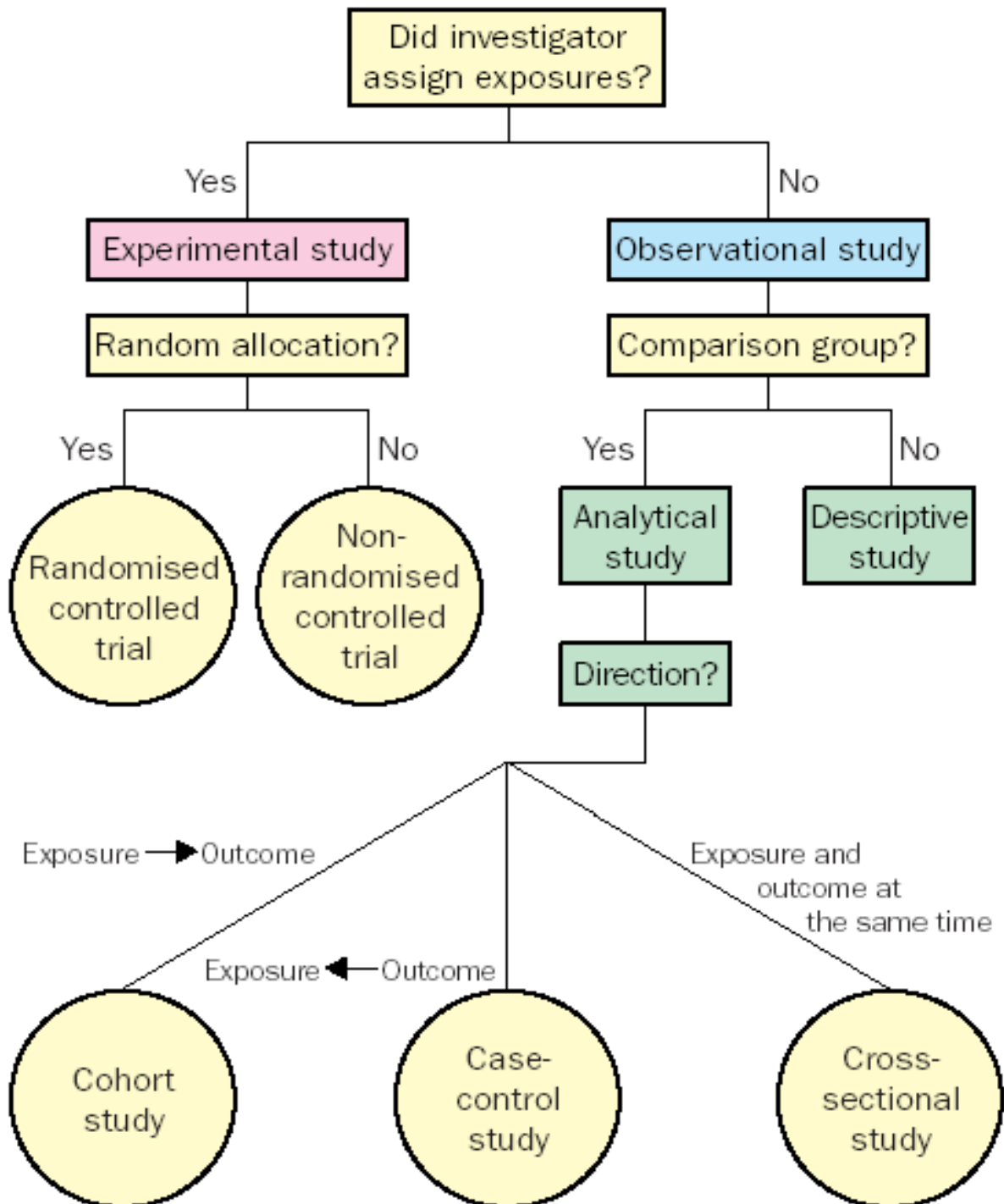


Introduction to Study Design

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(From Grimes and Schulz, *Lancet* 2002; 359: 57–61)

I. Observational designs

A. Exploratory studies used when the state of knowledge about the phenomenon is poor: small scale, of limited duration. Their aim is to explore an unknown field.

B. Descriptive studies (often surveys) also known as **statistical research**, describes data and characteristics about the population or phenomenon being studied. However, it does not answer questions about eg: how/when/why the characteristics occurred, which is done under analytic research. Although the data description is factual, accurate and systematic, the research cannot describe what caused a situation. Thus, Descriptive research cannot be used to create a causal relationship where one variable affects another.

C. Analytical Studies used to test hypotheses: small / large scale. Examples: case-control, cross-sectional, cohort

Case Series

Clinical case-series: usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from the practice of one or more health care professionals or health care setting.

