Evidence-Based Practice and the Use of Reliable Change Methods
Gordon J. Chelune, Ph.D.

Learning Objectives:
As a result of attending this presentation, participants will be able to:
1. Discuss and explain the critical factors that affect the reliability and fidelity of serial assessments and the unique statistical features of change scores;
2. Compare and contrast reliable change methods that estimate and/or measure the dispersion of change scores and how these methods can be linked to base-rate information and Test Operating Characteristics to inform clinical practice and enhance clinical research;
3. Use simple summary data in test manuals and research reports to create regression equations to evaluate the significance between observed and predicted retest scores.

Themes
Evidence-Based Practice
Clinically Meaningful Change
A Tool for Assessing Change
Evidence-Based Practice and the Use of Reliable Change Methods
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What is Evidence-Based Clinical Neuropsychology?

A value-driven pattern of clinical practice that attempts to integrate “best research” derived from the study of populations to inform clinical decisions about individuals within the context of the provider’s expertise and individual patient values with the goal of maximizing clinical outcomes and quality of life for the patient in a cost-effective manner while addressing the concerns and needs of the provider’s referral sources.

Adapted from Chelune, 2010

Clinical Practice and Evidence-Based Medicine

The impetus of evidence-based practice medicine has its roots in the “outcomes movement” of the 1980s when it became increasingly apparent to payers and many practitioners that a significant portion of health care expenditures was wasted on unproven or ineffective tests and treatments.

Horwitz, 1996

Outcomes Management

A value-driven, evidence-based health care system

Outcomes accountability and the management of individual patients on the basis of epidemiologic information regarding outcomes became increasingly critical to the practice of medicine.

Johnson, 1997

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What is a Clinical Outcome?

In a broad sense, clinical outcomes are discrete measurable events, marked by a change in status, performance, or other objectively defined endpoint, that can be tracked both in the aggregate on a group level but also, importantly, at the level of the specific patient.

To be useful in the care of patients, outcomes data must be analyzed and packaged in such a manner that they can be directly "used" by the end-user, namely the clinician.

Chelune, 2002, 2010

Assumptions:

Every Clinical Patient Assessment...

➢ Represents a Clinical Outcome
➢ Can be interpreted within context of Evidence-based Research

Evidence-based Practice and Research

One of the defining features of evidence-based practice is the use of data derived from research based on populations to inform clinical decisions about individuals...

...how do we move from group data to data that is applicable at the level of the individual?

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Change
Has there been a "change" in the patient's clinical status?

How Do We Go About Recognizing Significant Change in Neuropsychological Performance?

And Why is it important?

Clinical Assessments Involve Inferences About CHANGE
- Single-Point Assessment – Does the observed test score represent a meaningful difference from an inferred premorbid?
- Serial Assessment – Does the observed retest score represent a meaningful change/difference from baseline?

It’s All About Change and the Base Rates of Change
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The Role of Serial Assessments in Clinical Neuropsychology
- Evaluating recovery from an injury
- Documenting progression of a neurodegenerative process
- Examining the impact of rehabilitation or other intervention (surgical intervention, drug therapy, etc)
- Providing a routine follow-up to a previous evaluation
- Conducting forensic neuropsychological assessments

Has there been a “change” in my patient’s clinical status?

Serial Assessment

Test 1 Test 2 Test 3
Difference 1 Difference 2

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"No man ever steps in the same river twice, for it's not the same river and he's not the same man.”

Heraclitus 535–475 BC

Reliable vs. Meaningful Change
Matarazzo & Herman: JCN, 1984

Statistical Reliability describes whether an observed level of difference between 2 scores is apt to be a reliable and repeatable difference from 0 and not due to measurement error and chance fluctuations in the scores.

Addresses the Question of "How Much"

Is the difference between groups statistically reliable?

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Reliable vs. Meaningful Change
Matarazzo & Herman: JCN, 1984

Clinical Abnormality describes whether an observed difference between 2 scores is sufficiently rare in a normal population that it is more likely to be obtained in a population that is external to the normative group (i.e. an “abnormal” population).

Addresses the Question of “How Many”

The Question: “How Many”

COI

Optimal Cut-off
Maximizes Sensitivity and Specificity
Best Over All Hit Rate

RP

True Positives (Sensitivity)
True Negatives (Specificity)
Performance

Assessment of Test-Retest Change
Statistical Issues

Stability
↓ (Bias)

Reliability
↓ (Error)

Variable of Interest
Practice Effects
Demographic Influences

Measurement Error
Regression to the Mean
Random Events

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Distribution of Difference (Change) Scores

Perfect Stability and near perfect Reliability

Distribution of Difference (Change) Scores

Perfect Stability but less than perfect Reliability

Distribution of Difference (Change) Scores

Less than perfect reliability and a systematic bias or practice effect

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Regression to the Mean

\[ X_{sp2} = X_{sp1} - \left( (X_{sp1} - M) (1 - r_{12}) \right) \]

