

# Challenges and Recommendations Related to Assuring Quality Outcomes Data Collected via Electronic Platforms

Panel:

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# ePRO Consortium Members



Bracket™



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# Learning Objectives



- Ability to identify the level of modification for migration from paper to electronic
- Ability to determine the level of evidence required to support equivalence of the data generated from the electronic migration

# Agenda

- Introduction
  - Is paper different from electronic?
  - Why measurement equivalence matters
- Overview of Instrument Migration Evidence
  - Usability Testing
  - Cognitive Interviewing
  - Equivalence Testing
- Two Scenarios for Migration of SQLS
  - Schizophrenia Quality of Life Scale (SQLS)
  - Scenario 1: Paper to PDA
  - Scenario 2: Paper to IVR
- Summary and Discussion

# Is Paper Different from Electronic?

- Operationally: Yes!
  - Usability testing
  - Additional site/subject training
  - Study start up, database build, and study close
- Data Quality: Yes!
  - Compliance monitoring – date/time stamp
  - Less missing/more complete data
  - Fewer data inconsistencies
- Conceptually: Perhaps!
  - It depends.
  - What types of modifications are needed to administer it electronically?

# Why Measurement Equivalence Matters



- Outcome comparisons using the same instrument across
  - Therapeutic products
  - Studies
- Data pooling

# Sponsor Resource

## ISPOR ePRO Task Force Efforts



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VALUE IN HEALTH

### **Recommendations on Evidence Needed to Support Measurement Equivalence between Electronic and Paper-Based Patient-Reported Outcome (PRO) Measures: ISPOR ePRO Good Research Practices Task Force Report**

Stephen Joel Coons, PhD,<sup>1</sup> Chad J. Gwaltney, PhD,<sup>2</sup> Ron D. Hays, PhD,<sup>3</sup> J. Jason Lundy, PhD,<sup>4</sup> Jeff A. Sloan, PhD,<sup>5</sup> Dennis A. Revicki, PhD,<sup>6</sup> William R. Lenderking, PhD,<sup>7</sup> David Cella, PhD,<sup>8</sup> Ethan Basch, MD, MSc,<sup>9</sup> on behalf of the ISPOR ePRO Task Force

# Instrument Modification Supporting Evidence

Level of Modification	Examples	Level of Evidence
<b>Minor</b>	<p><b>Changes in</b></p> <ul style="list-style-type: none"> <li>• <b>instructions</b> e.g. from circling a response to touching the response on a screen</li> <li>• <b>format</b> e.g. one question per screen rather than multiple answers on a page of paper</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Usability Testing</b></li> <li>• <b>Cognitive Interviewing</b></li> </ul>
<b>Moderate</b>	<p><b>Changes in</b></p> <ul style="list-style-type: none"> <li>• <b>item wording</b> that could alter interpretability</li> <li>• <b>mode of administration</b> involving different cognitive processing e.g. paper to IVR</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Usability Testing</b></li> <li>• <b>Cognitive Interviewing*</b></li> <li>• <b>Equivalence Testing</b></li> </ul>
<b>Major</b>	<p><b>Substantial changes in</b></p> <ul style="list-style-type: none"> <li>• <b>item wording</b></li> <li>• <b>response options</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Usability Testing</b></li> <li>• <b>Full Psychometric Validation</b></li> </ul>

Adapted from Coons, et. al., Value in Health 2009; Shields, et. al., Applied Clinical Trials 2006

\* Scientific community consensus development ongoing



# SQLS Migration Source Version

We are interested in finding out about the quality of your life **OVER THE PAST SEVEN DAYS**. Please respond to all the following statements by ticking one box for each statement.

- |   |                          |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. I lack the energy to do things.                | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I am bothered by my <u>shaking/trembling</u> . | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I feel unsteady walking.                       | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I feel angry.                                  | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

# SQLS Migration

## Scenario 1: Paper to PDA

1. What type of evidence will be required to migrate the paper SQLS to a PDA format?
  - A. Usability and Cognitive Interviewing
  - B. Equivalence Testing
  - C. Full Psychometric Validation
  - D. A & B
  - E. A, B, & C

# SQLS Migration

## Scenario 2: Paper to IVR

1. What type of evidence will be required to migrate the paper SQLS to an IVR format?
  - A. Usability and Cognitive Interviewing
  - B. Equivalence Testing
  - C. Full Psychometric Validation
  - D. A & B
  - E. A, B & C

# Usability Testing

## ■ ISPOR ePRO Taskforce

- *“Usability testing examines whether respondents from the target population are able to use the software and the device appropriately”*
- *“The overall goal is to demonstrate that respondents can complete the computerized assessment as intended”*

# Usability Testing - Procedure

- Script should be developed to ensure patients interact with the device in a way that reflects how it will be used in “real life”
  
- Vital that testing is conducted in a representative sample
  - Any specific considerations that might impair patients ability to interact and respond to the instruments should be tested in detail

# Usability Testing - Procedure

- Device specific
  - Weight of the device
  - Interacting with the device
  - Turning device on
  - Recharging
  
- Software specific
  - Entering answers
  - Navigating through the questionnaire
  - Editing responses
  - Edit checks

# Usability Testing

## - Considerations

- Usability testing should be conducted early enough that any feedback provided can be taken into consideration for the final instrument
- Depending on complexity and number of instruments will drive considerations for number of participants
  - 5 to 20+