Clinical case-series are of value in epidemiology for:

- Studying predictive symptoms, signs and tests
- Creating case definitions
- Clinical education, audit and research
- Health services research
- Establishing safety profiles

What to look for

- The diagnosis (case definition) or, for mortality, the cause of death
- The date when the disease or death occurred (time)
- The place where the person lived, worked etc (place)
- The characteristics of the population (person)
- The opportunity to collect additional data from medical records (possibly by electronic data linkage) or the person directly
- The size and characteristics of the population at risk

Who, what, why, when, where

1. **Who** has the disease in question?
2. **What** is the condition or disease being studied?
3. **Why** did the condition or disease arise?
4. **Where** does or does not the disease or condition arise?

Conclusions:

- *'Case reports and case series can be well received, and have significant influence on subsequent literature and possibly on clinical practice.'*
- Many are followed by clinical trials.
- Often, report rare conditions for which trials may not be feasible.
- Strong publication bias favouring positive results

Cohort studies

A **cohort study** is a form of longitudinal observational study. It begins with a group of people who do not have the disease, takes baseline measurements, then follows them over time to determine whether uses correlations to determine the absolute risk of subject contraction. A cohort is a group of people who share a common characteristic or experience within a defined period (e.g., are born, are exposed to a drug or vaccine or pollutant, or undergo a certain medical procedure). Thus a group of people who were born on a day or in a particular period, say 1948, form a birth cohort. The comparison group may be the general population from which the cohort is drawn, or it may be another cohort of persons thought to have had little or no exposure to the substance under investigation, but otherwise similar. Alternatively, subgroups within the cohort may be compared with each other. An example of an epidemiological question that can be answered by the use of a cohort study is: does exposure to X (say, smoking) associate with outcome Y (say, lung cancer)? Such a study would recruit a group of smokers and a group of non-smokers (the unexposed group) and follow them for a set period of time and note differences in the incidence of lung cancer between the groups at the end of this time

- Usually very expensive
- Complete source population denominator
- Can calculate incidence rates or risks and their differences and ratios
- Convenient for studying many diseases

Several famous large cohort studies continue to provide important information. (*Ndoff R, Peto R, Boreham J, Sutherland I. Smoking and dementia in male British doctors: prospective study. BMJ 2000;320:1097-1102*)

Case-Control Studies

It is a type of observational study in which two existing groups differing in outcome are identified and compared on the basis of some supposed causal attribute. Case-control studies are often used to identify factors that may contribute to a medical condition by comparing subjects who have that condition/disease (the 'cases') with patients who do not have the condition/disease but are otherwise similar (the 'controls').

- Usually less expensive
- Sampling from source population
- Can usually calculate only the ratio of incidence rates or risks
- Convenient for studying many exposures

Cross-sectional studies

A cross-sectional study is a descriptive study in which disease and exposure status are measured simultaneously in a given population. Cross-sectional studies can be thought of as providing a "snapshot" of the frequency and characteristics of a disease in a population at a particular point in time. This type of data can be used to assess the prevalence of acute or chronic conditions in a population. However, since exposure and disease status are measured at the same point in time, it may not be possible to distinguish whether the exposure preceded or followed the disease, and thus cause and effect relationships are not certain.

Observational studies dominate the literature (Funai et al. Distribution of study designs in four major US journals *Gynecol Obstet Invest 2001;51:8-11*)

II. Experimental studies (Randomized Controlled trials)

Randomized trials

These are cohort studies where allocation to treatment and control groups is achieved by a random process, akin to flipping a coin. Random allocation is helpful for reducing ‘**selection bias**’ and ‘**allocation bias**’, especially when combined with allocation concealment. Because they are experiments, randomized trials can also employ **blinding** of participants and caregivers, which reduces ‘**performance bias**’. (see session on appraising randomized trials)

III. Qualitative studies

Qualitative	Quantitative
<ul style="list-style-type: none">• Understanding• Interview/observation• Discovering frameworks• Textual (words)• Theory generating• Quality of informant more important than sample size• Subjective• Embedded knowledge• Models of analysis: fidelity to text or words of interviewees	<ul style="list-style-type: none">• Prediction• Survey/questionnaires• Existing frameworks• Numerical• Theory testing (experimental)• Sample size core issue in reliability of data• Objective• Public• Model of analysis: parametric, non-parametric

IV. Systematic reviews

These studies involve systematic literature searches to identify, appraise, and synthesize all relevant research. They should be conducted **no matter what the study design** and their justification is based on the scientific principle of replication and simple good academic practice.

Resources

- Grimes DA, Schulz KF. An overview of clinical research: The lay of the land. *Lancet* 2002;359:57-61.
- Grimes DA, Schulz KF. Descriptive studies: What they can and cannot do. *Lancet* 2002;359:145-9.
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- Schulz KF, Grimes DA. Case-control studies: Research in reverse. *Lancet* 2002;359:431-4.
- Hill, Austin Bradford (1965). "[The environment and disease: association or causation?](#)". *Proceedings of the Royal Society of Medicine* **58**: 295–300.
- Howick, J. *The Philosophy of Evidence-Based Medicine*. Oxford: Blackwell-Wiley.
- OCEBM Table of Evidence Glossary: <http://www.cebm.net/index.aspx?o=1116>