Test A:

<table>
<thead>
<tr>
<th>M</th>
<th>( r_{12} )</th>
<th>( X_{sp1} )</th>
<th>( X_{sp2} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.90</td>
<td>120</td>
<td>118</td>
</tr>
<tr>
<td>80</td>
<td>0.90</td>
<td>80</td>
<td>82</td>
</tr>
<tr>
<td>70</td>
<td>0.90</td>
<td>70</td>
<td>73</td>
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</tbody>
</table>

Test B:

<table>
<thead>
<tr>
<th>M</th>
<th>( r_{12} )</th>
<th>( X_{sp1} )</th>
<th>( X_{sp2} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.75</td>
<td>120</td>
<td>115</td>
</tr>
<tr>
<td>80</td>
<td>0.75</td>
<td>80</td>
<td>85</td>
</tr>
<tr>
<td>70</td>
<td>0.75</td>
<td>70</td>
<td>77.5</td>
</tr>
</tbody>
</table>

"Change" is a Variable:

Has its own Unique Statistical Properties

They are dependent on the Stability and Reliability of the assessment tool

Alternately, the degree of independence from Bias and Error

How Should We Deal With Issues of Bias and Error?

1. Alternate Forms
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Four alternate forms administered 4x, 1-2 weeks apart

“Reasonable alternate form comparability was demonstrated ... Nonetheless, alternate forms are likely to be an insufficient means of controlling practice in speeded measures at brief (1-2 weeks) retest intervals. Reliable change indices demonstrated that practice must be accounted for in individual retesting.”

How Should We Deal With Issues of Bias and Error?

1. Alternate Forms
2. Extend the Test-Retest Interval
3. Reliable Change Methods

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Reliable Change Indexes

2. Reliable Change Index (Jacobsen & Truax, 1991)
3. Practice Adjusted Reliable Change Index (Chelune, et al., 1993)
4. Modified Practice Adjusted Reliable Change Index (Iverson, 2001)
5. Reliable Change based on Standard Error of Prediction (Basso, et al., 1999; Theisen et al., 1998)

Two ways to determine the frequency or base rate of an observed score relative to a reference population:

1. Simple Difference Approach
2. Predicted Difference Approach

<table>
<thead>
<tr>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient A</td>
<td>100</td>
</tr>
<tr>
<td>Patient B</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1</td>
<td>99.85</td>
<td>13.63</td>
</tr>
<tr>
<td>Time 2</td>
<td>104.36</td>
<td>14.97</td>
</tr>
<tr>
<td>Difference</td>
<td>4.51</td>
<td></td>
</tr>
</tbody>
</table>

Test-Retest Sample (N=373)

WAIS-III

Simple Difference Approach

\[
\frac{(X_2 - X_1)}{SD_{diff}} = z-score
\]
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Case Example

Patient A  
95 - 100 = -5.00
- 4.51
- 9.51

z - score = (- 9.51 / 4.77) = -1.99
*p = 2.3% statistically rare

*Area under the Unit Curve

Case Example

Patient B  
105 - 100 = +5.00
- 4.51
+ .49

z - score (+0.49 / 4.77) = .10
*p = 46% ns

*Area under the Unit Curve

Estimated Reliable Change Indexes
(Jacobson & Truax, 1991)

RCI Describes a Confidence Interval
Around the Mean Difference Score

Represents the standard error of the difference between two test scores
and describes the spread of the distribution of changes scores that
would be expected if no actual change had occurred

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Estimating the Standard Deviation of Differences:
\[ S_{\text{diff}} \]

Standard Error of the Difference

Represents the standard error of the difference between two test scores and describes the spread of the distribution of changes scores that would be expected if no actual change had occurred

Standard Error of Measurement:
\[ SE_m = SD_1 \sqrt{1 - r_{12}} \]

Standard Error of the Difference:
\[ S_{\text{diff}} = \sqrt{2(SE_m)^2} \]

Jacobsen & Truax, 1991

\[ S_{\text{diff}} \] of T2–T1 Differences

Individual Change:
"...in the same spirit of Cohen's effect size"

\[ Z\text{-Score} = (T2 - T1) / S_{\text{diff}} \]

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Reliable Change Index

Practice Adjusted Reliable Change Index

\[
\begin{array}{l}
\text{Mean} \quad \text{SD} \\
\text{Time 1} \quad 99.85 \quad 13.63 \\
\text{Time 2} \quad 104.36 \quad 14.97 \\
\text{Difference} \quad 4.51 \quad 4.77 \\
\text{Test-Retest } r_{xy} \quad 0.949 \\
\end{array}
\]

Standard Error of Measurement:
\[ SE_{m} = SD \sqrt{1 - r_{12}} = 3.078 \]

