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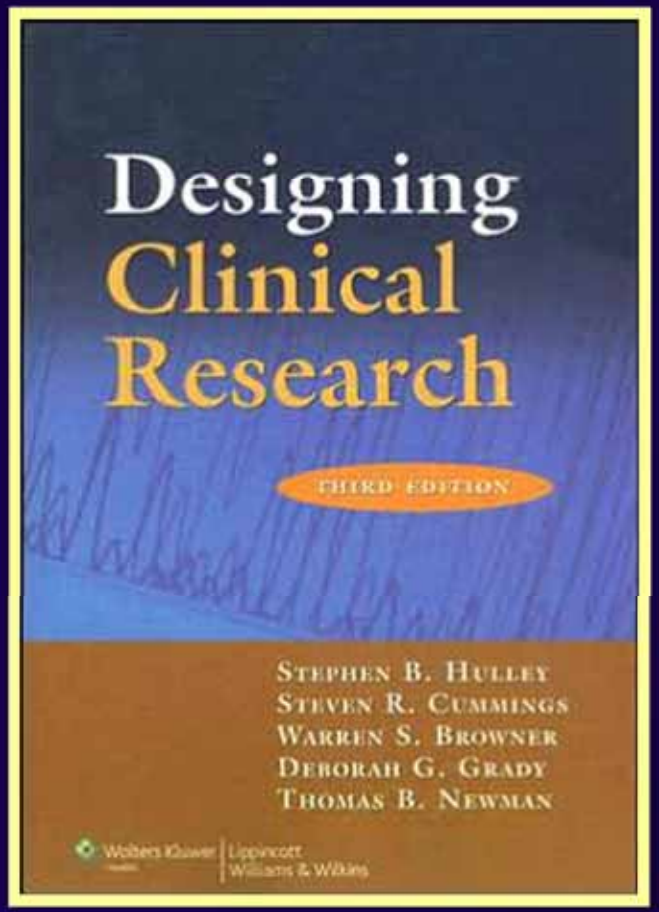
I. Precision and Accuracy: An Overview (adapted from Hulley, et al., 2007)

Hulley, S. B., et al. (2007). *Designing Clinical Research*. Philadelphia: Wolters Kluwer.



Just about every statistic (descriptive and inferential) is an expression of a basic ratio.

In the numerator goes a measurement of the influence of the research hypothesis.

In the denominator goes a measurement of the influence of error.

The ratio is very much like signal:noise.

This series of notes presumes a really good research hypothesis and centers on enhancing signal and reducing noise.

A. Experimental precision is closely related to, among other issues, reliability.

   Imprecision is brought about by random error

   Enhancing precision is akin to reducing noise in your system.

1. Sources of random error variance
    a. Observers
    b. Instruments
    c. Participants

2. Preventative steps (minimize opportunities for chance at play)

   a. Standardize observation protocols

      Make the protocols as explicit, simple, and straightforward as is possible

   b. Standardize interventions (consider a treatment algorithm)

      a & b translate to writing an Operations Manual.

c. Train observers and clinicians to criterion

d. Simplify all instructions for clarity

e. Use pooled observations if possible

f. Assess and report reliability within an experiment

B. Experimental accuracy is a function of validity

Inaccuracy is brought about by systematic error -- AKA bias

Enhancing accuracy is brought about by increasing the signal in your system

1. Sources of systematic error variance

    a. Observer bias

        e.g., they become more expert with experience, they have knowledge of the hypothesis

    b. Instrument bias

        e.g., ceiling or floor effects, under representation of construct

    c. Participant bias

        e.g., selection bias, differential attrition, compensatory rivalry, maturation

These are nothing more than Cook & Campbell's (1979) various threats to experimental validities.

