

OMERACT Instrument Selection

Topic: Feasibility

This document provides readers with a guide to various resources on the assessment of feasibility using OMERACT Instrument Selection methodology.

A. Guidance on assessment of feasibility

A.1. Instrument selection overview whiteboard:

<https://omeract.org/instrument-selection/> [see 3:38]]

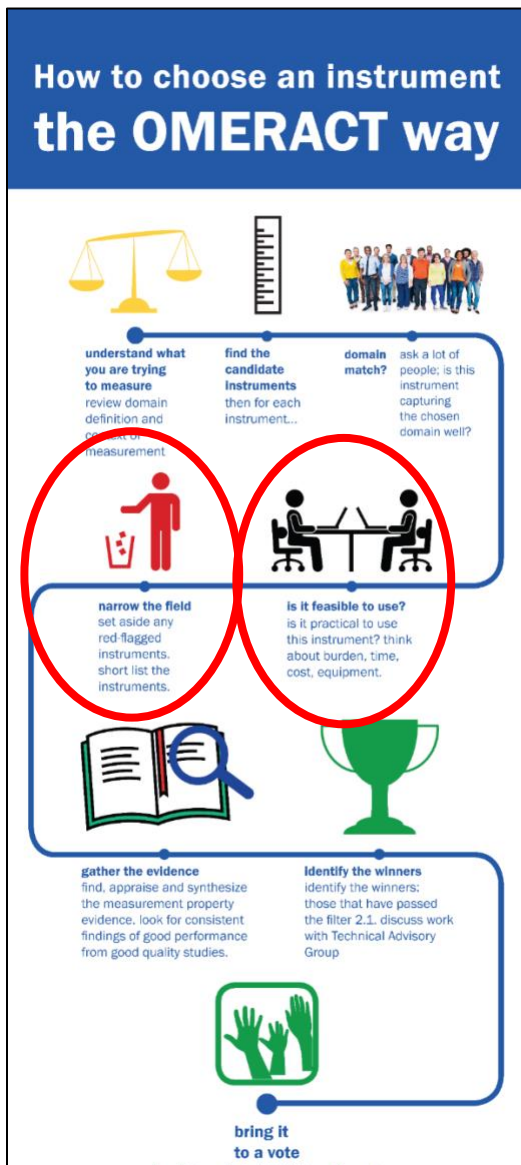
A.2. Feasibility video:

<https://omeract.org/instrument-selection/>

A.3. Instrument selection detailed discussion video:

<https://omeract.org/instrument-selection/> [see 7:30]

