

Taxonomy of Clinical Research Designs

Experimental

- Controlled Trials
 - Non-Randomized
 - Randomized
- Other Intervention Studies
 - Before vs After
 - External Controls
 - Historical Controls

Observational

- Prospective Cohort Study
 - Concurrent
 - Non-Concurrent
- **Case-Control Study**
- Cross-Sectional Study
- Other / Mixed / ?

Comparison of 4 Major Study Designs

Goal or Feature	RCT	CS	CC	X-S
• Estimate Prevalence	F	F	F	A+
• Estimate Incidence	B-	A+	F	F
• Prove Causality	A+	B+	B-	D
• Generalizability	B-	A-	A-	A
• Feasibility	C	B	A	A

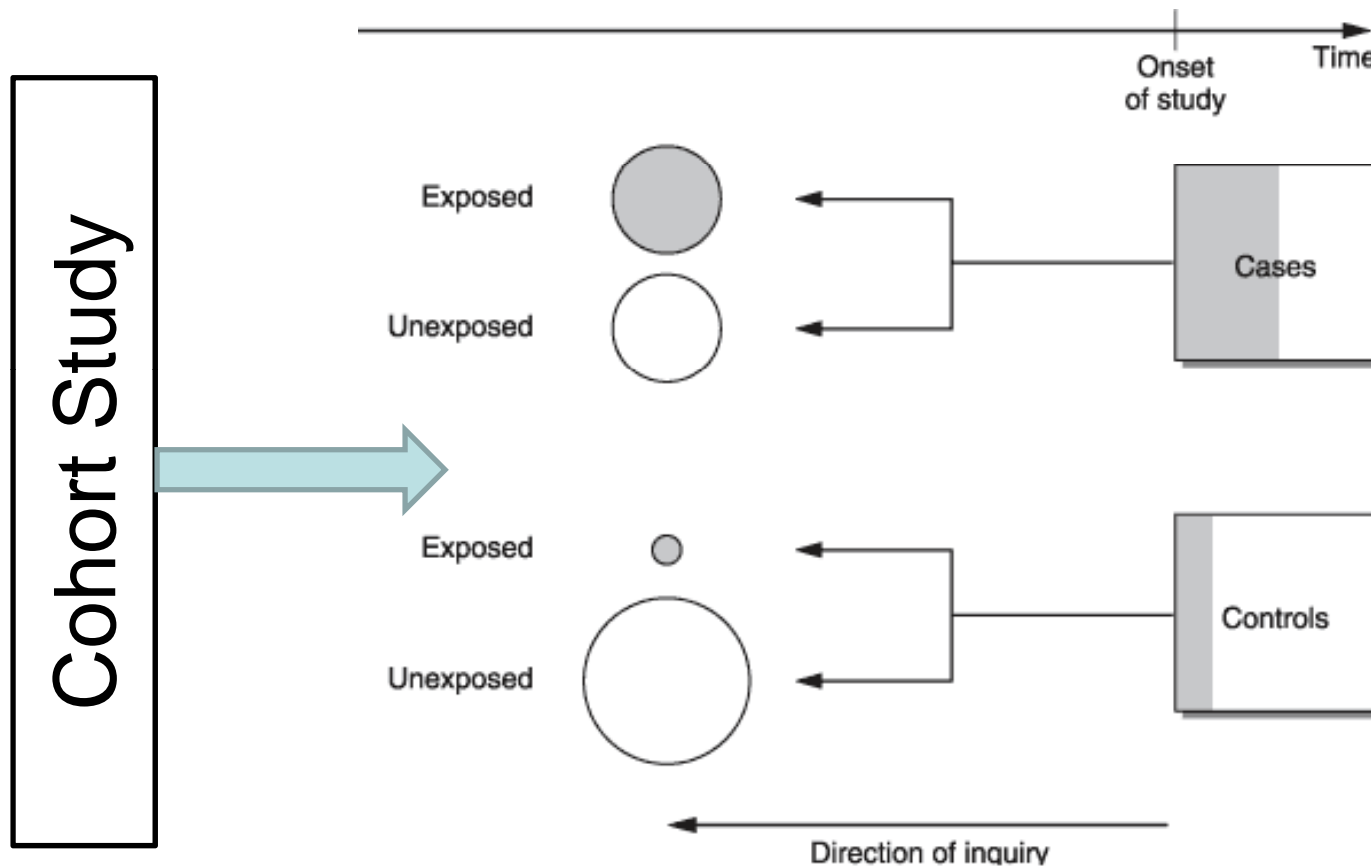
RCT=Randomized, controlled trial;

CS=Cohort study;

CC=Case-control study;

X-S=Cross-sectional study

Design of Case-Control Studies



Nested
Case-Control

Source: Greenberg RS, Daniels SR, Flanders WD, Eley JW, Boring JR:
Medical Epidemiology, 4th Edition: <http://www.accessmedicine.com>

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Figure 9-1. Schematic diagram of the design of a case-control study. Shaded areas represent subjects who were exposed to the risk factor of interest.

Case Control Studies

- Ppts selected on disease
 - Present = cases; Absent = controls
 - Look back at exposures
- Can look for Etiology of Disease
 - Are high risk sexual practices and HPV-infection more common in people with oropharyngeal cancer?
 - Is MI more common in women on HRT?
- Can look for Outcomes based on Exposures
 - Is history of FOB testing less common in people with colon CA?

Examples of Exposures & Outcomes in Clinical Research

Exposures

- **Traits & Behaviors**
- Genetic Variants
- **Infectious Agents**
- Environmental Toxins
- Medications
- Surgical Procedures
- Behavior Modification
- Screening Programs

Outcomes

- Death
- **Disease**
- Sub-clinical Indicators of Disease
- Health-Related Traits
- Quality of Life
- Physical Function
- Costs

GIM

Housestaff Research Awards

- **The L. Randol Barker Award** in medical education.
- **The Diane Becker Award** in clinical epidemiology and prevention.
- **Daniel Ford Award** in health services and outcomes research
- **David M. Levine Award** in behavioral medicine and health disparities
- **The Jeremy Sugarman Award** in bioethics.
- Prize:
 - \$1000 (for local residents), plus a nice dinner out
 - Present at GIM Grand Rounds, November 20th
- **Deadline October 2nd**

http://www.hopkinsmedicine.org/gim/GIM_awards