Best Practices on Response Scale Options for Electronic Implementation of Patient-Reported Outcomes

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Acknowledgment of Source

- ePRO Consortium of the Critical Path Institute (April 2014)

- c-path.org/programs/epro

Outline

- Introduction
- Verbal Rating Scales
- Visual Analog Scales
- Numeric Rating Scales

Introduction

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- Patient-reported outcome (PRO) endpoints are often needed to evaluate medical products in clinical trials
- Move from paper-based to electronic PRO (ePRO) has enhanced integrity and accuracy of PRO data
- US Food and Drug Administration as made it clear that electronic capture is preferred

Introduction

- Numerical response scales are commonly used PRO measures
- Describing these response scales on electronic platforms are becoming standard
- Special consideration exists for different platforms
  - Interactive voice response (IVR)
  - Handheld
  - Tablet
  - Web-based
- Best practices are needed

Verbal Rating Scales

Adjectival Scale

- **Description**
  - Discrete, ordered, uni-directional, verbal descriptors intended to describe a gradation of the dimension (e.g., intensity, frequency) of the concept being measured

- **Elements**
  - Adjectival scales consist of an item stem and a uni-directional, verbal response scale

Example

Over the past 7 days, how tired have you felt?

a. Not at All
b. A Little Bit
c. Moderately
d. Quite a Bit
e. Extremely

Likert-Type Scale

- **Description**
  - Similar to adjectival scales but are bi-directional
  - Used to assess agreement, attitude, probability

- **Elements**
  - Likert-type scales consist of an item stem and a bi-directional, verbal response scale

Example

Compared to the start of the study, would you describe your depression as:

a. Much better
b. Better
c. No change
d. Worse
e. Much worse

Considerations for Electronic Implementation: IVR

- Requires response choices in spoken format
  - E.g., “For not at all, press 1”
- Response choice should precede entry value
- Number and length of responses should be considered
- Order of response options should be presented consistently
- Responses should be confirmed by the subject

Considerations for Electronic Implementation: Handheld and Tablet

- Minimum screen size and font size should be established
- Same font size regardless of the amount of text
- Entire item response scale should appear on one screen
  - Some response scales may need vertical placement
- Each adjacent response option should be equidistant
- Tapped or touched area for response should be same size

Considerations for Electronic Implementation: Web

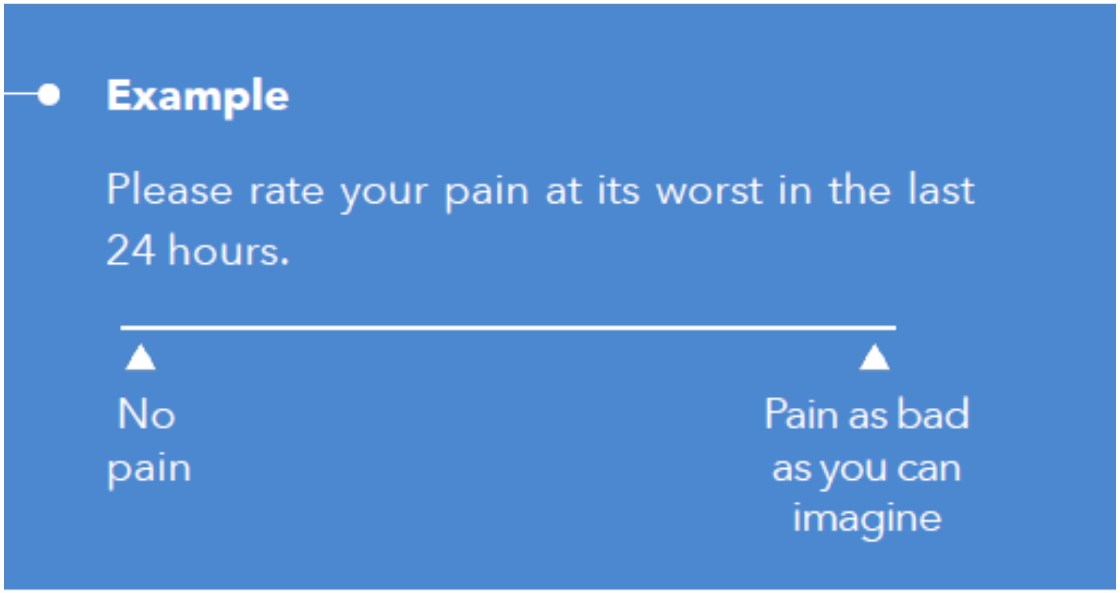
- Same as for the handheld and tablet platforms
- Critical distinction is that Internet can be accessed by multiple devices (e.g., smartphones, tablets, laptops, desktops)
- Recommended to have minimum requirement -- for example,
  - Browsers supported
  - Minimum screen size
  - Whether access is blocked for mobile devices

Visual Analog Scale (VAS)

VAS

- Description
  - Consists of a line of fixed length (typically 10cm)
  - Verbal anchors at the extreme ends
  - No descriptors at intermediate positions on the scale
  - True VAS has no numeric values at points along the scale

- Elements
  - Item stem with line between two verbal anchors



Considerations for Electronic Implementation: IVR

- The VAS requires subjects to place a mark on the line
- Thus, it is difficult to implement a true VAS on an IVR platform

Considerations for Electronic Implementation: Handheld

- For new PRO instrument, the VAS is not recommended because the scale itself is problematic
- The length of the line on a paper version is measured with a ruler to determine where the line was marked
- In most situations the length of the line or orientation may need to be modified for electronic formatting

