Best Practices for Electronic Implementation of Response Scales for Patient-Reported Outcome Measures

c-path.org/programs/epro
This document describes commonly used response scales in patient-reported outcome (PRO) measures. The target audiences are those developing PRO measures and those implementing PRO measures in electronic formats for clinical studies. Following the description of each response scale, considerations for implementation of these response scales on electronic platforms are provided. When selecting a mode of electronic implementation, the mode should support all the response scales to be utilized in the study. The considerations documented apply to interactive voice response (IVR), handheld, tablet, and web-based implementations. These considerations do not apply to nominal response options (e.g., checklists, dichotomous responses). Generally, this document recommends that each response scale is rendered the same on a given device/platform; for example, the font type and the orientation of the items (i.e., landscape or portrait) should be consistent throughout the assessment.

The scales presented in this document are ones commonly used by PRO instrument developers; they do not represent an exhaustive list of all the potential types of response scales available. Below is a review of the verbal rating scale (VRS), visual analogue scale (VAS), and numeric rating scale (NRS).
Verbal Rating Scale (VRS)

Unipolar VRS

**Description**

A unipolar VRS provides subjects with discrete, ordered, uni-directional, verbal descriptors intended to describe increasing or decreasing levels of the attribute (e.g., intensity, frequency) of the construct being measured.

**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

Bipolar VRS (e.g., Likert-Type Scale)

**Description**

A bipolar VRS, often called a Likert-type response scale, is similar to a unipolar scale in terms of the use of verbal descriptors, where a response is selected to best describe an outlook or experience, but with one exception; Likert-type scales are bi-directional, whereas adjectival scales are uni-directional, and measure a positive or negative response to a statement. Likert-type scales are most often used to assess agreement, attitude, and probability. Likert-type scales always have an implicit or explicit midpoint. The provision of an odd number of response categories allows raters to choose a middle, or neutral, response. An even number of response categories forces the respondent to commit themselves to one side of the scale or the other. The choice between odd and even response categories depends on the desirability of allowing a neutral position.

**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 of Verbal Rating Scales

**IVR:** IVR systems will require the response choices to be presented in aural (spoken) format (e.g., “For ‘Not at all’ press 1”). It is recommended that the response choice is stated before the entry value (e.g., “For ‘Not at all’ press 1” instead of “Press 1 for ‘Not at All’”) to ensure that the subject hears the entire response. The number and length (words) of the response options for the item should be considered due to the cognitive load, as the subject has to remember the entire item and response scale. The order of the responses options, if the same or similar, should be presented consistently to limit subject burden and confusion. The use of non-interruptible (non-bargeable) items and response scales should be considered, so that the subject must listen to the entire item and response scale before responding. Responses should be repeated and confirmed by the subject to ensure the response was entered as intended (e.g., “You entered ‘Not at all’, is that correct?”).

**Handheld and Tablet:** Minimum screen size and minimum font size should be established when including verbal rating scales, considering the length of the item stem and response scale. The entire item should be self-contained (i.e., include the entire item and response scale) on one screen. Scrolling should be avoided. Some response scales may need to be represented as a vertical array due to screen size. It is recommended that each response option be formatted to appear equidistant from other response options. It is important that only one response choice can be selected for a given item. When designing the screen, the hit-spot (the area on screen that can be tapped or touched to enter the response) for each response should be the same size and use the same font size regardless of the amount of text.

**Web:** Everything stated above for the handheld and tablet platforms applies to web-based platforms. The critical distinction for web-based platforms is that the internet can be accessed by multiple devices (e.g., smartphones, tablets). To ensure that the instrument is displayed as intended, it is recommended that the specifications include minimum requirements such as the browsers supported, minimum screen size, whether access is blocked for mobile devices, etc.
Visual Analog Scale (VAS)

Description

The FDA’s PRO Guidance defines the visual analogue scale (VAS) as consisting of a line of a fixed length (typically 10cm or 100mm), with verbal anchors at the extreme ends, and no descriptors of the intermediate positions on the scale. Typically no numbers are presented at the anchor positions either. Respondents are asked to place a mark on the line corresponding to their perceived state.

Note: Although the EuroQol Group calls the last item of the EQ-5D a visual analogue scale (EQ VAS), it is not a true VAS because a true VAS does not have numeric values at points along the scale. The EQ VAS will not be discussed in this document.

Example

Please rate your pain at its worst in the last 24 hours.

No pain

Pain as bad as you can imagine

Considerations for Electronic Implementation of Visual Analog Scales

- **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.

- **Handheld**: For new PRO measures, 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, and in most situations the length of the line or orientation may need to be modified for electronic data collection format.

- **Tablet**: Everything stated above for the handheld applies to the tablet implementation. Depending on the size of the tablet, the length of the line of a VAS may be replicated. However, there are multiple tablet sizes available and providers may need to recommend a minimum screen size or alter the length of the line.

- **Web**: Everything stated above for the handheld and tablet platforms applies to web-based platforms. The critical distinction for web-based platforms is that the internet can be accessed by multiple devices (e.g., desktops, laptops, smartphones, and tablets). To ensure that the items are displayed as intended, it is recommended that the specifications include minimum requirements such as the browsers supported, minimum screen size, whether access is blocked for mobile devices, etc. The design of the study should ensure that every time a subject sees the VAS, it is always the same size.
**Numeric Rating Scale (NRS)**

**Description**

A numeric rating scale consists of numbers representing an ordered continuum of some attribute. An NRS typically includes verbal descriptors/anchors at the extreme ends and might include a verbal anchor of the intermediate positions of the scale. Respondents are asked to select the number that best reflects their perceived state. This type of scale is often used to assess pain intensity. Although various iterations exist, the most commonly used is the 11-point NRS with responses ranging from 0 to 10.

**Example**

Please rate your pain at its worst in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10

No pain                      Pain as bad as you can imagine

**Considerations for Electronic Implementation**

- **IVR**: Implementing an NRS on an IVR platform 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”). The system should collect up to the maximum number of digits of the response choices (e.g., ‘11’, ‘100’) and may require the use of the pound or hash key to indicate that all digits have been entered. Responses should be repeated and confirmed by the subject that they are entered as intended (e.g., We recorded that you entered 10, is that correct?). Repeating and confirming the responses may add to the time it takes to complete the questionnaire but ensures better data quality on IVR platforms.

- **Handheld and Tablet**: The entire item should be self-contained and fit on one screen without scrolling possibilities. Include an indicator (e.g., a vertical line or an arrow) to associate the verbal anchors with the number at each end of the scale (see example below). When implementing
an NRS on various screen sizes, the text may overlap different numbers, so it is important to make it clear that the anchor text refers to the true ends of the scale. A minimum screen size and a minimum font size should be established when implementing NRSs on screen-based devices.

Example of Indicator Mark on an NRS on a Handheld Device

Web: Everything stated above for the handheld and tablet platforms applies to web-based platforms. The critical distinction for web-based platforms is that the internet can be accessed by multiple devices (e.g., desktops, laptops, smartphones, tablets). In order to ensure that the items are displayed as intended, it is recommended that the specifications include minimum requirements such as the browsers supported, minimum screen size, whether access is blocked for mobile devices, etc.

References
