Comparability of a Provisioned Device Versus Bring Your Own Device for Completion of Patient-Reported Outcome (PRO) Measures by Participants with Chronic Obstructive Pulmonary Disease (COPD): Qualitative Interview Findings

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Sasha Villarosa on behalf of the Patient-Reported Outcome (PRO) Consortium and the ePRO Consortium

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INTRODUCTION

• Capture of patient-reported outcome (PRO) data electronically has historically been corrupted with provisioned devices (PD).
• The desire to move from drug development to ease patient burden, combined with better access to hand-held devices (e.g., smartphones and tablets), has led to increased interest in having participants use their own device (BYOD)

METHODS

• Participants were asked to complete three study visits. Participants were given a device (PD Group A) or instructed to use their own device (BYOD Group B). Participants in Group A were provided with the software already installed on the PD and Group B downloaded and activated the application on their own device (BYOD).

RESULTS

Figure 1. Study Design Flow Diagram

Figure 2. Features Liked About Completing the PRO Measures on the PD and BYOD

Figure 4. Reasons for Preferring BYOD – Example Quotes

Figure 3. Reasons for Preferring PD – Example Quotes

CONCLUSIONS

• Overall, the data illustrate that participants’ experience completing the PRO measures was largely consistent across PD and BYOD with no clear preference between device type, with 45.6% (n=26) preferring PD and 54.4% (n=32) preferring BYOD.
• Although many of the same features were endorsed across both device types, some participants specifically liked the “dedicated” purpose of the PD, whereas others enjoyed the flexibility of BYOD.

Objectives

• To qualitatively evaluate, using longitudinal PRO data collection, participant experiences using a PD versus BYOD to complete PRO measures.

Background and Objective

This observational, cross-sectional study recruited participants with a clinical diagnosis of chronic obstructive pulmonary disease (COPD) from four clinical sites in the US.

Demographic and Clinical Characteristics

• In terms of participation, a total of 56 participants were enrolled to be included in the study. The most common reason for non-participation was a lack of FEV1, data available in the participant’s medical record (n=25, 42.4%). BYOD-related reasons (either not owning a smartphone or not wanting to use it in the study) accounted for n=14 (23.7%) of the 59 who could not take part in the study.
• Sixty-four participants were enrolled (mean age [SD]: 59.0 [15.5], 65.2% male, 51.0% Black/African American, 26.5% Hispanic, 8.8% Asian, 4.4% Native American, 2.2% another).

Table 1. Baseline Demographic and Clinical Information (FAS)

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<tr>
<th>Demographic</th>
<th>Group A</th>
<th>Group B</th>
<th>Overall N</th>
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<tr>
<td>Mean (SD)</td>
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<td>23 (45.3%)</td>
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<td>Group B</td>
<td>21 (46.8%)</td>
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<tr>
<td>Overall N</td>
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<td>High school diploma</td>
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<td>Degree</td>
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<td>7 (15.2%)</td>
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</table>

Methods – Continued

After the interview, the participant was assigned to the second device type and completed training to use it. The second period of the study involved the participant completing the PD for EXACT® every day for an additional 15 days and CAT and PDGS on Days 16, 23, and 30 using the alternate device type.

At the end of the second period of the study, participants returned for visit 3 and fill out a second QRG to decide on their device preference.

The interview was conducted by a trained interviewer and reviewed by a study coordinator. Interviewers discussed the following aspects of each device type:

- Ease of use/overall experience (also assessed quantitatively using an 11-point Likert scale, ranging from 1 = very easy to use to 10 = very easy to use)
- Capacity to complete the PRO measures using the alternate device type and their preferences, if any, for PD or BYOD
- Interviews were audio-recorded and transcribed, asking participants to discuss the following aspects of each device type:

• Participants were asked to complete three study visits. Participants were given a device (PD Group A) or instructed to use their own device (BYOD Group B). Participants in Group A were provided with the software already installed on the PD and Group B downloaded and activated the application on their own device (BYOD). Figure 1:

• In the first study phase, participants completed 14-day EXACERBATIONs of Chronic pulmonary disease Tool (EXACT®) every day for 15 days and the 8-Item Respiratory Distress Scale (COPD) Assessment Tool™ (CAT) and the Patient Global Impression of Severity (PGIS) tool (Figure 2).

• After 15 days, each participant returned for Visit 2 and took part in a 60-minute face-to-face semi-structured interview about the experience of completing the PRO measures using the device type to which they were assigned.

- At the second period of the study, participants returned for visit 3 for a second interview about the experience of completing the PRO measures using the alternate device type and their preferences, if any, for PD or BYOD.

- The interview was conducted by a trained interviewer and reviewed by a study coordinator. Interviewers discussed the following aspects of each device type:

- Ease of use/overall experience (also assessed quantitatively using an 11-point Likert scale, ranging from 1 = very easy to use to 10 = very easy to use)

- Capacity to complete the PRO measures using the alternate device type and their preferences, if any, for PD or BYOD

- Interviews were audio-recorded and transcribed, asking participants to discuss the following aspects of each device type:

• Most participants described the training on the PD and BYOD as good and sufficient to show how to complete study diary measures, with some suggestions for improvement. A small number of participants (on both PD and BYOD) described that they had not had enough time to learn how to use their device and completed multiple questionnaires to complete on some days but not others.

• In addition, the QRG was generally considered easy to understand and helpful across device types, although a large number of participants (PD = 18, BYOD = 21) reported not reviewing it during the study because they were sufficiently prepared by the training.

• Twenty-three participants (37%) reported missing the diary on at least one day using the PD, and 24 (40%) reported missing at least one day using the BYOD; eight participants commented that they missed a day when using both device types.

• There were no unique device-related reasons given by participants for not completing the diary; the most frequently reported reasons were:

- Social engagements (n=13)
- Time-intensive tasks (n=11)
- Poor health (n=11)
- Forgetting (n=10)

• Overall, just over half of participants reported receiving the reminder notification from the PD and 47% from BYOD to aid in completing the PRO measures on the PD (n=36) and BYOD (n=37).

- Many participants set their own reminder in addition to the programmed notification (PD = n=13, BYOD = n=14) so that they were not so easily missed or simply as an extra precaution against forgetting.

• Typically, this involved setting the alarm function on their own smartphone, receiving physical reminders (such as written notes), or setting a family member to remind them.

- Seventeen participants reported that while completing the diary on their BYOD they received a phone call (n=13), a text message (n=2), or a notification from another application (n=1).

- The majority of participants (n=10) always ignored the interruption and completed the diary.

- Most participants (n=9) received only one to two interruptions during the 15-day period.

• Participants were not overly concerned about data safety on either device type because they were confident that the experience of completing the PRO forms on any activity.

REFERENCES


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