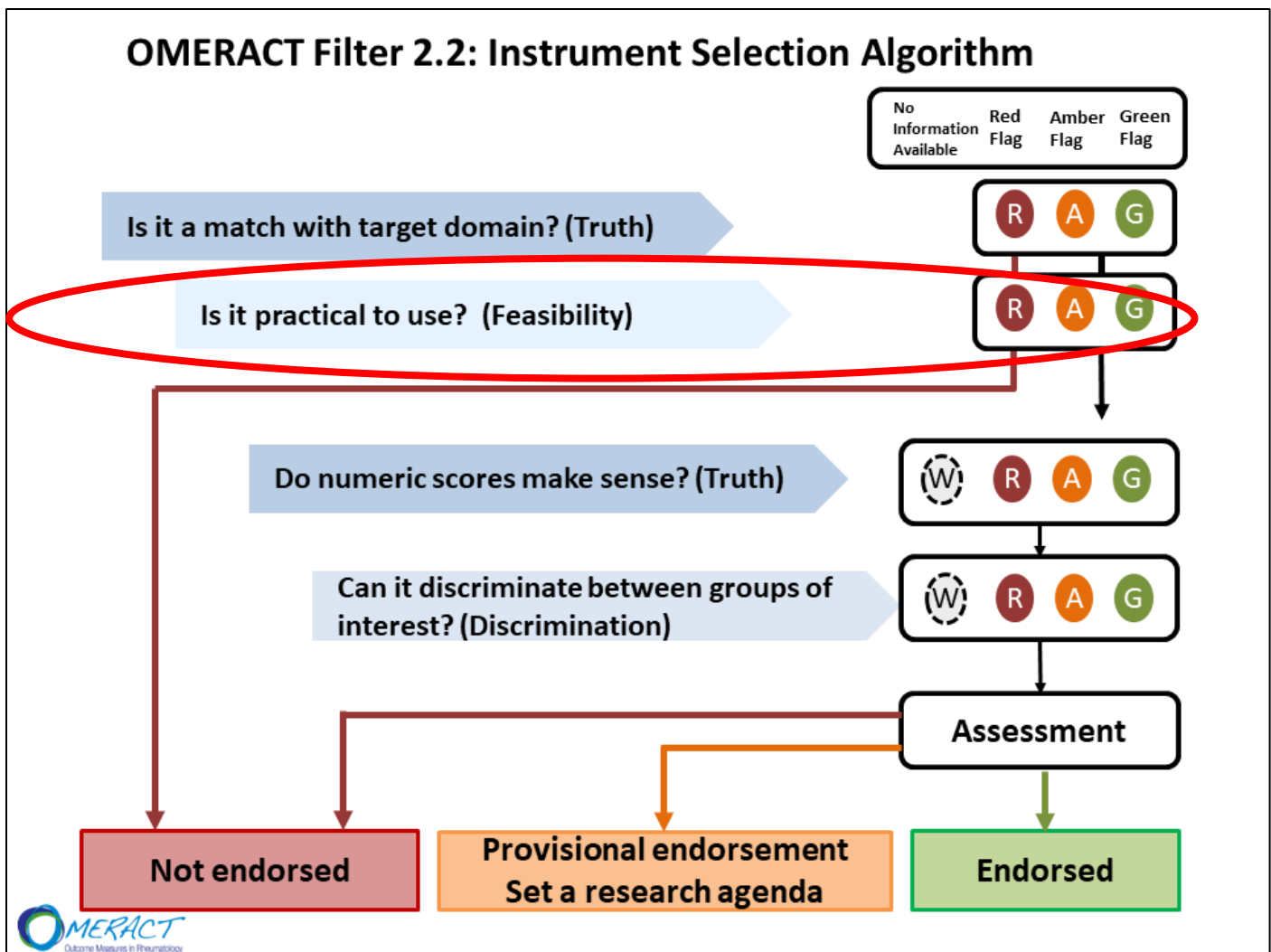
B. OMERACT Way



C. OMERACT Master checklist for instrument selection. Feasibility: Steps 6 & 7

OMERACT Master Checklist for Instrument Selection		
Name of Instrument:		
Step #	OMERACT Instrument Selection Process Checklist Item	Mark when complete
Assembly of working group and protocol development		
1	Assemble working group	<input type="radio"/>
2	Decide on methods protocol for Core Outcome Instrument Set selection	<input type="radio"/>
3	Deliverable: Submit protocol using Instrument Selection Workbook to Technical Advisory Group [TAG]	<input type="radio"/>
4	Review and approval of final protocol by TAG	<input type="radio"/>
Review of evidence of instrument performance for existing or new instrument		
Part A: Domain match and Feasibility assessment		
5	Obtain Working Group and others assessment of match with the target domain	<input type="radio"/>
6	Obtain Working Group and others assessment of feasibility	<input type="radio"/>
7	Is the instrument a match with the domain AND feasible? Yes _____ → if yes, continue with Part B of checklist below No _____ → If no, set instrument aside (find new one or develop new one)	<input type="radio"/>
Part B: Review of evidence of performance of an instrument across key measurement properties		
8	Conduct literature search; create PRISMA diagram; place articles of measurement properties in Summary of Measurement Properties (SOMP) Table	<input type="radio"/>
9	Conduct COSMIN-OMERACT Good Methods check, add findings into the SOMP Table	<input type="radio"/>
10	Conduct data extraction, create summary reporting tables, fill in SOMP Table with assessment of adequacy of results	<input type="radio"/>
11	Conduct synthesis across evidence available for each measurement property	<input type="radio"/>
12	Decide if any gaps exist in evidence of measurement properties If gaps found, draft protocol for new study to fill gaps If no gaps, finish the SOMP Table with proposed level of endorsement	<input type="radio"/>
Initial submission to TAG: literature review findings & protocol for gaps		
13	Deliverable: Submit the Instrument Selection Workbook to TAG	<input type="radio"/>
14	Receive final response from TAG	<input type="radio"/>
15	If studies are needed to fill gaps, conduct new measurement property studies, submit to TAG for Good Methods check, add to body of evidence (SOMP) and go back to Step 12 If no studies are needed, put X here: _____ and move to Step 16	<input type="radio"/>
Final submission to TAG for approval		
16	Obtain agreement on final report	<input type="radio"/>
17	Set timeline for next review of instrument	<input type="radio"/>
Ratification of level of endorsement by OMERACT Community and communication of results		
18	Ratification of level of endorsement by OMERACT Community	<input type="radio"/>
19	Implement communication and dissemination plan	<input type="radio"/>

D. OMERACT Filter 2.2. Instrument Selection Algorithm (OFISA): Feasibility is second signaling question



In the SOMP we note the assessment of feasibility by the Working Group. We also track if there is any literature published on feasibility in the population of interest. It is acceptable that there is no published literature and we will move forward with the working group's decision on feasibility.