2. Preventative steps (minimize opportunities for chance at play)

    a. Parsimony in admitting variables into an experiment and calibrate instruments

    b. Streamline and standardize observation and intervention protocols

    c. Make unobtrusive measurements

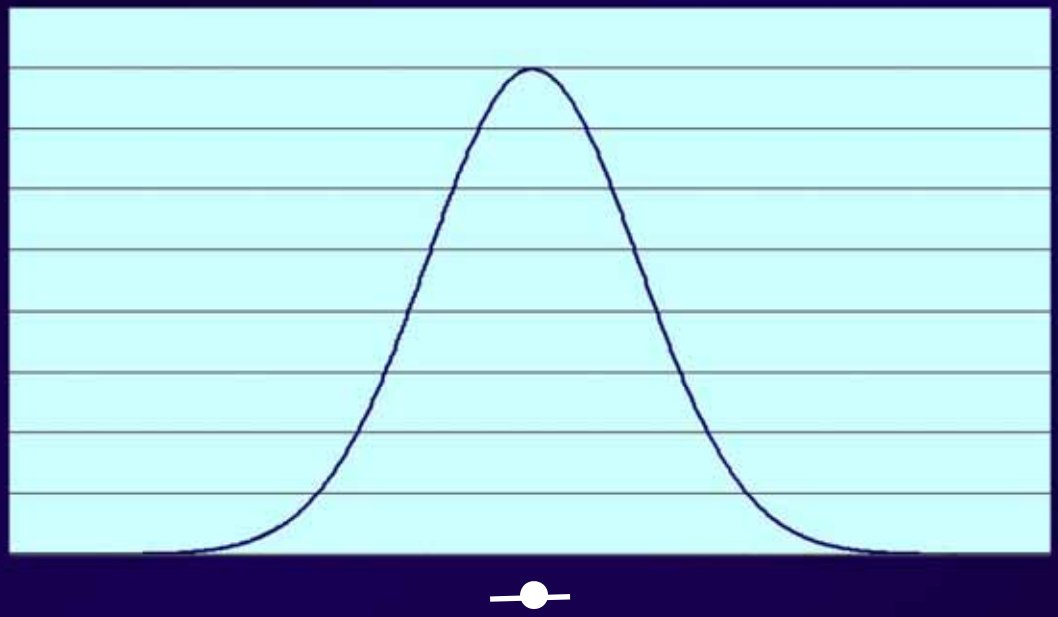
d. Take great care forming a protocol for participant selection

