



University of Pittsburgh

**Individuals with Knee Impairments Identify
Items in Need of Clarification in the Patient
Reported Outcomes Measurement Information
System (PROMIS) Physical Function and Pain
Interference Item Banks –
A Qualitative Study**



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Purpose

- **To use qualitative methods to identify items in the PROMIS Physical Function & Pain Interference Item Banks that:**
 - **May not be relevant to individuals with impairment of the knee**
 - **Be unclear or otherwise difficult to complete based on wording of item**
- **Secondarily we sought to suggest revisions to reduce errors associated with interpretation of item**



Methods

Level 2 Conceptual Qualitative Study

- **Previously identified individuals with knee impairments:**
 - ACL injury
 - Degenerative meniscus tears
 - Knee OA
- **Purposeful Sampling:**
 - Acute and chronic conditions
 - Severe and mild pain
 - Good and poor function
 - At least 2 males and females in each category

5-phase Testing and Analysis Process:

- **Binning process to sort items by content.**
- **Primary interview sessions and the item screening process**
- **Preliminary analysis of interview to determine if items needed to be re-written**
- **Secondary interview sessions**
- **Final analysis**



Methods

Subjects (n=29):

- **14 individuals with acute knee injury**
 - All had ACL injury, 6 females, ages 15-35
- **15 individuals with chronic conditions**
 - **7 degenerative meniscus lesions, 4 females**
 - **8 OA, 2 females**
 - **ages 42-75**



Phase 1 – Item Binning

Items Sorted into 3 Bins:

- **Bin 1 - items highly likely to be influenced by impairment of knee (e.g. climbing stairs)**
 - 81 PF items
 - All 41 PI items
- **Bin 2 - items somewhat likely to be influenced by impairment of knee (e.g. being able to reach into a cupboard overhead)**
 - 11 PF items
- **Bin 3 - items not likely to be influenced by knee joint impairment (e.g. buttoning a shirt)**
 - 32 PF items



Phase 2 – First Round of Interviews & Item Screening Process

Initial Interviews for Bin 1 Items

- Describe the question to me in your own words.
- What aspects of the item are confusing?
- What do you think of this item?
- How would you go about selecting your answer?
- On what time frame was your answer based?
- How would you change this item to improve it?
- Is your knee joint relevant to the way you would respond to this item?

Conducted Screening Process for Bin 2 & 3 Items

- 20 participants reviewed the items from bins 2 and 3
- Is your knee joint relevant to the way you would respond to this item?
 - **Knee could affect answer to item**
 - **Knee could possibly affect answer to item**
 - **Knee would not affect answer to item**



Phase 3 – Analysis of Primary Interviews

- **Interviews analyzed after each item had been reviewed 5 times**
- **Items deemed clear and relevant were removed from further cognitive interviews**
 - 23 PF and 5 PI items
- **Items identified as confusing or unclear were revised & subjected to further interviews**
 - 23 PF items
- **Some items remained in the interviews without modification**
 - 34 PF & 36 PI items



Phase 4 – Second Round of Interviews

Items Included:

- **Items in need of further review**
 - 34 PF & 36 PI items
- **Newly developed items**
- **Items identified as potentially relevant from the Screening Process**
 - 12 PF items
- **Items with similar content were presented in the same block to facilitate direct comparisons.**
 - Ascending five flights of stairs
 - Descending five flights of stairs



Phase 5 – Final Analysis and Disposition

Based on Item Screening:

- **31 PF items representing activities not relevant for those with impairment of knee identified**
 - **hand and shoulder function, reaching, and basic self-care**



Phase 5 – Final Analysis and Disposition

Results of Cognitive Interviews

**3 themes were identified which
contributed to confusion in interpreting &
responding to items**



Results of Cognitive Interviews

Theme 1: “Your Health”

- **25 items in the Physical Function Item Bank begin with the phrase “does your health now limit you in...”**
 - Cued participants to think about their whole body & some did not consider their knee joint in such decision-making
 - Respondents suggested that the alternative phrase “your current condition”
 - Used clinical context to determine which provider was asking for the information (e.g. orthopedic surgeon vs. cardiologist)

PFB54

Does your health now limit you in going OUTSIDE the home, for example to shop or visit a doctor's office?