Considerations for Electronic Implementation: Tablet

- Everything stated for handheld applies to tablet implementation
- Depending on tablet size, the length of the VAS line may be replicated
- However, with multiple tablet sizes available, providers may need to recommend a minimum screen size
  - Or the length of the line may need to be altered

Considerations for Electronic Implementation: Web

- Everything stated for handheld and tablet platforms applies to Web-based platforms
- Critical discussion is that the Internet can be accessed by multiple devices
- For items to appear as intended, minimum requirements are recommended
  - Browsers supported
  - Minimum screen size
  - Whether access is blocked for mobile devices
- Design of the study should ensure that every time a subject sees the VAS, it is always the same size

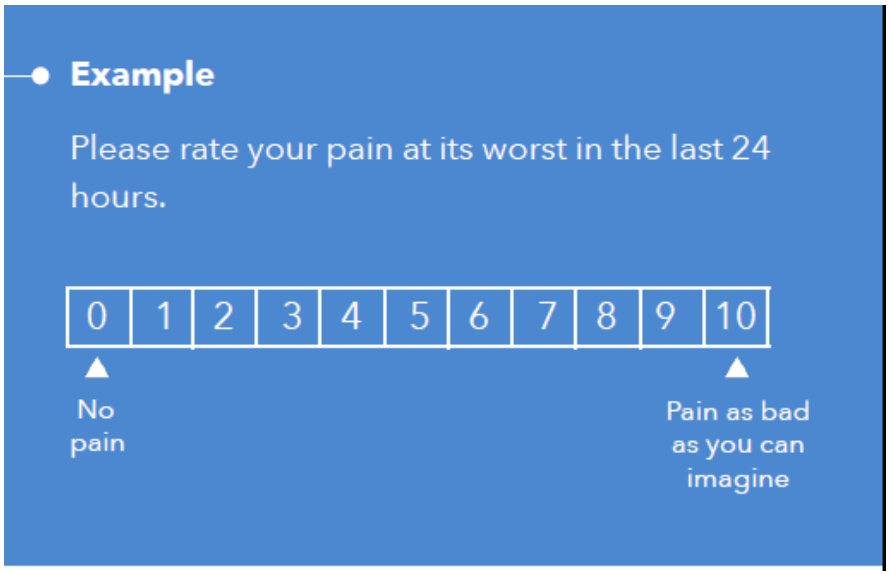
Numeric Rating Scale (NRS)

NRS

- Description
  - Consists of numerical gradations on continuum of some attribute
  - Typically, verbal descriptions at extremes and intermediate positions
  - Select the number corresponding to the perceived state

- Elements
  - Consists of item stem and numerical gradations (with and without verbal descriptors)

- Example



Considerations for Electronic Implementation: IVR

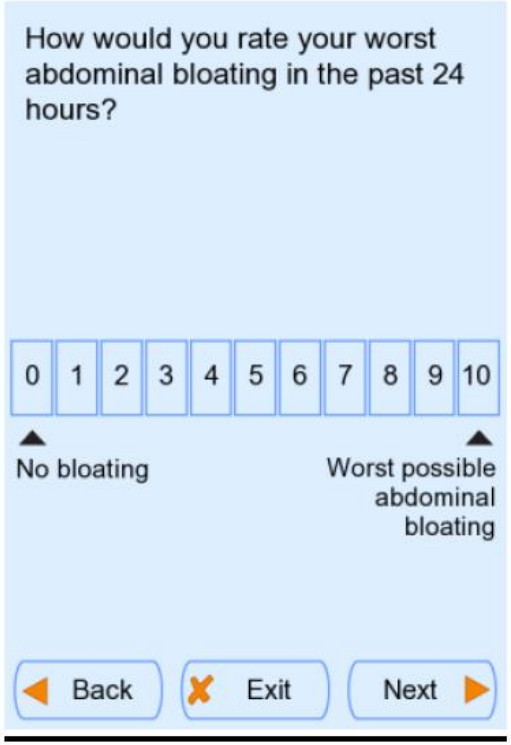
- Requires the item and response choices to be presented in verbal format – e.g., “Please rate your pain on a scale of 0 to 10, with 0 being no pain’ and 10 being the worst possible pain”

- System should collect up to the maximum number of digits of response choices (e.g., ’11,’ ‘100’)
  - May require use of the pound or hash key

- Responses should be repeated and confirmed by the subject
  - “We recorded you entered 10, is that correct?”
  - Adds time but ensures data quality

Considerations for Electronic Implementation: Handheld and Tablet

- Entire item should be self-contained and fit on one screen
  - Establish minimum screen size and a minimum font size
- Include an indicator to mark verbal anchors at ends of the scale
  - An indicator can be vertical line or arrow
- Anchor text should pertain to true ends
  - Caution: text may overlap different numbers



Considerations for Electronic Implementation: Web

- Everything stated previously for handheld and tablet platforms also applies for web-based platforms

- Critical distinction: the Internet can be accessed by multiple devices (desktops, laptops, smartphones, tablets)

- Recommended that specification include minimum requirements
  - Browsers support
  - Minimum screen size
  - Whether access is blocked for mobile devices

Summary

Summary

- Described three types of rating scales
  - Verbal Rating Scale
  - Visual Analogue Scale
  - Numeric Rating Scale
- Highlighted their electronic implementation
  - IVR
  - Handheld and tablet
  - Web