The Development of the Early Morning Symptoms of COPD Instrument (EMSCI)

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Introduction
The morning hours are a difficult time for patients with chronic obstructive pulmonary disease (COPD). COPD symptoms are commonly experienced in the morning. Patients have reported that morning is the time when their symptoms are the most troublesome.2,9 Morning symptoms have been reported to limit morning activities of daily living10 which, in turn, may have a negative impact on quality of life.2

Two patient reported outcome (PRO) instruments have been used in clinical trials11 to collect data about early morning symptoms. However, the published literature about these instruments suggests that they may not have been developed with sufficient evidence of content validity in order to make their development consistent with the US Food and Drug Administration’s requirements9 of a patient-reported outcome (PRO) instrument to collect data to support label claims. The two instruments were:
• The Global Chest Symptoms Questionnaire (GCOSQ)12
• Used to assess COP symptoms in the morning (pre- and post-morning dose)
• The Capacity of Daily Living during the Morning (CDSL)13

Objectives
• The objective of this study was to develop and test a PRO instrument that:
• assesses patients’ experience of COPD symptoms during the early morning
• meets the evidence requirements for content validity, as described in the FDA PRO Guidance
• can be used to collect data in clinical trials to support treatment benefit claims

Methods
• This study used the methods recommended for concept elicitation, item generation, and cognitive debriefing interviews as described in the FDA Guidance for Industry on Patient Reported Outcome Measures.2
• The methods used are described in Figure 1.

Results

Concept Elicitation
• Concepts that reflect patients’ experience of early morning symptoms of COPD and impacts of those symptoms on patients’ daily activities were identified through the analyses of focus group transcripts.
• Key concepts were confirmed by participants in subsequent discussions and no new emerging concepts were mentioned, thus saturation of concepts was reached.
• A saturation grid depicting emergent early morning symptoms of COPD and the impact of these symptoms are shown in Table 2.

Saturation Grids

Table 2. Symptoms and impacts as experienced by focus group participants

<table>
<thead>
<tr>
<th>Symptom</th>
<th>FG3 (Original)</th>
<th>FG3 (New York)</th>
<th>FG1 (New York)</th>
<th>FG1 (North Carolina)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Coughing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Muscle or pain</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Concom</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Tightness in chest</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Impact (limitations to activities)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Cognitive Debriefing
• Cognitive debriefing interviews with patients demonstrated that the items were understandable, relevant, and interpreted as intended.
• Participant feedback from cognitive debriefing interviews were used to revise the measure. One example of this modification is shown in Table 5.

Conclusions
• A new PRO measure has been developed to evaluate early morning symptoms of COPD.
• The measure was developed using the methodology outlined in the FDA requirements for use in clinical trials to support label claims.
• Evidence of content validity of the measure has been documented.

Future Directions
• The sample was limited in terms of ethnic diversity. The relevance of concepts will be tested in a more diverse sample during additional patient testing (e.g. usability testing).
• An electronic version of the measure is being developed and tested for use in clinical trials.
• Psychometric testing, including item reduction and evaluation of measurement properties, is planned for the current EMSCI.

References

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