PATIENT-CENTERED INSTRUMENT DESIGN: PROBLEMS AND SOLUTIONS BASED ON PATIENT FEEDBACK

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Patient-Centered Instrument Design: Problems and Solutions Based on Patient Feedback

Poster Session 1

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OBJECTIVE:

Cognitive debriefing feedback of patient global impression measures (PGIs) reveals repeated and serious comprehension issues which threaten accurate assessment of instruments' target constructs and their ability to pool data across languages.

Patient-centered approaches to PRO development can account for differences in understanding and experience between patients and developers that can drive comprehension and translatability problems.

Patient-centered design considers:

- Differences in education, socioeconomic status culture, age
- Disease symptom or state
- Patient burden of testing

And it generally acknowledges differences between patients and PRO developers that may unintentionally contribute to barriers to understanding and equity in the experience of completing PROs, and so diminish the clinical utility of the data they collect.

Here, we review four investigations focused on conceptually unclear or difficult-to-translate terms and phrases routinely found in PGIs to highlight and provide solutions to problems posed to patients and general PGI design.

Four investigations with patients:

- Comprehension and translation of "global"
- Comprehension and translation of "disease activity"
- Comprehension of common PGI response options
- Impact of response set size on comprehension and translation

This work provides qualitative and quantitative data from patients intended to facilitate instrument development, with the overall goals of:

- Improving the patient experience of completing PGIs
- Improving consistency and validity of translations of PGIs
- Improving overall quality of data collected by PGIs
- Extending insights from PGIs to development of PROs in general

PGIs:

PGIs tend to be brief instruments, in which patients respond to one or two questions about their health or condition. For instance:

Patient's Global Impression of Change:

Since the start of the study, my [condition] is:

☐ Much improved ☐ Minimally improved ☐ Not changed ☐ Minimally worse ☐ Much worse

METHODS:

STUDY 1: "GLOBAL" PROBLEMS IN PGI MEASURES

30 languages for 35 countries; Patients (N = 575) were aged 18-92 years (mean = 50.4), with length of education ranging from 2-20 years (mean = 13.2).

Table 1: Patient suggested revisions for ***global*** to improve comprehension and naturalness

	Language	Country	Miscomprehension % for *Global*	Suggested Revision
1	Afrikaans	South Africa	60%	remove entirely
2	Dutch	Belgium	40%	*algemene*
3	English	Australia	60%	*overall*
4	English	Canada	80%	*general*
5	English	UK	70%	*overall*
6	English	South Africa	80%	*overall*
7	French	Switzerland	50%	*en général*
8	French	France	40%	*en général*
9	German	Germany	60%	*Gesamtheit*
10	Hungarian	Hungary	40%	*összefoglaló*
11	Italian	Italy	50%	*generale, complessivo*
12	Spanish	Mexico	60%	*general*
13	Spanish	Puerto Rico	60%	remove entirely
14	Spanish	US	60%	*general*
15	Swedish	Finland	80%	remove entirely

Figure 1: The distribution of comprehension issues across the 115 translations.
Global accounted for 17% of issues. Other common issues included confusion about instructions, accord between the question and response options, as well as the phrase *disease activity.*

Distribution of Comprehension Issues (N=248)

- Disease Activity (N=72)
- Global (N=51)
- Accord of Question and Response Set (N=39)
- Other (N=41)
- Instructions for Responding (N=45)

Study 1 Background

- *Global* is defined as "comprehensive" or "overall" and appears early in PGIs, typically in the instrument name, to frame a patient's assessment of their health.
- Patients commonly thought that *global* meant "worldwide", "around the world", or "international", or referred to everyone involved in the study (N=35).
- Patients frequently reported that global was confusing, uncommon as patient-facing terminology, contextually inappropriate, or too clinical (N=26).

Study 1 Conclusions

Unclear wording used to frame PROs can impact patient comprehension and may cause PROs to function differently across languages. Our findings show that *global*, a frequent PGI term, can be problematic for patients, especially in English-variants, Germanic, and Romance languages. We recommend simple, low register, non-clinical phrasing, such as "overall", in PRO creation to increase concept validity and to mitigate contingent translation issues.

STUDY 2: ISSUES IN THE TRANSLATION AND COMPREHENSION OF DISEASE ACTIVITY IN PGIs

29 languages for 33 countries; Patients (N = 515, 268 female) were aged 18-92 years (mean = 51.2), with length of education ranging from 2-20 years (mean = 12.7).

Table 2: Languages with and without comprehension errors for the term disease activity, along with the percentage of total errors that each language accounted for.