Standard Error of the Difference:
\[ S_{diff} = \sqrt{2(SE_{m})^2} = 4.353 \]

Case Example

Patient A  
\[ 95 \rightarrow 100 = -5.00 \]
\[ -4.51 \]
\[ -9.51 \]

\[ z - \text{score} = (-9.51 / 4.35) = -2.19 \]
\[ *p = 1.43\% \text{ statistically rare} \]

*Area under the Unit Curve

Modified Practice Adjusted Reliable Change Index

\((Iverson, 2001)\)

Standard Error of Measurement:
\[ SE_{m1} = SD_{1} \sqrt{1 - r_{12}} = 3.078 \]
\[ SE_{m2} = SD_{2} \sqrt{1 - r_{12}} = 3.381 \]

Standard Error of the Difference:
\[ S_{diff} = \sqrt{(SE_{m1} + SE_{m2})^2} = 4.571 \]

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Reliable Change Index
Reliable Change based on Standard Error of Prediction
(Wais-III Test-Retest Sample (N=373))

Standard Error of the Prediction (SEₚ)
SEₚ = SD₂√(1 - r₁²)

= 4.719

Comparison of RCI Methods

<table>
<thead>
<tr>
<th></th>
<th>Obs SD of diff</th>
<th>RCI</th>
<th>Mod RCI</th>
<th>SEₚ</th>
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<tr>
<td>Sₑₑₑ</td>
<td>4.77</td>
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<td>z-score</td>
<td>-1.99</td>
<td>-2.19</td>
<td>-2.17</td>
<td>-2.02</td>
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<tr>
<td>%</td>
<td>2.30</td>
<td>1.43</td>
<td>1.50</td>
<td>2.17</td>
</tr>
</tbody>
</table>

Limitations of the
Simple Difference Method

The mean difference score (practice effect /
discrepancy) is treated as a constant.
No provision is made for the influence of regression
to the mean.
Does not account for other factors that might affect
the difference scores.
When the observed SD of differences is not known,
RCI methods vary in how they estimate the SDₑₑₑ.
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Reliable Change Index Scores
(Simple Difference Approach)

Rest in Peace
– along with pneumoencephalograms, Piotrowski sign, kussatones...

Predicted Difference Method

• Regression Equation to predict WHERE a person should be on variable Y given knowledge of variable X.

Prediction Equation — \( Y_{\text{p}} = bX + C \)
Yields predicted retest scores based on baseline scores and relevant demographic characteristics.

• (Observed – Predicted): How FAR away a person is from where s/he should be on Retest/Variable Y.

• Normalized Z-Scores of Change —
\[ z = \frac{(Y_{\text{o}} - Y_{\text{p}})}{\text{SEE}} \] (Standard Error of Estimate)

(Observed-Predicted)/SEE

Regression Based Change Scores

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Predicting Retest FSIQs

Baseline FSIQ
Age
Education
Sex
Test-Retest Int.

Retest FSIQ

WAIS-III FSIQ

\[ Y_p = \beta Y_b + \beta X_{age} + C \]

\[ Y_p = (1.036 \times \text{FSIQ}_1) + (-0.04155 \times \text{Age}) + 3.064 \]

\[ R = 0.951 \quad R^2 = 0.904 \quad \text{SEE} = 4.6478 \]

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\[ Y_p = (1.036 \times FSIQ_1) + (-0.04155 \times Age) + 3.064 \]
\[ Y_p = (1.036 \times 100)^{-0.04155 \times 67} + 3.064 \]

**Observed Retest = 95.00**
**Predicted Retest = -103.88**
\[ z-score = \frac{-8.88}{4.6478} = -1.91 \]
\[ *p = 2.81\% \text{ statistically rare} \]

Advantages of the Predicted Difference Method

- Differences in Initial Baseline Scores
- Practice Effects
- Regression to the Mean
- Differences in Reliability Between Measures
- Takes into account relevant demographic variables

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But ….

I don’t have access to the standardization data to derive the regression equations and to do the computations.

Besides, doing all of those computations for each patient seems really tedious and prone to error!

RegBuild_MR.exe:

What is needed:
1. Sample Size (N)
2. Means and Standard Deviations
3. Zero-order Correlations

Available at:
http://homepages.abdn.ac.uk/j.crawford/pages/dept/

Or
http://www.utahmemory.org

Education tab: Professional CE/CME Courses
INS 2014 Jerusalem: EBM & Reliable Change

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Predicting Retest FSIQs

Baseline FSIQ
Age
Education
Sex
Test-Retest Int.