Instrument: ABC Domain: Physical function					Date completed: 2021-02-11			
Population: rheumatoid arthritis		Intervention(s): drug		Control: placebo/drug			Type of studies: clinical trials	
Author/year	Truth Domain match*	Feasibility*	Truth Construct validity Inter-method reliability		Discrimination Test retest reliability Long'l construct validity Clinical trial discrimination Thresholds of meaning			
Working Group Appraisal (n=20 including 7 PRPs)	+	+						
Tugwell 2005			+/-			+		
Shea 2004						+		+
Smith 1999								
Beaton 2015							+	
De Wit 2018							+	
Wells 2004			+					
March 2008							+	+/-
D'Agostino 2011						+/-		+
Bingham 2018			+		+/-			
Singh 2010			+					
Strand 2015			+/-					
Simon 2011						+		+/-
New data from Conaghan 2021					+			
Total available studies for each property			5	N/A	3	5	3	4
Total studies available for synthesis			5	N/A	2	4	3	4
Synthesis Rating	GREEN From Working group	GREEN From Working group	GREEN	N/A	AMBER	GREEN	GREEN	AMBER
OMERACT Endorsement	Based on the OMERACT algorithm this instrument is: Provisionally endorsed <i>More research needed on test-retest reliability and thresholds of meaning.</i>							

6. Obtain Working Group and others assessment of feasibility

Is it practical to use? (Feasibility)

The next step is the assessment of *Feasibility*. Feasibility includes those very practical considerations about cost, burden, access to the instrument in the necessary language(s), and mode of administration etc., that provides evidence to determine whether it is practical to use a given instrument. Input is needed from both the users of the instrument to comment on administration (researcher burden and cost issues), and from respondents to comment on burden and suitability of format and administration.

OMERACT requires an evaluation of the practicalities of using an instrument. Keeping the setting of the core set in mind, the cost, burden (patient, responder), equipment needs, sensitivity of content and overall ease of use are appraised (see optional appraisal forms you can choose to use if you wish in OMERACT Instrument Selection Workbook). Existing appraisal systems have been brought together to guide the types of questions to be asked of an instrument to assess its' feasibility. Different perspectives should be included in this evaluation. As well as the clinician or researcher perspective, we feel direct input from patients is integral to the OMERACT Filter 2.2 process. Each offers an important contribution to the perspective of whether the tool is feasible (reasonable equipment needs, reasonable costs, training needs are feasible, comprehensive, easy enough to use). The decision makers will be balancing feasibility of the assessment process with having enough and the right content (items) to capture the full spectrum of the domain. Feasibility covers a broad array of factors and for more reading on this please refer to Tang et al., 2012; and Auger et al., 2006 review.

Examples of Feasibility Assessments:

Jensen 1986 et al. reported that NRS was “extremely quick and easy to administer”; only 5.3% of 75 patients made a mistake in the use of the scale.

Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: A comparison of six methods. Pain 1986; 27: 117-126.

Example: Tang et al, 2012 ran a survey to ask patients about their perceptions of a set of worker productivity measures. The tools were completed by the respondents and then they were asked about their preference of tool, and for each tool how difficult it was to reply, whether the items made sense, etc., and covered all important aspects, and whether the time to complete the tool was suitable.

Tang K, Beaton DE, Lacaille D, Gignac MA, Bombardier C. Sensibility of five at-work productivity instruments was endorsed by patients with osteoarthritis or rheumatoid arthritis. Journal of Clinical Epidemiology. 2013; 66(5): 546-56.

Example: In imaging, scan time must be just long enough to acquire sufficient information, but short enough to minimize radiation exposure, patient discomfort from immobilization, etc.

The result of the appraisal is then scored and recorded in the SOMP in the ‘Feasibility’ column using the traffic light system of Green, Amber, or Red.