Languages with Comprehension Issues (N = 19)		Languages without Comprehension Issues (N = 10)
Italian (15%)	Polish (4%)	Croatian
German (11%)	Hungarian (3%)	Czech
Estonian (9%)	English (2%)	Danish
Spanish (9%)	French (2%)	Hebrew
Swedish (8%)	Gujarati (2%)	Icelandic
Dutch (8%)	Portuguese (2%)	Kannada
Chinese (5%)	Punjabi (2%)	Latvian
Greek (5%)	Slovak (2%)	Lithuanian
Russian (5%)	Ukrainian (2%)	Romanian
Marathi (4%)		Telugu

Study 2 Background

Disease activity can be defined as "manifestations of a disease" or "severity and extent of symptoms", and typically appears in instruments assessing the state of a patient's disease signs and symptoms. We collected qualitative feedback from CD interviews on patients' understanding of the term *disease activity.*

Study 2 Results and Conclusions

- Patients commonly thought that disease activity referred to physical activity or pain (N=11)
- Or clinical and uncommon as a patient-facing term (N=7)

Recommendations include revising *disease activity* concept / wording via:

- Inclusion of the concept of "symptoms" or "severity" in the target term itself
- Replacing of "activity" with easier-to-understand terms such as "condition", "state", or "progression"
- Parenthetical elaboration of *disease activity* that explicitly links the term with the level or intensity of a patient's symptoms

STUDY 3: INVESTIGATION OF CONCEPTUAL DISTINCTION BETWEEN RESPONSE SET OPTIONS

115 separate patients (aged 18-75 years, education 8-17 years) from 12 English-speaking locales.

Figure 2: Rating distributions for each response option tested. A rating of 0 indicates "lowest level of severity", while a rating of 100 indicates "highest level of severity".

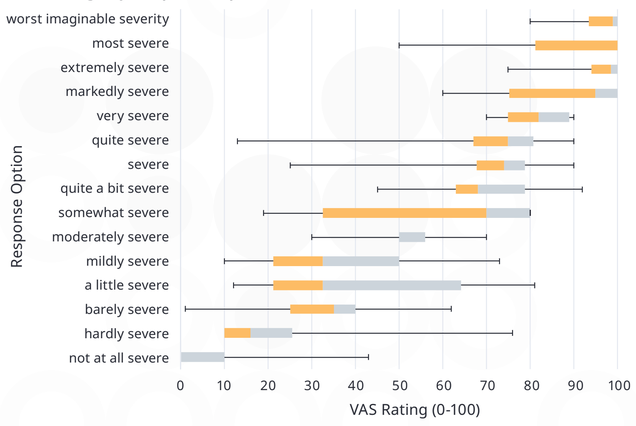

Figure 3: An example of the prompt that participants responded to in rating response options.

Study 3 Background

Ordinal scales with discrete response options are commonly used in assessment of patient's experience with a given health condition or treatment. Close conceptual spacing within response sets can interfere with translation during linguistic validation (LV), reduce comprehension for patients, and impact data validity.

Participants rated between 1 and 3 response options from a set of 15 (see Figure 2) on a VAS scale

Study 3 Conclusions

- Common response options are conceptually clustered and highly variable
- Target concept comprehension is poor in some cases, and will be worse in translation
- Using smaller response sets with conceptually distinct options is recommended

STUDY 4: EFFECTS OF RESPONSE SET SIZE WITHIN PATIENT GLOBAL IMPRESSION MEASURES

84 language-country pairs and 421 patients (57% female; 5 - 85 years of age; 10.1 average years of education, SD = 4.1) were analyzed.

Figure 4: Of 21 language-country pairs with comprehension issues related to the response options themselves, 19% were found in 5-point PGIs, while 81% were found in 7-point PGIs.

Comprehension Problems by Size of Response Set

- 7-point PGI
- 5-point PGI

Table 3a: An example of a 7-point PGI response set.

Not severe at all
Minimally severe
Mildly severe
Moderately severe
Markedly severe
Very severe
Extremely severe

Table 3b: An example of a 5-point PGI response set.

Not at all
A little bit
Somewhat / moderately
Quite a bit
Very much

Study 4 Background

- PGIs typically contain response sets with 5 or 7 descriptive options (see Table 3a and 3b).
- Although PGIs can provide more descriptive response options compared to NRS or VAS scales, one possible drawback is conceptual spacing of response sets that is too tight
- Causing adjacent response options to seem very similar to each other
- Resulting in advantages for patients with languages which can better distinguish conceptually clustered response options

Study 4 Conclusions

7-point PGI scales can be problematic in comparison to 5-point scales across many languages, and difficulty can arise in distinguishing between conceptually similar response options (e.g., "a little better" vs "moderately better"; "minimally" vs "mildly").

We recommend using smaller and more distinct response sets wherever possible in the construction of PGIs; where larger sets are necessary, switching to another type of scale (e.g., NRS or VAS) may improve data quality.

OVERALL CONCLUSIONS:

Despite their brevity, PGIs are prone to many design, conceptual, and translation problems. We show that these problems arise largely from deviations from patient-centered design approaches, and suggest practical, evidence-based solutions to improve the patient experience of completing PGIs. Broadly, these involve:

- Eliminating complex medical terminology or replacing it with patient-friendly, easily-translatable terms;
- Simplifying ordinal response sets to reduce conceptual clustering and improve translatability.

Patient-centered approaches to instrument design are essential:

- They are more likely to exclude inappropriately complex phrasing and design choices
- And can therefore improve translatability
- They do this by including the patient voice
  - With its diversity of experience across languages, cultures, and socioeconomic opportunity

Patient-centered design is about giving the patient's voice and variability of experience the same weight and respect that we give to clinical outcomes, so that treatments and assessments fit with patients' lives, abilities, and expectations.