at the time of release, by measuring the gap between the end of the reference period to which the data pertain and the date on which the data become available to users (11). It is typically involved in a trade-off against accuracy. The timeliness of information will influence its relevance (12). ✓ Are data made available in a reasonable amount of time? ✓ Are key documents released on time?
6 Coherence	Reflects the degree to which it can be successfully brought together with other statistical information within a broad analytic framework and over time. Coherence covers the internal consistency of data collection as well as its comparability both over time and with other data sources (14). The use of standard concepts, classifications and target populations promotes coherence, as does the use of common methodology across surveys. Coherence does not necessarily imply full numerical consistency (12). ✓ Does the database use standard definitions for data definitions? ✓ Can common groupings be derived from the data? ✓ Can databases be joined via a common data element? ✓ Are data values being converted correctly? ✓ Are data comparable with themselves over time?

Seven essential means of improving data quality

Table 4.2: Essentials for improving data quality

Leadership & Management	•What: involves having in place executive-level responsibility, accountability and leadership. •Why: knowing who does what (e.g. the establishment of a governance committee that will ensure the registry is committed to data quality). Decision-wise, this includes the selection of only essential data elements when datasets are established.
Policies and procedures	•What: developing and implementing clear policies and procedures on data quality for staff that are based on legislation and standards. •Why: can help ensure that a high level focus on data quality is translated into good practice amongst all those involved in data collection and handling within the registry.
Standardisation	•What: ensuring that data are collected and processed in a standardised fashion (e.g. use of minimal datasets, data dictionaries and the creation of standard templates for data collection), designing the registry with respect to national and international standards. •Why: facilitates data interoperability and making data available. Also can improve consistency and reduce error.
Data quality dimensions	•What: set of data quality attributes upon which data can be assessed, aligned with policies, procedures and training. •Why: measuring and monitoring level of data quality within a registry.

Seven essential means of improving data quality

Training

- What: training of the staff in the requirements and importance of data quality.
- Why: ensuring that policies and procedures adopted to generate high quality data are implemented and understood in practice.

Data quality audits

- What: independent systematic examination of data (internal or external).
- Why: providing feedback to all staff, indicating the areas for improvement, highlighting good practice in order to facilitate learning (e.g. automation of data collection over manual collection where possible will reduce error rate, however, this will not be verified without planned audits of data quality).

Make data available

- What: availability of data when and where needed, in accordance with information governance safeguards (security, privacy).
- Why: fulfilling the purpose for which the registry was created, increasing quality of registry data through its efficient utilization and dissemination.

Method of data capture

Data collection can be considered with respect to two major domains;

- data source
- data provider

Data Source

Paper-based

- Questionnaire
- Paper health record review
- Documentation review
- Laboratory reports
- Other

Data Source

Electronic

- Questionnaire
- Electronic Health Record
- Laboratory reports
- Databases
- Mobile applications
- Health devices
- Social media
- Other

Data Provider

Clinical units	Disability registries
Laboratories/central services	Centres of expertise
Discharge registries	Birth registries
Patients and families	Cause of death registries
Patients user groups (associations/federations)	Insurance funds (public and private)

the Importance of Interoperability

Interoperability

“ability of a system or a product to work with other systems or products without special effort on the part of the customer”

the Importance of Interoperability

Planning for integration

As “interoperability is made possible by the implementation of standards” the selection of standard datasets and terminology to facilitate local and cross-border interoperability.

Considering Legal Aspects and Confidentiality

Ensuring compliance with data protection regulations is not only vital, but a legal requirement, the breach of which may result in termination of the registry project.

Adopting a gold standard, transparent data protection practice is likely to increase the confidence that registry participants will place in a registry and add to its value.

Privacy and Privacy Impact Assessments

"Privacy is the right of individuals to keep information about themselves from being disclosed"

A privacy impact assessment (PIA) is a process that "facilitates the protection and enhancement of the privacy of individuals" and is best conducted at a planning stage to protect the registry.

Data Protection Policy

Even following a PIA, it is advisable to develop a data protection policy for the registry project and ensure that all involved with design and implementation of the registry are appropriately trained in this regard and regularly made aware of their responsibilities.