e. Take great care forming a protocol for participant allocation

f. Take great care forming a protocol for interim analyses

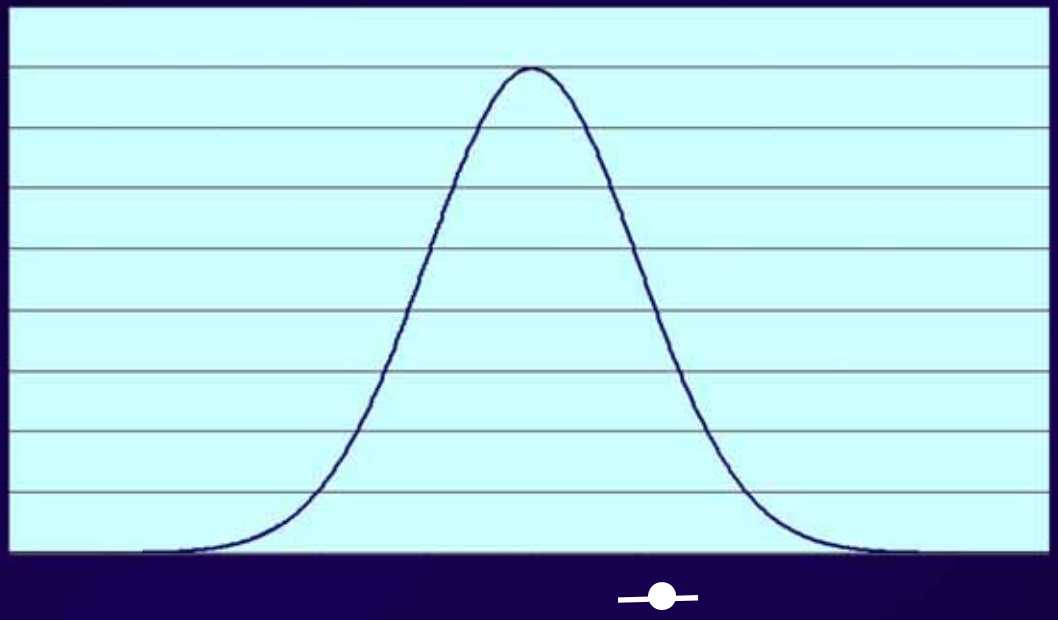
e. Blind as possible

Good precision, good accuracy



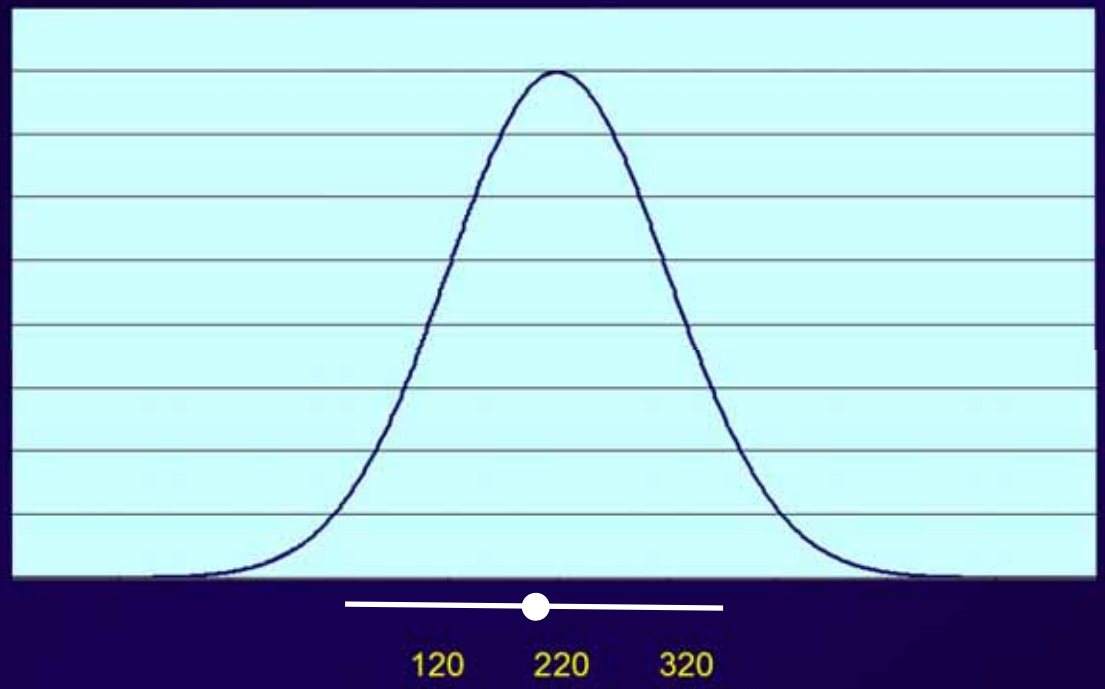
120 220 320

Good precision, poor accuracy

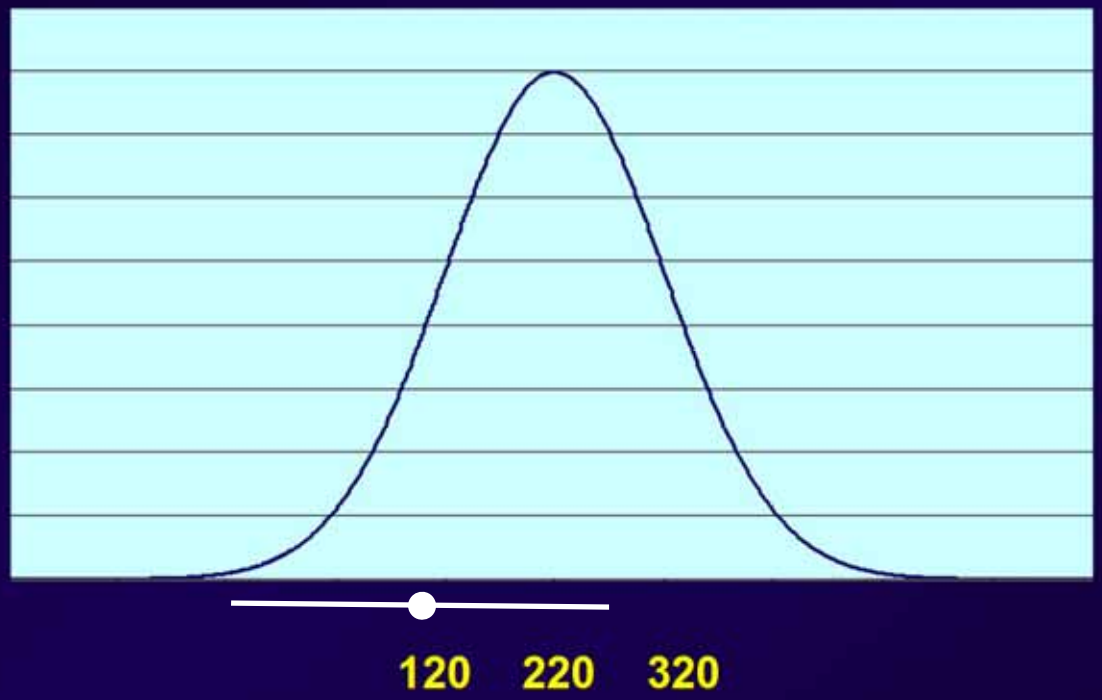


120 220 320

Poor precision, good accuracy

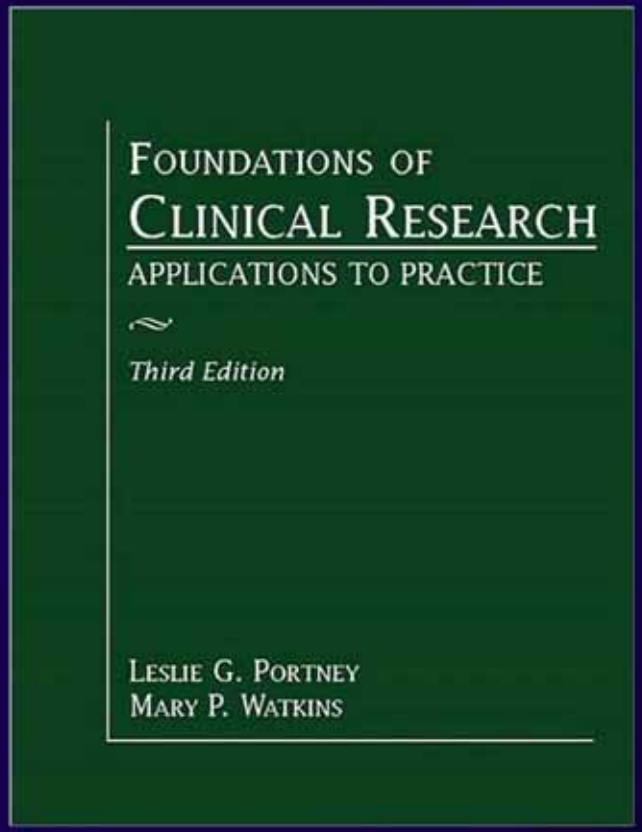


Poor precision, poor accuracy



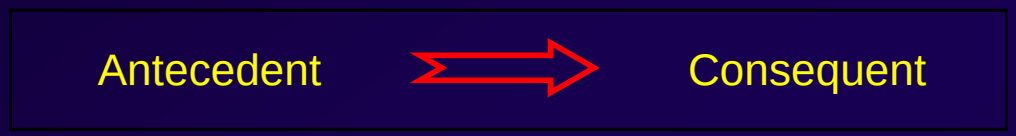
II. Confounds and Effect Modifiers (adapted from Portney & Watkins, 2009)

Portney, L. G., & Watkins, M. P. (2009). *Foundations of Clinical Research: Applications to Practice,* (3rd Ed.). Upper Saddle River, NJ: Pearson.



That which is screwed up in design cannot be fixed through analysis.

A. A straightforward challenge in logical conclusion



Exposure	Event	Good Thing or Bad Thing
Risk	Outcome	
Predictor Variable	Observed Variable	
Independent Variable	Dependent Variable	

Confounders and effect modifiers make rival explanations for the results

AKA a threat to internal validity

B. Confounders

1. A confounder is an extraneous or nuisance variable

   a. It is associated with the antecedent -- co-occurs to some extent

   b. It is associated with the consequent – exacerbates or suppresses the outcome

2. **Confounders are fundamentally the threats to internal validity first described by Cook & Campbell (1979)**

Under representation of the population

Misrepresentation of the population

Allocation Imbalance

(Differential) history

(Differential) maturation

(Differential) testing

(Differential) regression

Diffusion of treatment

Compensatory equalization of control treatment

Compensatory rivalry

C. Effect modifiers

1. Effect modifiers are not a nuisance; they are not extraneous

2. Effect modifiers are variables that moderate the relationship between antecedent and consequent

3. **Remedies**

   Requires a priori identification of potential confounders that are measured for later uses needed.

   a. **Unbiased recruiting independent of assignments**

   b. **Random assignment**

      Monitoring and breaking protocol

      Representativeness

c. Blinding (as possible)

   i. Participant

   ii. Clinician

   iii. Analyst

d. Intention-to-treat analysis

   i. Completer analysis
   ii. Non-completion = fail
   iii. Last observation brought forward
   iv. Persuade a return for post testing only

e. Matching

f. Narrow inclusion criteria

g. Stratification

h. Analysis of covariance

III. Resources for Assessing Quality Indicators

A. Case Reports and Case Series

Jabs, D. A. (2005). Improving the reporting of clinical case series. *American Journal of Ophthalmology, 139*, 900-905.

Vandenbroucke, J. P. (2001). In Defense of Case Reports and Case Series. *Annals of Internal Medicine, 134*, 330-334.

B. Cross Sectional Designs

STROBE Checklist for Cross-Sectional Studies
http://www.strobe-statement.org/index.php?id=checklists

STROBE Statement: Available checklists - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://www.strobe-statement.org/index.php?id=checklists

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Strengthening the reporting of observational studies in epidemiology

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STROBE checklists

Version 4 as published in Oct / Nov 2007!

- STROBE checklist for **cohort, case-control, and cross-sectional studies** (combined)
  download PDF / Word
- Checklist for **cohort studies**
  download PDF / Word
- Checklist for **case-control studies**
  download PDF / Word
- Checklist for **cross-sectional studies**
  download PDF / Word

For translations in other languages see Translations page.

...print page!

Done

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants

C. Case Control Designs

STROBE Checklist for Case-Control Studies

D. Cohort Designs

STROBE Checklist for Cohort Studies

E. Parallel-Groups RCTs

Moher, D., Kenneth F. Schulz, K. F., & Altman, D. for the CONSORT Group (2001). The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials. *JAMA, 285, 15*, 1987-19991.

http://www.consort-statement.org/consort-statement/

F. Parallel-Groups CTs

Des Jarlais, D. C.,PhD, Lyles, C., Crepaz, N. & the TREND Group (2004). Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement. *American Journal of Public Health, 94*,361-366.

http://www.trend-statement.org/asp/trend.asp

G. Cross Over RCTs

Senn, S, (2002). *Crossover Designs in Clinical Research*. Wiley.

H. Single-subject trials

Chambless, D. L., & Hollon, S. D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66,* 7-188.