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

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* eResearch Technologies Inc at time of submission
ePRO Consortium Members

ALMAC

Bracket

CRF REAL PATIENT DATA 24/7

ERT Getting It Done. Right.

ICON A Symbol of Excellence

invivo data simply better data

PHT
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

Stephen Joel Coons, PhD, Chad J. Gwaltney, PhD, Ron D. Hays, PhD, J. Jason Lundy, PhD, Jeff A. Sloan, PhD, Dennis A. Revicki, PhD, William R. Lenderking, PhD, David Cella, PhD, Ethan Basch, MD, MSc, on behalf of the ISPOR ePRO Task Force
## Instrument Modification
### Supporting Evidence

<table>
<thead>
<tr>
<th>Level of Modification</th>
<th>Examples</th>
<th>Level of Evidence</th>
</tr>
</thead>
</table>
| **Minor**             | Changes in  
  • instructions e.g. from circling a response to touching the response on a screen  
  • format e.g. one question per screen rather than multiple answers on a page of paper |  
  • Usability Testing  
  • Cognitive Interviewing |
| **Moderate**          | Changes in  
  • item wording that could alter interpretability  
  • mode of administration involving different cognitive processing e.g. paper to IVR |  
  • Usability Testing  
  • Cognitive Interviewing*  
  • Equivalence Testing |
| **Major**             | Substantial changes in  
  • item wording  
  • response options |  
  • Usability Testing  
  • Full Psychometric Validation |

Adapted from Coons, et. al., Value in Health 2009; Shields, et. al., Applied Clinical Trials 2006  
* Scientific community consensus development ongoing
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
   □    □    □    □    □

2. I am bothered by my shaking or trembling. Never | Rarely | Sometimes | Often | Always
   □    □    □    □    □

3. I feel unsteady walking. Never | Rarely | Sometimes | Often | Always
   □    □    □    □    □

4. I feel angry. Never | Rarely | Sometimes | Often | Always
   □    □    □    □    □
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
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

Coons et al. (2009) also mentions randomized parallel groups design as an option.
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
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

2. I am bothered by my shaking/trembling.  
   Never  | Rarely  | Sometimes  | Often  | Always

3. I feel unsteady walking.  
   Never  | Rarely  | Sometimes  | Often  | Always

4. I feel angry.  
   Never  | Rarely  | Sometimes  | Often  | Always
### SQLS Migration

**Scenario 1: Paper to PDA**

<table>
<thead>
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<th>SQLS</th>
</tr>
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<tbody>
<tr>
<td>We are interested in finding out about the quality of your life <strong>OVER THE PAST SEVEN DAYS</strong>. Please respond to the following statement by selecting one box.</td>
</tr>
</tbody>
</table>

1. I lack the energy to do things.

   - Never
   - Rarely
   - Sometimes
   - Often
   - Always

2. I am bothered by my shaking/trembling.

   - Never
   - Rarely
   - Sometimes
   - Often
   - Always

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SQLS Migration
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### Scenario 2: Paper to IVR
### SQLS: Items 1-10 on IVR script

<table>
<thead>
<tr>
<th>Items</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I lack the energy to do things.</td>
</tr>
<tr>
<td>2</td>
<td>I am bothered by my shaking or trembling.</td>
</tr>
<tr>
<td>3</td>
<td>I feel unsteady walking.</td>
</tr>
<tr>
<td>4</td>
<td>I feel angry.</td>
</tr>
<tr>
<td>5</td>
<td>I am troubled by a dry mouth.</td>
</tr>
<tr>
<td>6</td>
<td>I can’t be bothered to do things.</td>
</tr>
<tr>
<td>7</td>
<td>I worry about my future.</td>
</tr>
<tr>
<td>8</td>
<td>I feel lonely.</td>
</tr>
<tr>
<td>9</td>
<td>I feel hopeless.</td>
</tr>
<tr>
<td>10</td>
<td>My muscles get stiff.</td>
</tr>
</tbody>
</table>

### Scale
- Press 1 for Never.
- Press 2 for Rarely.
- Press 3 for Sometimes.
- Press 4 for Often.
- Press 5 for Always.
1. What type of evidence will be required to migrate the paper SQLS to an IVR format?

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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)
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• Discussion
Discussion and Audience Questions
Thank you!