

Measurement
in Clinical Research

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OBJECTIVE

Enhance understanding of key principles of measurement relevant for clinical research

Performance

Time

Distance

Speed

Calories

CONSTRUCT

A theoretical concept

MEASUREMENT

A system of defining the level of a construct

Operational Definition

The method used for examining some domain

Examples

Depression

Hamilton Depression Rating Scale

Beck Depression Inventory

Tremor

Judge rated spirals

Computer evaluated spirals

Heart Disease

Cholesterol

C-Reactive Protein

OUTLINE

Validity

Reliability

Sensitivity to Change

Scale

Feasibility

VALIDITY

How well does the measure reflect the construct?

VALIDITY

VALIDITY: Types

Construct

Face

Content

Criterion-related

Convergent

Divergent

RELIABILITY

Consistency of measurement

RELIABILITY

RELIABILITY and VALIDITY

RELIABILITY: Types

Internal Consistency

Inter-Rater

Test-Retest

RELIABILITY: Problems

Lack of reliability introduces error into your measurement

Less sensitive statistics

Larger sample size

Uninterpretable results

Reliability and Sample Size

RELIABILITY: Improving

Provide standardized procedures

Train raters

Monitor raters

Use multiple raters for each rating

Take repeated observations

SENSITIVITY to CHANGE

Ability to detect improvement or worsening

SENSITIVITY to CHANGE

Can assess with effect size

Cohen's $d = (\text{Mean}_2 - \text{Mean}_1) / \text{SD}$

Standard Interpretation

.8 Large

.5 Moderate

.2 Small

SENSITIVITY to CHANGE

SENSITIVITY to CHANGE

SCALE

No order

Ordered (ranked)

Ordered + Equal spacing

Ordered + Equal spacing + Absolute zero

SCALE

Nominal

Ordinal

Interval

Ratio

SCALE

Continuous

Categorical

When should you use these?

(Kraemer, et al., J Psychiatric Res., 2004)

Continuous – study outcome

Categorical – clinical relevance

Clinical Relevance

If have illness, how often is test positive?

If no illness, how often is test negative?

If test positive, how often have illness?

If test negative, how often no have illness?

Sensitivity and Specificity

Positive and Negative Predictive Value

FEASIBILITY

Cost

Time

Environment

RESOURCES

International Conference on Harmonization (1998). E9: Statistical principles for clinical trials.

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/Step4/E9_Guideline.pdf

Kraemer (1991). To increase power in randomized clinical trials without increasing sample size. *Psychopharmacology Bulletin*.

Lachin (2004). The role of measurement reliability in clinical trials. *Clinical Trials*.

Rosenthal & Rosnow (2008). *Essentials of Behavioral Research: Methods and Data Analysis*.