“Your health’ makes me think of all kinds of things – blood pressure, dermatological issues, my knee, my Achilles, mental health. The more you know, the harder it is to answer.”



Results of Cognitive Interviews

Theme 2 – Substituting Other Symptom or Condition Interference for Pain Interference

- **Pain Interference Item Bank Items begin with “how much did pain interfere with...”**
 - **Participants without pain often substituted other aspects of their condition that interfered with their life**
 - **Substitutions included reduced mobility, having to use crutches, and having to attend rehabilitation or complete exercises**

PAININ31 How much did pain interfere with your ability to participate in social activities?

“The interference is more with my CPM, crutches, and brace than to do with true pain.”

PAININ53 How often did pain restrict your social life to your home?

“My lack of mobility is more pertinent when it comes to restricting my social life to home.”



Results of Cognitive Interviews

Theme 3: Age and Gender Roles

- Some items related to athletic activities not relevant to older individuals with chronic impairments
- Gender roles may influence item responses
 - One male participant indicated that he did not do housework.
 - One female indicated that her husband did the lifting of heavy objects.

| | | |
|---------|---|--|
| PFA1 | Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports? | “I didn’t even consider the ‘participating in strenuous sports’ part – not in my age bracket.” |
| PFA41.a | Are you able to squat like a baseball catcher and get back up? | <p>“My age and my caution limit me in doing these things.”</p> <p>“Squatting like a catcher is irrelevant for someone my age.”</p> |



Cognitive Interviews

Item Revisions Based on Cognitive Interview Feedback

- **23 items were unclear & in need of revision, resulting in the creation of 43 items**
- **Stair Negotiation**
 - Most stair-related items dealt with stair ascent.
 - Many individuals indicated stair descent was more difficult than ascent
 - Parallel items were constructed such that each item measuring ascent had a corresponding item measuring descent, with consistent wording (i.e. ‘going up’ and ‘going down’)
- **Squatting**
 - “Are you able to squat and get up?” was interpreted inconsistently.
 - 3 replacement items were constructed to capture a range of squatting tasks from daily life to sports



Cognitive Interviews

Item Revisions Based on Cognitive Interview Feedback

- **Sport and Recreation Activity Categories and Descriptions**
 - Multiple activities included in item stem & not all were important to the individual
 - Resulted in difficulty in generating a response
 - Respondents had inconsistent definitions of the modifiers “vigorous” and “strenuous” and work modifiers “heavy” and “moderate”
 - Replacement items were constructed such that each aspect of the original item was broken out into its own item.
- **Confusing Word Choices**
 - In the existing items, the term “heavy” is accompanied by the descriptor “10 pounds”
 - Participants indicated a “heavy” item could weigh anywhere from 40 to 200 pounds.
 - Replacement items were constructed without a qualifier such that the respondent is able to determine what the term “heavy” means



Conclusion

- **Further evidence for item clarity and relevance is needed to improve the PROMIS Physical Function and Pain Interference tools for individuals with an impairment of the knee**
- **The PROMIS PF & PI item banks were designed as general measures of physical function and pain interference**
 - **Condition-specific filtering of items may be useful**
- **Generally, the items were well understood by the participants, but some items would benefit from re-wording to improve clarity**
 - **We have attempted to clarify those items and are pilot testing new & revised items to calibrate within the existing PROMIS Item Banks and to identify DIF**



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Thank You



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Phase 2 - Primary Interview Sessions and the Item Screening Process

Primary Interview Sessions

Item Screening Process

- 20 participants reviewed the items from bins 2 and 3
- Is your knee joint relevant to the way you would respond to this item?
 - **My knee could affect the way I answer this question.**
 - **My knee could possibly affect the way I answer this question.**
 - **My knee would not affect the way I answer this question.**