Data Ownership, Access and Intellectual Property

While considering data security it is prudent to consider data ownership, access and intellectual property

Eliciting Expert Opinion & Generating an Advisory Board

Expert elicitation refers to the "solicited exchange of knowledge, information, or opinion from an expert"

If the initial planning processes suggest that there is a valid opportunity to establish a registry, further planning can be greatly facilitated by expert guidance

Defining the Scope of the Registry & Building a Registry Development Team

At this point, to consider with the advisory board and funders what the scope of the registry will be.

The scope should aim to highlight the value of achieving the purpose(s), objectives and outputs of the registry with the minimal complexity possible, and in a manner that is most likely to be successfully accepted by users.

Performing Stakeholder Engagement and Analysis

"Stakeholder engagement is an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue"

The process of stakeholder engagement should also be seen as an inclusive "hearts and minds" campaign.

Identification of Stakeholders

Primary stakeholders are intrinsically involved in the design and funding of the registry, but may also include parties with a regulatory capacity.

Secondary stakeholders may be affected by and involved in using and operating the registry, but do not have direct involvement in its design.

Engagement

As the stakeholders of a registry may be extremely diverse, it is recommended that a flexible approach is adopted towards engagement.

None-the-less, to facilitate transparency, consistency and relevance it is advised that a standard information document is prepared and distributed in advance, where feasible.

Recording Stakeholder (& expert participation)

- High-level categories of contacts include:

Clinical groups	Academia
Public health and regulatory groups	Relevant experts
Product and device manufacturers	Professional groups and societies
Health care service providers	Registry groups
Health funding and insurance groups	Registry sponsor groups
Patient and advocacy groups	Development groups (informatics and management)

Re-defining the Scope of the Registry

Following stakeholder assessment it is advisable to reconsider the scope of the project.

While factors likely to improve stakeholder engagement and ultimately increase the chance of the registry's success are important, these should be weighed against the considerable expense the extra scope is likely to add.

Re-defining the Scope of the Registry

It is also worth noting that increasing the volume of data collection is typically associated with a decrease in completeness of data entry

Changes to the scope may result in significant resource utilization and, as such, a change management strategy should be created which outlines how further adaptations to the scope should occur in the future.

Governance, Oversight and Registry Teams

To focus on the practical implementation of the registry, it is advisable to establish a governance plan and to develop teams that will facilitate design of the registry and maintenance following implementation.

Governance, Oversight and Registry Teams

1. Creating teams can involve end-users, increasing buy-in.

2. Facilitating a better understanding of how the registry will operate and how intellectual property will be handled.

3. Creating the governance framework for data sharing and dissemination of data or information created by the registry.

4. Ensuring oversight and that the registry development is progressing as planned.

Project management team

The involvement of a person skilled and experienced in project management is advised. If this is not possible, it would be worthwhile considering training for a project manager and consideration given to the use of project management software

Scientific Committee

It is suggested that the committee aim to meet four main objectives:

- Question identification
- Data element identification and selection
- Dissemination of results
- External data access/study proposal adjudication

Quality assurance Committee

Ensuring that the registry's quality is validated will increase the value of the registry.

Resource requirements

Resource requirements will vary significantly depending on the scope of the registry project.

Resources to consider include:

Human Resources

Depending on the scope of the registry project, this might include staff:

Administration	Programming
Project management	Design
Data management	Training
Data collection	Financial
Study design, epidemiology & statistical support	Legal/data security & protection
Data dissemination	Clinical

Information Technology Resources

Depending on the environment in which the registry is to be established, requirements can range from analysis software to an extensive hardware and software budget. It should be stressed that information technology support with experience of registry design is extremely valuable.

Financial Resources

Financial resources will vary significantly depending on the scope of the registry; however, by following a planning process with an inclusive stakeholder assessment, it is more likely to identify appropriate funding avenues and collaborations that may maximize financial investments in addition to the financial value of registry outputs.

Funding Strategy

At all times, funding should be arranged in a manner that is transparent and without conditions that might undermine the validity of the scientific study.

Risks and feasibility

Risks accompany each component of the registry establishment and maintenance process, from excessive dataset selection and lack of adherence to recognized standards through to a failure to consider a registry termination strategy.

Developing an Implementation Plan

It is suggested that a further review of the steps involved in planning the registry is undertaken to develop an action plan and timeframe for each step in conjunction with the appropriate expert or stakeholder identified by the planning process.

Developing an Implementation Plan

Within this, rate-limiting steps should be identified to help determine the "critical path" which will dictate how long the project is likely to take.

As part of the implementation plan, it may be useful to consider a pilot project as a proof-of-concept model before proceeding with a full implementation

Developing an Implementation Plan

This can generate significant support for a registry, create useful outcomes and identify significant obstacles that may not have been initially obvious.

It can also create a wealth of knowledge and experience at a manageable level that can increase the chances of ultimate success.

A project proposal should be formalized with firm time and budgetary constraints outlined to facilitate regular oversight by the project management committee (or similar).

Developing an Implementation Plan

Though numerous measures of quality have been mentioned, ultimately, the registry will need to be regularly evaluated against the objectives and purpose it was designed to meet.

This can facilitate review and adjustment of the registry that can further improve outcomes, efficiency and ensure that relevance is maintained.

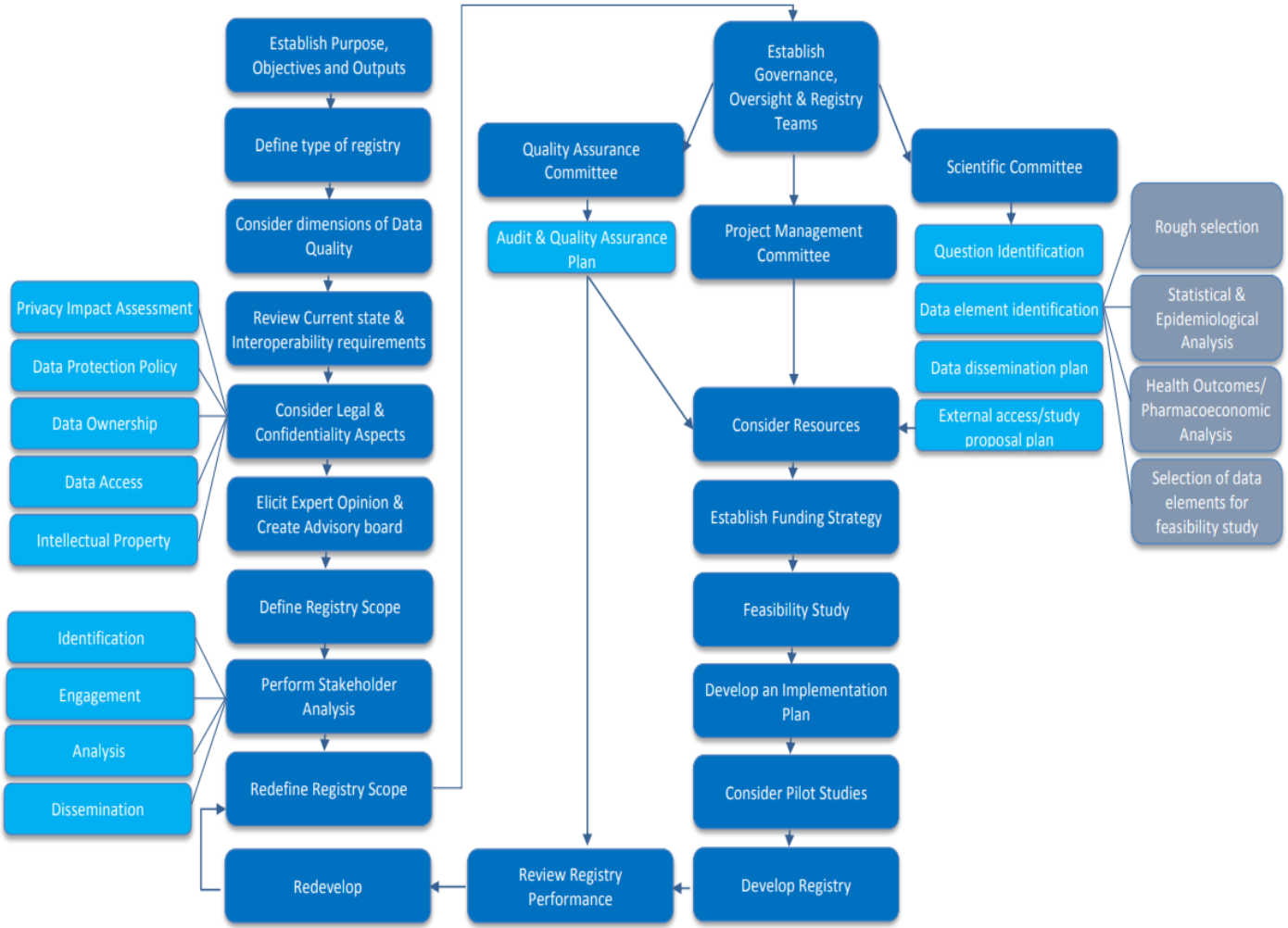


Figure 6.1: Planning a Registry Process

General principles for building a registry dataset

Minimalist approach in building a dataset:

Data elements need to be carefully considered in relation to the purpose of the registry.

Every data element must support the purpose and goals of the registry. If there is no strong argument for its collection, it should not be included.

General principles for building a registry dataset

The burden and costs for data collecting

The success or failure of a registry is often determined by the costs and burden of data collection. When building a dataset for a registry it is necessary to consider the burden of data collection that will be put on a patient, physician/health provider, and a registry team as well. The likelihood of loss to follow-up or limited usability due to the burden of data collection should be also considered.

General principles for building a registry dataset

Availability of data sources for data elements

It is recommended to identify existing data sources and assess their usefulness. Linkage to other data sources can significantly lower the cost and burden of data collecting.

General principles for building a registry dataset

Privacy aspect

They must assess whether the dataset complies with information privacy principles, and how the inclusion of data elements that are private or confidential in nature will affect the patient's response.

General principles for building a registry dataset

Consideration of data quality

Data elements of uncertain quality or coverage should not be included in the registry dataset. Unless reliable information can be collected on a majority of cases, the item should not be part of a registry dataset.

General principles for building a registry dataset

Use of data standards

Standard data elements and definitions should be used when possible.

Standards promote consistency, comparability, and common understanding of data elements.

General principles for building a registry dataset

Explicit definitions

When there are no suitable internationally standardized data elements or they cannot be used in a specific registry, the registry team needs to define and select their own data elements.

General principles for building a registry dataset

Selecting value domains, setting validation rules

For each data element a set of permitted values (i.e. value domain) must be determined.

A value domain can be enumerated, or non-enumerated.

General principles for building a registry dataset

Selecting value domains, setting validation rules

Setting validation rules is another activity that is highly recommended.

Selecting possible ranges of the values (e.g. person's age cannot be above 120 years, body height in centimetres cannot contain more than 3 characters).

General principles for building a registry dataset

Minimum dataset

The registry team should decide on the minimum/core dataset which is a list of variables that are essential to collect the data for any case/subject.

General principles for building a registry dataset

Modifying data elements

When changing the data elements a registry team should try to comply with the existing standards and to retain longitudinal comparability. In any case, it is important that a registry considers the impact that these changes will have on a collection and interpretation of findings.

General principles for building a registry dataset

Testing dataset

Each data element should be checked separately whether its definition, value domain, any rules or other descriptions are properly determined, comprehensive and understandable.

A registry team should check the overall consistency of the dataset, assess the data collection burden and evaluate the possibility of making errors in the data collection process.

General principles for building a registry dataset

Methodological guide

Normally, every dataset, together with the data collection process, requires a methodological guide that includes detailed information about what is collected and how. It is used to provide the user with advice or interpretation on how to treat particular data elements and successfully perform the data collection.

General principles for building a registry dataset

Methodological guide

(a) the interpretation of data element's definition and value domain

(b) the explanation of what exactly is collected/included in the observation and what is not, covering all unclear cases/situations.

(c) the introduction of rules and restrictions for specific data elements.

(d) the information about the data collection and data reporting

General principles for building a registry dataset

Well-documented and accessible data elements

Data elements should be well-documented and readily accessible to everyone who is interested in a registry's dataset. Well-documented and transparent data elements give an understanding of the collected data and ensure consistency in the data collection process.

International coding systems, terminologies and common data sets

As already mentioned, a registry should use existing standards wherever possible since this facilitates consistency, comparability, data exchange and reuse.

Table 6.5: International coding systems and terminologies

Area	Standard	Developer	Website
Diseases	ICD-10-CM ICD-9-CM ICD-O	WHO	www.who.int/classifications/icd/en
	ORPHA-codes	ORPHANET	www.orpha.net
Medical Nomenclature	SNOMED	International Health Terminology Standards Development Organization	www.ihtsdo.org/snomed-ct
Devices	Global Medical Device Nomenclature (GMDN)	GMDN Maintenance Agency	www.gmdnagency.com/
	Universal Medical Device Nomenclature System (UMDNS)	WHO Collaborating Centre ECRI	www.ecri.org.uk/umdns.htm
Drugs	ATC/DDD Index	WHO Collaborating Centre for Drug Statistics Methodology	www.whocc.no/atc_ddd_index/
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	www.meddra.org/
	WHO Drug Dictionary	WHO	www.umc-products.com/DynPage.aspx?id=73588&mn1=1107&mn2=1139
Adverse Reactions	WHO-ART	WHO, maintained by the Uppsala Monitoring Centre	www.umc-products.com/DynPage.aspx?id=73589&mn1=1107&mn2=1664
	EU SPC ADR database	EMA	www.imi-protect.eu/methodsRep.shtml
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	www.meddra.org/

Adverse Reactions	WHO-ART	WHO, maintained by the Uppsala Monitoring Centre	www.umc-products.com/DynPage.aspx?id=73589&mn1=1107&mn2=1664
	EU SPC ADR database	EMA	www.imi-protect.eu/methodsRep.shtml
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	www.meddra.org/
Disability	ICF	WHO	www.who.int/classifications/icf/en/
External Causes of Injury	ICECI	WHO	www.who.int/classifications/icd/adaptations/iceci/en/
Primary care	ICPC-2	WHO	www.who.int/classifications/icd/adaptations/icpc2/en/
Procedures	ICD-10-PCS ICD-9-CM Vol. 3	WHO	www.who.int/classifications/icd/en
Health Interventions	ICHI	WHO	www.who.int/classifications/ichi/en/
Medical Laboratory Observations	LOINC	Regenstrief Institute	loinc.org/
Genes, genetic disorders and traits	Online Mendelian Inheritance in Man (OMIM)	McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University (Baltimore, MD)	www.omim.org/
Genes	HGNC	Human Genome Organization (HUGO)	www.genenames.org/about/overview

The role of IS expert

It is recommended to involve persons with knowledge and experience in IS methodologies and techniques such as system analysts and/or business process modellers or other persons with the knowledge in this domain as early as possible in the development of the patient registry

The role of IS expert

They are only there to facilitate the process of defining the right content and to provide guidance on how to accomplish these important tasks with different IS techniques. Health domain experts (usually clinicians) are those who define the content, as they have the knowledge of the patient registry domain.

IS experts cannot and should not define on their own the scope, content, outcomes, etc. of the patient registries. They are only facilitators of the PR creation process and responsible for proper modelling.

The role of IS expert

Communication between health domain experts and IS experts is the key issue when modelling the PR.

The IS expert is responsible for proper modelling and to be able to do so it is crucial to gather the right information from the right people.

The role of IS expert

The commonest way of gathering information is to conduct guided interviews with health domain experts; another option is to have an interactive modelling workshop, where the model is prepared during the session. In both cases it is very important to properly manage the process of information gathering from preparation,


THANK YOU