6	Obtain Working Group and others assessment of feasibility	○
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7. Obtain Working Group decision based on results of domain match & feasibility: Is the instrument a match with the domain AND feasible?

Decision point: Does the Working Group agree that this instrument has passed these first two questions?

We are now at an important decision point in the OMERACT instrument selection process. This decision point is a unique feature to the OMERACT process. If an instrument is not a good match for the target domain or is not feasible to use in the intended setting, it can be set aside by the Working Group. Ongoing attention should focus on only those instruments that have *passed* these two questions with a GREEN or AMBER rating. Many groups have found that a quick check of these first two steps eliminated several instruments that are covering the wrong content for the intended application, or are considered too long, expensive, and/or complex to use. It is best to set them aside and continue only with those that have content/concept match and are feasible to use in the intended application.

7	<p>Is the instrument a match with the domain <u>AND</u> feasible?</p> <p>Yes ____ → if yes, continue with Part B of checklist below</p> <p>No ____ → If no, set instrument aside (find new one or develop new one)</p>	○
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6. Obtain Working Group and others assessment of feasibility

Is it practical to use? (Feasibility)

To answer this question, there are three tasks to complete:

1. Survey of working group members about the feasibility
2. Survey of patients and other key stakeholders about the feasibility
3. Working group comes to a conclusion about the feasibility

Readily available information on each instrument should be gathered and considered – instructions, costs, copyright, copy of the questionnaire, etc. Contact with the developers often helps with this as does reviewing the manual.

With a copy of the instruments and instructions for administration and scoring in hand, the working group can use the example questions below to evaluate the feasibility in the intended setting of the core set.

6.1 Survey of working group members about feasibility

Sample survey questions are provided in [Appendix A](#). You can use any survey software to obtain this information.

Please provide a summary of your working group's input regarding the Feasibility of the selected instrument. Below are samples of the types of questions we need you to address; you can use these or similar questions but please provide a summary of your working group's responses at this level of detail.

SUMMARY OF FEASIBILITY (IF NECESSARY, REPLACE & PROVIDE YOUR RESULTS HERE):

Instrument: Click here to enter text.

Date: Click here to enter a date.

Question	Working Group's Summary Response	
Is it easy for respondents to understand (considering reading level, instructions, health, and literacy needed)? Comments: Click here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Can it be completed within a reasonable amount of time given your study context? Comments: Click here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)

Is the method of administration feasible for your application (i.e., computer-based, paper, equipment needs)? Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Are the costs feasible? (consider licensing fees, equipment and training costs). Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Are the copyright issues (if any) reasonable and manageable? Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Are the equipment, space and training needs feasible for you to carry out? Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Is it available in the right language/culture for your intended application? Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No	N (%) N (%) N (%)
Final decision based on working group data (check one): <input type="checkbox"/> Good to go <input type="checkbox"/> some cautions but okay <input type="checkbox"/> not right for this application		

6.2 Survey of patients and other key stakeholders about feasibility

It is essential for the working groups to get feedback from the people who will be responding to the instrument (i.e. patients, caregivers, clinicians for a PRO). We suggest you survey 5-10 people to provide good insight into this appraisal of feasibility from the respondent's perspective. Respondent input (from outside the working group) should be sought to ensure that people like those who will be participating in a study will be giving their opinion.

*The survey in [Appendix A](#) was designed to gather information on **both** the match with domain and the feasibility of this instrument. At this point your group will consider the responses to the questions about feasibility.*

Please use the responses to the part of the survey addressing “feasibility” to provide the summary results. You can use any survey software to obtain this information.

PLACE YOUR SUMMARY RESULTS HERE:

Working Group's conclusion on respondents' data (check one):

- ☐ **Good to go**
- ☐ **some cautions but okay**
- ☐ **not right for this application**

Results: Feasibility

Based on the Results above (working group survey, respondent's survey), complete the Working Group's assessment of whether the instrument is feasible to use.

Red flag (stop, do not continue): _____ **Amber (some cautions, but continue):** _____ **Green (good to go):** _____

Is it practical to use? (Feasibility)



7. Obtain working group decision based on synthesis of overall ratings of domain match and feasibility

Working Group's vote: you should now do a vote across your own working group members and record how you feel about this instrument based on the assessments of domain match and feasibility. This vote is important, and the result should be recorded in this workbook. Groups should achieve at least 70% agreement that this instrument can move forward (that is either a GREEN or AMBER vote). If less than that, the instrument should be set aside.

