

# Measurement in Clinical Research

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## OBJECTIVE

Enhance understanding of key principles  
of measurement relevant for clinical  
research

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**Performance**

- Time
- Distance
- Speed
- Calories

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**CONSTRUCT**  
• A theoretical concept

**MEASUREMENT**  
• A system of defining the level of a construct

• **Operational Definition**  
• The method used for examining some domain

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**Examples**

**1. Depression**  
A. Hamilton Depression Rating Scale  
B. Beck Depression Inventory 

**2. Tremor**  
A. Judge rated spirals  
B. Computer evaluated spirals 

**3. Heart Disease**  
A. Cholesterol  
B. C-Reactive Protein 

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**OUTLINE**

1. Validity
2. Reliability
3. Sensitivity to Change
4. Scale
5. Feasibility

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**VALIDITY**  
How well does the measure reflect the construct?



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**VALIDITY**



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**VALIDITY: Types**

- 1. Construct**
  - A. Face
  - B. Content
  
- 2. Criterion-related**
  - A. Convergent
  - B. Divergent

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**RELIABILITY**  
Consistency of measurement



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**RELIABILITY**



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**RELIABILITY and VALIDITY**

	Valid	Not Valid
Reliable		
Not Reliable		

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### RELIABILITY: Types

1. Internal Consistency
2. Inter-Rater
3. Test-Retest

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### RELIABILITY: Problems

Lack of reliability introduces error into your measurement

1. Less sensitive statistics
2. Larger sample size
3. Uninterpretable results

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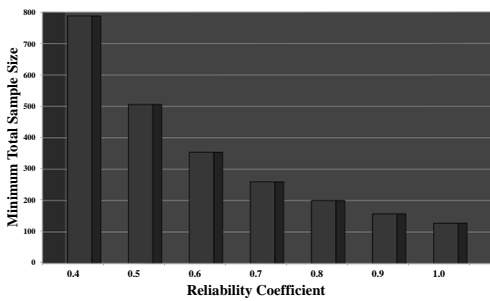
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### Reliability and Sample Size



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**RELIABILITY: Improving**

1. Provide standardized procedures
2. Train raters
3. Monitor raters
4. Use multiple raters for each rating
5. Take repeated observations

Kraemer, et al., Psychopharm Bull, 1991

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**SENSITIVITY to CHANGE**

Ability to detect improvement or worsening

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**SENSITIVITY to CHANGE**

Can assess with effect size

Cohen's  $d = (\text{Mean2} - \text{Mean1}) / \text{SD}$

- Standard Interpretation
  - .8 Large
  - .5 Moderate
  - .2 Small

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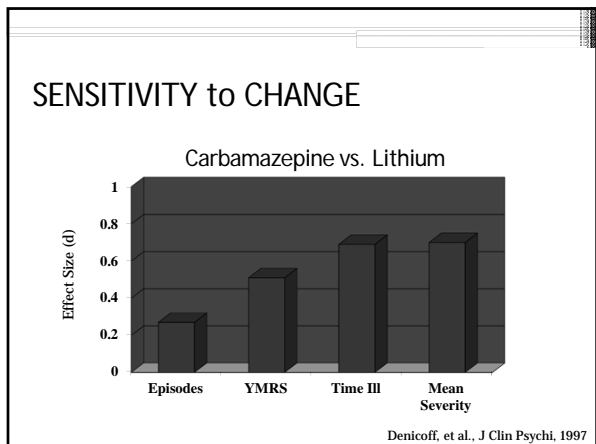
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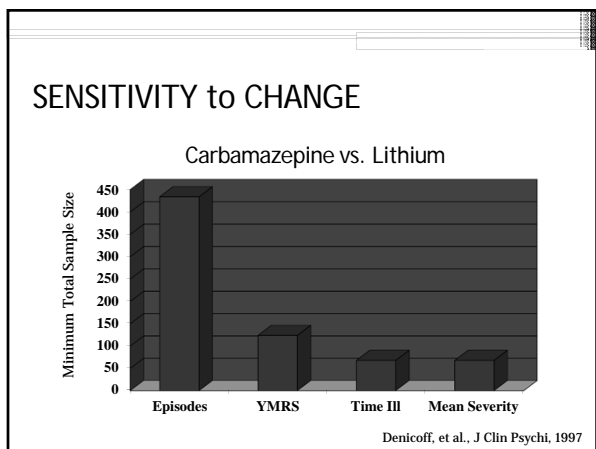
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- ### SCALE
1. Nominal  
No order
  2. Ordinal  
Ordered (ranked)
  3. Interval  
Ordered + Equal spacing
  4. Ratio  
Ordered + Equal spacing + Absolute zero

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**SCALE**

1. Nominal  
Diagnostic status (yes/no)
2. Ordinal  
Stage of illness
3. Interval  
Severity of illness
4. Ratio  
Number of doctor visits

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**SCALE**

1. Continuous
2. Categorical
3. When should you use these?  
(Kraemer, et al., J Psychiatric Res., 2004)  
A. Continuous – study outcome  
B. Categorical – clinical relevance

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**Clinical Relevance**

1. Sensitivity  
If have illness, how often is test positive?
2. Specificity  
If no illness, how often is test negative?
3. Positive Predictive Value  
If test positive, how often have illness?
4. Negative Predictive Value  
If test negative, how often no have illness?

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### Sensitivity and Specificity

		Illness	
		Yes	No
Test	Positive	118	39
	Negative	30	47
		<b>0.797</b>	<b>0.547</b>
		118/(118+30)	47/(39+47)
		<b>Sensitivity</b>	<b>Specificity</b>

Olie, et al., J Aff Dis, 2011

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### Positive and Negative Predictive Value

		Illness		
		Yes	No	
Test	Positive	118	39	0.752 118/(118+39) <b>Positive Predictive Value</b>
	Negative	30	47	0.610 47/(30+47) <b>Negative Predictive Value</b>

Olie, et al., J Aff Dis, 2011

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### FEASIBILITY

1. Cost
2. Time
3. Environment

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## 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](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.

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