Creating a Registry

Design

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Creating a Registry

Planning

Design

Data Elements

Data Sources

Software

Ethical and Legal Issues

Registry Design

Questions for Registries

Descriptive questions;

Understanding characteristics cases

How disease generally progresses

Analytic questions;

Clinical effectiveness,

Assessing safety or harm

Evaluating effects of specific treatments on patient

Research questions should address ***registry's purposes***

Research Questions in Registries

Natural history studies; *observe* ***clinical practice & patient experience***

Measures of *clinical effectiveness*;

Followup for long-term *benefits* or *harm*

Surveillance for rare events

Evaluations of standard medical practice

Research Questions in Registries

Studies;

for treatments in which *randomization is unethical or not necessary*

for which *blinding* is challenging or unethical

of conditions with *complex treatment*

of health care *access* and *barriers* to care

of heterogeneous patient populations;

of effectiveness and safety

Registry Design

Translating *clinical questions* into *measurable exposures* & *outcomes*

Clinical questions in registry will guide *definitions* of;

Study subjects,

exposure,

outcome measures,

study design,

data collection,

analysis

Registry Design

Finding necessary data

Identification of key outcomes, exposures & patients, ***drive strategy*** for data collection

Generally, ***not possible*** to collect all desired data (key challenge to registries)

Data collection should be both ***parsimonious*** & ***broadly applicable***

Registries should focus on collecting ***relevant data***

Registry data can be obtained from;

patients, clinicians, medical records, linkage with other sources

Registry Design

Study Designs for Registries

Case Series Design;

Commparison case series

Self-controlled case series, controls for all confounders that do ***not vary over followup time***

Registry Design

Study Designs for Registries

Cohort Design ;

follow over time, to see particular ***endpoint*** or ***outcome***

is used for *descriptive studies*

to evaluate *comparative effectiveness* and/or safety or quality of care

may include *only people with exposures* ***(a particular drug)***

may include *one or more comparison groups*

Registry Design

Study Designs for Registries

Case - Control Design;

Gathers patients who have a ***particular*** *outcome / an adverse event* (cases) & who have not (controls)

Representative of source population **(from which cases arise)**

Employed for etiology of ***rare diseases***

Cases & **controls** may be ***identifiable*** within a ***single registry***

Note; controls from **outside** registry must be **comparable** with cases

Registry Design

Study Designs for Registries

Nested case - control Design;

a variant of case-control study

controls are selected via ***risk-set*** sampling,

each person in source population has a probability

of being selected ***as a control***; (in proportion to

person-time contribution to cohort)

Registry Design

Study Designs for Registries

Case - Cohort Design;

a variant of case-control study

each control has ***an equal probability*** of being sampled

from source population

This allows *for collection of data* for ***cases*** and a ***sample***

of full cohort, instead of ***whole cohort***

Choosing Patients for Study;

Target Population

population to which the findings are meant to apply,
(all patients with a disease or a common exposure)

registries will enroll all, or nearly all, of target population,
most, enroll only a sample of target population

Study population

subset of those who can ***actually be identified*** & ***agree to participate***

rarely possible study groups ***fully representative***

clear definitions *of inclusion /exclusion criteria*
registries typically have few *inclusion / exclusion criteria*

Choosing Patients for Study;
Comparison Groups

To collect data on ***comparators*** (parallel cohorts)??

Depending on purpose of registry*, internal, external, or historical groups can be used*

*Comparison groups are most **useful**;*

*to strengthen understanding of whether observed effects are **real***

to distinguish between alternative decisions

to assess differences, magnitude of differences, and strength of associations between groups

Challenges*;*

Comparison groups may yield significant complexity, time, cost;

Multiple comparisons: dificulties in interpretation of registry results

Registry Design

Choosing Patients for Study;

Sampling *(in terms of patients and sites)*

Representativeness of sample affects generalizability

Probability sampling;

Simple random sampling

Stratified random sampling

Systematic sampling

Cluster (area) sampling

Multistage sampling

Nonprobability sampling:

Selection is not random

Registry Design

Registry Size and Duration;

Precision in measurement and estimation

corresponds to ***reduction of random error;***

improved by ***increasing size*** of study

Duration of registry *enrollment and follow up determined by*

required ***sample size*** *&*

time-related considerations

Sample size & Duration

Aims of a registry,
Desired **precision** of information sought,
Hypotheses to be tested**,**

determine

process and inputs for arriving at a *target sample size* and specifying *duration of follow up*

Registry Design

Internal validity*;*

extent to which;

study results are free from bias,

and reported ***association*** *between exposure and outcome is not due to* ***unmeasured or uncontrolled-for*** *variables*

External validity *(generalizability);*

refers to utility of the inferences for broader population that the study subjects are intended to represent

Registry Design

Internal and External Validity;

Registries, usually focus on ***generalizability***

include more heterogeneous populations

Registries have more opportunities to ***introduce bias***

Registry Design

Information Bias;

Selection Bias;

Loss to Followup;

attrition of patients and sites

Bias from study of Existing rather than New Product Users

incidence/prevalence bias, survivorship bias, and followup bias

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