It is common, and a very good practice, to put instruments that are not doing well aside at this point. There is no way to repair or retest a mismatch with the target domain, or a lack of feasibility in using the tool. These instruments should not continue and as shown in the OMERACT Instrument Selection Algorithm they will land in the "STOP" area and not be considered further. This will save you a lot of time, so think this through carefully.


Result of Working Group Vote:

Date:	Agree it is a domain match & feasible (%)	Do not agree it is a domain match & feasible (%)
Working Group (N= __)		

Based on the Results above, complete the Working Group's final assessment of whether the instrument matches the target domain and is feasible to use.

Green (good to go): ____ **Amber (some cautions, but continue):** ____ **Red flag (stop, do not continue):** ____

Complete step 7 on the Instrument Selection checklist. If the decision is to continue to assess the measurement properties of the instrument selection, move on the next section in the workbook, Part B. If the decision is to put the instrument aside, stop here in the workbook. Submit the workbook to admin@omeract.org to be kept on file.

7	Obtain working group decision based on synthesis of overall ratings of domain match and feasibility: Is the instrument a match with the domain <u>AND</u> feasible? [Select Yes or No] Yes ____ → if yes, continue with Part B of checklist below No ____ → If no, set instrument aside (find new one or develop new one)	
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Appendix A: Sample survey questions for surveying patients/other respondents on domain match and feasibility

The sample questions below are based on assessing domain match and feasibility of a PRO. They can be modified for use with other types of instruments using the considerations in this table:

PRO's	Composites	Imaging Outcome Instrument (scoring system)	Other biomarkers (e.g. ESR, CRP)
Match to domain definition	Is there a clear match with each domain to the target of the composite (i.e., disease activity?)	Does it capture the target domain?	Is this biomarker a good match to the domain definition?
Framing of the domain. Do the instructions for the instrument orient the respondent/ observer as to how to consider important sources of variability?	Does the questionnaire specify how to manage things like assistance, assistive devices, or coping strategies when answering?	Does the imaging technique description offer choices to avoid specific sources of variability? i.e., T2 weighting in MRI, or specific angle used for an Xray examination.	Does the instrument offer specific directions that help to avoid variability in scores? For example, blood pressure can vary by time of day, examiner, and environmental factors.
Do items cover the essential elements of the domain from detailed definition template?	Coverage of key elements of the target composite domain in the parts of the composite	Coverage of the elements of that domain	Is it capturing all the essential elements as described in the domain definition?
Response options	Scoring of each of the parts of the composite (remember inherent weighting given by the scaling of each domain)	Scoring of each element appropriate?	How is it quantified and is that standardized?
Weighting of items into score	How are elements weighted in the composite scoring system?	How the scoring system weights the elemental components in the score?	How is it scored compared to norms?

Feedback from respondents to instrument:

Is it a match with target domain? (Truth) & Is it practical to use? (Feasibility)

Instrument:Click here to enter text.

Date:Click here to enter a date.

<i>Match to Domain: Thinking about the content of the actual questions/items in the instrument, based on experience of this domain.</i>	Respondents answer
Are the items in this instrument relevant to you and your experience? Comments: Click here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain

	<input type="checkbox"/> No
<p>Do you think there should be any additional items (i.e., were there things that were missed)?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Do you think that there should be any items taken out of the instrument? If yes, tell us why.</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Were there overlapping, sensitive, or embarrassing items?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Does the instrument overall reflect your experience of your [domain]?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Did you find that all the items were easy to read? If not, which items were not easy to read?</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Did you feel that all the items were clear and understandable? Could you understand what all the questions were trying to ask? If not, which items did you feel were unclear?</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Did you think that the response options were clear and understandable (i.e. did the possible answers match well with the questions)? If not, which items did you feel had a mismatched response scale?)</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Were the instructions for answering the items clear?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Does the timing of the recall period seem reasonable to you (e.g. over the past week, last 24 hours) (if applicable)?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Feasibility: Questions about the practical considerations about this instrument.	Respondents answer
<p>Was it easy enough to complete?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
<p>Did it take a reasonable amount of time to complete?</p> <p>Comments:</p> <p>Click here to enter text.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No

Did the format seem appropriate (how it looked on the page, font size, how items and responses were organized)?	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No
Do you think there was too much equipment and training needed before you could be able to respond to this instrument? Comments: <div>Click here to enter text.</div>	<input type="checkbox"/> Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No