Development and Content Validity of the COPD Device Preference Questionnaire

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OBJECTIVE

- To develop and evaluate the content validity of questions assessing patient preference between two dry powder inhaler (DPI) devices—the Handihaler and a novel DPI— for the treatment of chronic obstructive pulmonary disease (COPD) based on ease of use.

METHODS

Development

- Important characteristics of COPD inhalers were identified through market research involving physician experts currently prescribing inhaler devices and patients with COPD currently using these devices.
  - Physicians and patients identified "ease of use" as an important feature.
- A draft 5-item set for the COPD Device Preference Questionnaire (CDPQ) was developed to assess inhaler device preference based on aspects of ease of use identified by patients and physicians.

Cognitive Interviews

- To refine and assess the content validity of the draft CDPQ, two iterative rounds of cognitive interviews were conducted with adult patients with COPD currently receiving medication via the Handihaler.
- The interviews were conducted by experienced interviewers in two locations in the United States: Detroit, MI, and Raleigh, NC.
- Participants were recruited and screened based on the following prespecified inclusion and exclusion criteria:
  - Age ≥ 40 years
  - Current or past COPD diagnosis
  - Taking Spiriva daily via the Handihaler
  - No requirement for oxygen outside the home
  - Current or former smoking history of ≥ 10 pack-years
  - Willing to participate in a 1-hour interview
  - Able to provide informed consent and read, understand, and provide responses in English
- All interviews were limited to 1 hour's duration, followed a semistructured interview guide, and were audio-recorded.
- To assess inhaler technique, all participants were asked to describe the steps required to use their Handihaler. The interviewers then described the key features of and demonstrated the steps to administer the novel DPI device, after which participants were asked to demonstrate the steps described using an empty novel DPI device.
- Cognitive debriefing of the draft CDPQ was conducted by having each participant review and provide feedback on the instructions, items, and response options. Patients were asked to describe their thought processes out loud as they reviewed the draft measure and completed the items.
  - The initial draft CDPQ items were phrased in two different ways (each question began with either "Which device do you prefer based on" or "Thinking about").
  - The three possible response options (Handihaler device, novel DPI device, or no preference) for each question were the same regardless of the phrasing used.
  - The CDPQ uses a "current" recall period.
- During Round 1 of the interviews, participants provided feedback on their preferred phrasing of the draft CDPQ and their suggestions for improvement.
- During Round 2 of the interviews, participants assessed the modified CDPQ and provided additional input to confirm the content validity of the final version.

TABLE 1. DEMOGRAPHIC CHARACTERISTICS FOR ALL PARTICIPANTS

Demographic Information	N = 16
Sex	
Female	8
Male	8
Age, average years (range)	62.5 (51-80)
Number of pack-years smoked, average years (range)	42.7 (10.0-87.5)
Race/ethnicity	
Caucasian	10
African American	6
Education	
Less than high school	1
High school diploma or equivalent	5
Some college	5
College graduate	4
Postgraduate or advanced degree	1
Employment	
Employed full-time	2
Employed part-time	6
Not employed or retired	8

RESULTS

- A total of 16 adults with COPD participated in this study.
  - Round 1: n = 8
  - Round 2: n = 8
- The interview participants represented a demographically diverse group (Table 1).
- All participants were able to describe the multiple steps involved in preparing and administering the Handihaler device.
- All participants were able to successfully complete the steps to actuate the novel DPI device.
- All participants spontaneously commented that the novel DPI device offered significant improvements in ease of use and convenience.
  - Use of the novel DPI device involved fewer steps and less time.
- A slight majority of Round 1 study participants preferred the question phrasing beginning with "Which device do you prefer based on" (Table 2).
- Most participants in Round 1 and all participants in Round 2 indicated that the response options for the questions were easy to understand and select.
- Only one "ease of use" concept was identified as missing in the draft CDPQ by 2 or more participants.
  - The dose counter on the novel DPI device was mentioned by 5 of the 8 Round 1 participants (specifically that the counter numbers were large and easy to read and that the counter indicator became red to alert the user that it was time to refill the medication); however, this aspect was mentioned by only 1 of the 8 Round 2 participants.
- An item-tracking matrix was constructed to summarize all changes to the CDPQ and accompanying rationale after each round of interviews (Table 3).
- Figure 1 presents the final version of the CDPQ.

TABLE 2. ROUND 1 PARTICIPANT PHRASING PREFERENCE (n = 8)

Question	Phrasing Preference, n		
	"Which device do you prefer based on…"	"Thinking about…"	No Preference
1	5	3	0
2	7	1	0
3	5	2	1
4	5	2	1
5	5[a]	3	0

[a] Three participants suggested similar alternative phrasing including, "Overall ease of use: which do you prefer," "Which device do you find easier to use," and "Which device is easier to use."

FIGURE 1. COPD DEVICE PREFERENCE QUESTIONNAIRE

INSTRUCTIONS: Please complete the following questions related to both the Novel dry powder inhaler and Handihaler devices that you used during this study. Check only one response for each question.