# Usability Testing

## - Considerations

- Usability testing should be adapted as appropriate to the type of outcome measure being tested
  - Unsupervised setting (i.e., non site-based)
    - Patient-reported
    - Observer-reported
    - Clinician-reported
  - Supervised setting (i.e., site-based)
    - Patient-reported
    - Observer-reported

# Cognitive Interviewing

# What is it?

- Part of a multi-stage approach to measure development
  - Methods developed in 1980s
- Analyse the questions from the respondent's viewpoint
  - How do patients/clinicians understand, mentally process and respond to PROs/ClinROs?
- Helps to unlock
  - Ambiguous wording
  - Difficult questions
  - Problematic response options



# Cognitive Interviewing Application Instrument Migration



- Objective:
  - Has the migration resulted in a change in the way that patients understand items?
  
- Assumptions:
  - Measure to be migrated has, as part of its development
    - Content validity
    - Has undergone a cognitive interview process
  - Established measure being migrated
    - Not possible to change the items

# Methods

- Development of protocol
- Recruitment of 10 patients
- Administration of instruments
- Verbal probing on migration changes and formatting options
- Audio-recording and transcribing
- Data analysis and formulation of recommendations
- Development of report

# Challenges

- Patient recruitment
  - Rare/acute conditions
- Length of interview
  - Battery of measures

# Equivalence Testing

# What is it?

## ISPOR ePRO Task Force:

- “Equivalence testing is designed to evaluate the comparability between PRO scores from an electronic mode of administration and paper-and pencil administration. The intent is to ensure that PRO scores from the ePRO do not vary significantly from those scores from a paper questionnaire (except for measurement error).” (p. 7)

Coons, et. al., Value in Health 2009



# Examples of Equivalence Study Designs

## Supervised End Use At Site (1 visit; N=60)

- Randomize order of mode
- Complete both modes within same visit session
- Distraction task in between
- Time between completions varies
  - Few minutes – 2 hours
- Results are compared statistically
- Usability interview may be added at the end

## Unsupervised End Use Diary or Field Instrument (3 visits; N=60)

- Randomize order of mode
- Visit 1: training on platform
- First mode completed between visit 1 and 2
- Second mode completed between visit 2 and 3
- Time between visits varies
  - 1 week – 2 weeks
- Results are compared statistically
- Usability interview may be added at Visit 3

# Statistical Comparisons

- Inter-class correlation (ICC)
  - Measures agreement between answers in the two modes
- Comparison of means
  - Measures mean differences between the two modes

# Issues and Concerns with Equivalence Testing

- What's an acceptable ICC value?
- Is there a recommended time interval between administrations?
  - Affected by recall?
  - Affected by nature of condition?
- How well do distraction tasks work?

# Revisit SQLS Scenarios

# SQLS Migration Source Version

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- |   |                          |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. I lack the energy to do things.                | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I am bothered by my <u>shaking/trembling</u> . | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I feel unsteady walking.                       | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I feel angry.                                  | Never                    | Rarely                   | Sometimes                | Often                    | Always                   |
|   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

# SQLS Migration

## Scenario 1: Paper to PDA

SQLS

We are interested in finding out about the quality of your life **OVER THE PAST SEVEN DAYS**. Please respond to the following statement by selecting one box.

1. I lack the energy to do things.

Never

Rarely

Sometimes

Often

Always

Back Next

SQLS

We are interested in finding out about the quality of your life **OVER THE PAST SEVEN DAYS**. Please respond to the following statement by selecting one box.

2. I am bothered by my shaking/trembling.

Never

Rarely

Sometimes

Often

Always

Back Next

# SQLS Migration

## Scenario 1: Paper to PDA

1. What type of evidence will be required to migrate the paper SQLS to a PDA format?
  - A. Usability and Cognitive Interviewing
  - B. Equivalence Testing
  - C. Full Psychometric Validation
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# Scenario 2: Paper to IVR

## SQLS: Items 1-10 on IVR script

Items	1	<u>I lack the energy to do things.</u>
	2	I am bothered by my shaking or trembling.
	3	I feel unsteady walking.
	4	I feel angry.
	5	I am troubled by a dry mouth.
	6	I can't be bothered to do things.
	7	I worry about my future.
	8	I feel lonely.
	9	I feel hopeless.
	10	My muscles get stiff.
Scale		Press 1 for Never.
		Press 2 for Rarely.
		Press 3 for Sometimes.
		Press 4 for Often.
		Press 5 for Always.



# SQLS Migration

## Scenario 2: Paper to IVR

1. What type of evidence will be required to migrate the paper SQLS to an IVR format?
  - A. Usability and Cognitive Interviewing
  - B. Equivalence Testing
  - C. Full Psychometric Validation
  - D. A & B
  - E. A, B & C

# Summary

- Electronic is different from paper
  - In many ways better – data quality
  - Measurement equivalence requires evidence
  - Resources are available to guide Sponsors
- Methods for evaluating measurement equivalence
  - Usability Testing
  - Cognitive Interviewing
  - Equivalence Testing
- Two Scenarios for Migration of SQLS
  - Schizophrenia Quality of Life Scale (SQLS)
  - Scenario 1: Paper to PDA
  - Scenario 2: Paper to IVR
- Discussion

# Discussion and Audience Questions

Thank you!