Sports Medicine Principals Concerning Observational Studies and Clinical Trials

Robert J. Johnson, MD
Bruce D. Beynnon, PhD

Department of Orthopaedics and Rehabilitation
McClure Musculoskeletal Research Center
University of Vermont
Burlington, Vermont

Purpose of Clinical Investigation

- Describing what is

  Assess association between:

  exposure and disease

  or

  exposure and injury

Purpose of Clinical Investigation

- Describing what is
- Predicting what could happen in the future

Assess association between:

risk factors and disease

or

risk factors and injury

Purpose of Clinical Investigation

- Describing what is
- Predicting what could happen in the future
- Establish cause and effect in therapeutic intervention
  - Efficacy
  - Effectiveness
  - Efficiency (quality of care)

How to Plan Clinical Research

Review the literature

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- What is known about the problem of interest?
- What is unknown or problematic about the known?

How to Plan Clinical Research

Review the literature

Define the research paradigm

ACL Disruption ➡ O.A. Paradigm

ACL Disruption ➡ O.A. Paradigm

Joint Kinematics

Normal Contact Stress

Normal Joint

Neuromuscular Function

Normal Biologic Response

Abnormal Kinematics

Abnormal Contact Stress

Progression of O.A.

Abnormal Neuromuscular Function

Abnormal Biologic Response

How to Plan Clinical Research

Review the literature

Define the research paradigm

Define the question (hypothesis)

Define the Question (Hypothesis)

- A major problem in clinical studies is establishing the hypothesis
- Research without a hypothesis may fail
- Match hypothesis with a research paradigm
- The hypothesis must be answerable with the methods available
- Define the study population
- Specify the exposure or intervention
- Specify the endpoint of interest in quantifiable terms

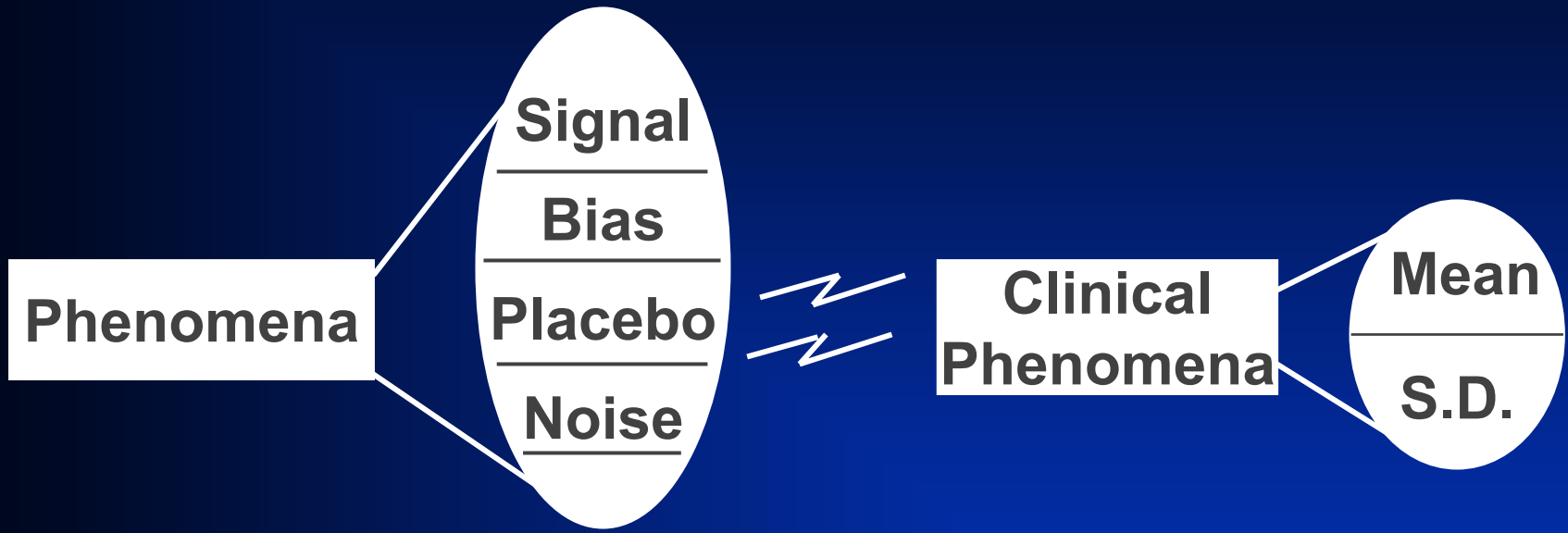
How to Plan Clinical Research

Review the literature

Define the research paradigm

Define the question (hypothesis)

Choose valid measurement tools


Phenomena
Signal
Bias
Placebo
Noise
Clinical Phenomena
Mean
S.D.

Patient-Centered Measures

- Content validity
- Face validity
- Construct validity
- Responsiveness to clinical change
- Reliability

How to Plan Clinical Research

Review the literature

Define the research paradigm

Define the question (hypothesis)

Choose valid measurement tools

Appropriate statistical procedures

Statistical Design

- Statistical methods should be matched with study hypothesis
- Statistical methods should be appropriate for data collected
- Consider drop outs/loss to follow-up
- Consult with a biostatistician

How to Plan Clinical Research

Review the literature

Define the research paradigm

Define the question (hypothesis)

Choose valid measurement tools

Appropriate statistical procedures

Choose an appropriate approach
(determine the method of data collection)

Clinical Research
Two Types of Studies

- Observational Studies:

  Investigators just observe
  - Case Study
  - Clinical (cohort) study
  - Case-control

- Experimental Studies: (RCT)

  Investigators set exposure/treatment