1. Which device do you prefer based on the number of steps needed to take your COPD medication?	❑ Handihaler device ❑ Novel dry powder inhaler device ❑ No preference
2. Which device do you prefer based on the time needed to take your COPD medication?	❑ Handihaler device ❑ Novel dry powder inhaler device ❑ No preference
3. Which device do you prefer based on how easy the device is to use?	❑ Handihaler device ❑ Novel dry powder inhaler device ❑ No preference

CONCLUSIONS

- Participant feedback indicates that the final CDPQ items reflect the most important concepts in determining COPD inhaler device preference relating to ease of use.
- The interviews support the content validity of the CDPQ by providing evidence that the measure adequately and appropriately assesses COPD DPI device preference relating to the ease-of-use concept identified as most important from the patient perspective.
- Participants found the items and response wording easy to understand and simple to complete.
- Additional research has been performed and the content validity of the CDPQ has been confirmed in the US Hispanic population.

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TABLE 3. ITEM TRACKING MATRIX: RECOMMENDED CHANGES TO CDPQ AND RATIONALE

CDPQ Section/Item #	Post–Round 1 Revisions		Post–Round 2 Revisions	
	Recommended Revisions	Rationale/ Team Decision[a]	Recommended Revisions	Rationale/ Team Decision[a]
Instructions				
Please complete the following questions related to both your Novel dry powder inhaler and your Handihaler devices. Check only one response for each question.	Add "that you used during this study" Test the following instructions in Round 2: "Please complete the following questions related to both the Novel dry powder inhaler and Handihaler devices that you used during this study. Check only one response for each question."	Added the phrase "used during this study" to the instructions to ensure that participants are thinking about their device preference based only on their use of both devices over the course of the GSK study period (vs. possible previous experience with the Handihaler before the clinical trial).	Add the heading "Instructions."	Because interviewers often had to point out to participants where the instructions were on the page, labeling the instructions was recommended.
Items				
1b. Which device do you prefer based on the total number of steps needed to use the device to take your COPD medication?	Remove "total" and "to use the device" Test the revised question in Round 2: "Which device do you prefer based on the number of steps needed to take your COPD medication?"	Based on participants' consistent understanding of the question, further simplification of the wording was suggested. When asked to interpret this question, most participants indicated that they were thinking about the several steps involved in preparing their Handihaler device to take their medication, vs. the Novel DPI device with fewer steps. The rewording is also more consistent with the remaining questions in the questionnaire.	No further changes were recommended.	The previous changes to this question based on Round 1 feedback seem to have clarified this question; no participants in Round 2 raised any concerns about the intent or clarity of this item.
2b. Which device do you prefer based on the number of steps involved in preparing the device to take your COPD medication?	Remove item	Most participants felt that questions 1 and 2 were redundant; removal of question 2 was recommended primarily because this question could be viewed as unduly favoring the Novel DPI device. Round 2 interviews confirmed the final wording of question 1.	N/A	N/A
3b. Which device do you prefer based on the time it takes to complete the steps required to take your COPD medication?	Modify underlining so that only "time" is underlined Modify "time it takes to complete the steps" to read "time needed." Test the revised question in Round 2: "Which device do you prefer based on the time needed to take your COPD medication?"	Underlining was modified for consistency with the other revised questions for Round 2, which emphasize the single most important word in each item. Although participants generally understood this item as written, interviewers thought that this item should be further simplified and structured similarly to the other rephrased questions for testing in Round 2. Additional probing in Round 2 focused on whether the concept of "time" was independent and important to assess separately from "number of steps."	No further changes were recommended.	The previous changes to this question based on Round 1 feedback seem to have clarified this question; no participants in Round 2 raised any concerns about the intent or clarity of this item. Five of the 8 participants considered time and steps to be the same concept; however, 3 of the 5 participants still felt it was important to ask about each concept separately.
4b. Which device do you prefer based on understanding how to use the device?	Remove item	Several of the participants found this question confusing, and 2 participants suggested rephrasing the item. Some participants felt this question was redundant with or less relevant than other items. Removal of this item was recommended because all clinical trial participants likely would have a very good understanding of how to use the Handihaler and the Novel DPI devices by the end of the clinical trial and thus are less likely to have a preference based on this particular concept.	N/A	N/A
5b. Which device do you prefer based on overall ease of use?	Remove and replace with "Which device do you prefer based on how easy the device is to use?"	The revised question for Round 2 testing is consistent with the revised phrasing for the remaining questions (i.e., beginning the question with "Which device do you prefer based on") and reflects the simplified phrasing for "ease of use" suggested by 3 Round 1 participants.	No further changes were recommended.	The previous changes to this question based on Round 1 feedback seem to have clarified this question; no participants in Round 2 raised any concerns about the intent or clarity of this item.

N/A = not applicable.
[a] The instrument development team included Marci Clark (RTI-HS), Susan Martin (RTI-HS), John Ervin (RTI-HS), Maggie Tabberer (GSK), and Alison Hofmann (GSK).
All questionnaire revisions were discussed and agreed on by the team.

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