Retest FSIQ

There is a wealth of data in the published research literature to which these methods can be applied

Assessing Reliable Cognitive Decline in Older Adults: Part I
Efficacy of Multivariate Regression Equations Derived from Summary Data
Gordon Chelune1, John Crawford1, John Sheehan2, Kevin Bui3, James Hodnick1, Otto Podreka4
1University of Utah School of Medicine, 2University of Kentucky, 3University of New Orleans, 4Wayne State University

<table>
<thead>
<tr>
<th>Variable</th>
<th>Test</th>
<th>Retest</th>
<th>Age</th>
<th>Edu</th>
<th>Sex</th>
<th>Retest</th>
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<td>329</td>
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<tr>
<td>Trails B</td>
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</tbody>
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How Many? -- Bayesian approach: Analyses of Changes in Base Rates

Bayes' Theorem: What we know after giving a test is equal to what we knew before doing the test times a modifier (based on the test results). Test results are used to adjust a prior distribution to form a new posterior distribution of scores.

Value Driven Pattern of Practice

The Basic 2x2 Table

<table>
<thead>
<tr>
<th>Condition of Interest</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong> + Factor (event)</td>
<td>True Positive A</td>
<td>False Positive B</td>
</tr>
<tr>
<td><strong>No</strong> -</td>
<td>False Negative C</td>
<td>True Negative D</td>
</tr>
</tbody>
</table>

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Bayesian Test Operating Characteristics

<table>
<thead>
<tr>
<th>% Prevalence</th>
<th>Odds</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Overall Correct Hit Rate</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Relative Risk Ratio</td>
</tr>
<tr>
<td>Specificity</td>
<td>Likelihood Ratio</td>
</tr>
<tr>
<td>Positive Predictive Power</td>
<td>Pre – Post Test Odds</td>
</tr>
<tr>
<td>Negative Predictive Power</td>
<td>Pre – Post Test Probabilities</td>
</tr>
</tbody>
</table>

Chelune, TCN 2010

<table>
<thead>
<tr>
<th>Table 1. Clinical Sample Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sample (N=503)</td>
</tr>
<tr>
<td>M</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>MMSE</td>
</tr>
<tr>
<td>Rated Interval (mo)</td>
</tr>
<tr>
<td>Sex (%Male)</td>
</tr>
<tr>
<td>Handedness (%Right)</td>
</tr>
</tbody>
</table>

MMSE Group Classifications per Tombaugh & Mahoney (1990)


g = .001 | .01 | .05

<table>
<thead>
<tr>
<th>Table 2. Comparison of Predicted-Difference t-scores of Change by MMSE level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td>DIS</td>
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<td>24-30</td>
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The Basic 2x2 Table

<table>
<thead>
<tr>
<th>Condition of Interest</th>
<th>RCD +</th>
<th>RCD -</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMSE 18-23 True Positive</td>
<td>A</td>
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</tr>
<tr>
<td>MMSE &gt; 24 False Positive</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>False Negative</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>True Negative</td>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Percentage of Reliable Cognitive Decline (RCD) by MMSE level with Odds and Likelihood Ratios

<table>
<thead>
<tr>
<th>Test</th>
<th>MMSE Level</th>
<th>% RCD</th>
<th>p-level</th>
<th>Odds Ratio</th>
<th>Likelihood Ratio</th>
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<tbody>
<tr>
<td>DRS</td>
<td>18-23</td>
<td>91.0</td>
<td>.0001</td>
<td>7.0</td>
<td>4.8</td>
</tr>
<tr>
<td></td>
<td>24-30</td>
<td>59.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BNT</td>
<td>18-23</td>
<td>50.0</td>
<td>.0001</td>
<td>2.5</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>24-30</td>
<td>38.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COWA</td>
<td>18-23</td>
<td>26.7</td>
<td>.051</td>
<td>1.8</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>24-30</td>
<td>16.5</td>
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<td></td>
<td></td>
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<tr>
<td>AVF</td>
<td>18-23</td>
<td>38.1</td>
<td>.026</td>
<td>1.6</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>24-30</td>
<td>29.2</td>
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<td></td>
</tr>
<tr>
<td>Trails A</td>
<td>18-23</td>
<td>36.8</td>
<td>.0001</td>
<td>2.9</td>
<td>2.1</td>
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<tr>
<td>Trails B</td>
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<td>nS</td>
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<td>0.7</td>
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<td></td>
<td>24-30</td>
<td>25.1</td>
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</table>

Conclusions

1. “Change” as a neurocognitive variable has its own unique statistical properties that are dependent on the reliability and stability of the tools used to assess change.
2. By taking into account the factors that affect change scores, it is possible to empirically identify changes that are relatively rare and likely to represent meaningful changes (outcomes) in a person’s cognitive status.
3. It is possible to use simple summary data in test manuals and research reports to create prediction equations to evaluate the significance between an individual’s observed and predicted retest scores, assisting the clinician to use research data obtained on populations to inform clinical decisions about individuals.

International Neuropsychological Society 2014 Mid-Year Meeting, Jerusalem, Israel
Selected References:


