

Creating a Registry - Planning

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Creating a Registry

Planning

Design

Data Elements

Data Sources

Software

Ethical and Legal Issues

Registries may be;

Large or small,

Target *rare* or *common* conditions & exposures

Require *limited* or *extensive* amounts of data

Operate for *short* or *long* periods

Funded *generously* or *limited* financial support

Focus on or expand to different geographical regions

*Registries require
good planning in order to be successful*

Steps in planning a registry

Articulate the *Registry's Purpose*

makes it easier to evaluate,
helps clarify need for certain data

Is a registry *appropriate means to* achieve purpose?

Consider; state of *current knowledge* and *gaps* in evidence;
breadth of *target population*,
length of an *period needed* to achieve objective;
scope and variety of *treatments* used;
amount of *funding* available to address objectives

Steps in planning a registry

Identify Key Stakeholders

Public health or regulatory authorities;

Product manufacturers;

Health care service providers;

Patients and/or advocacy groups;

Treating clinician groups;

Academic institutions

Steps in planning a registry

Assess Feasibility

Funding;

Scope of registry, rigor of data collection;

Number of sites & patients;

Scope & method of data collected

Projected life of the registry

Life cycle for a registry

Establishment

Continuation

Extension / Transition

Ending (???)

Not fulfil the objectives

Inability to address the objective

Staffing and funding shortage

Other.....

Steps in planning a registry

Build a Registry Team

Different kinds of knowledge, expertise, and skills are needed

Depending on size, scope, and purpose of registry;

Build a Registry Team

Project management,

Needed to *coordinate components* of registry:

Subject matter,

A registry must be contains *appropriate data* to meet *its goals* and *needs of its stakeholders*

e.g. experts in treatment of clinical disease to be studied, *who are also familiar* with potential *toxicities of treatment(s)* to be studied
(critical to success of registry)

Build a Registry Team

Registry science:

Epidemiology & biostatistics:

Design, implementation, analysis of registry data

*Health outcomes and economics **researchers***

Subject matter experts (clinicians)

Build a Registry Team

Data collection & database management:

Decision to include data elements (*consultation with experts*)

Final determination of *what is workable* for data collection tools should be approved by members of team

Experts may need to *write specific programs*, generate *reports*,
Responsible for implementing and maintaining *firewalls* to
protect data

Build a Registry Team

Legal issues / patient privacy:

Quality assurance:

The goals for quality assurance should be established,
Efforts made and the results achieved should be described

با تشکر و سپاس از توجه شما