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

Louise Newton,[1] Oliver Knight-West,[1] Sonya Eremenco,[2] Stacie Hudgens,[3] Mabel Crescioni,[4] Tara Symonds,[1] David S. Reasner,[5] Bill Byrom,[6] Paul O'Donohoe,[7] and Susan Vallow[8] on behalf of the Patient-Reported Outcome (PRO) Consortium and the ePRO Consortium

[1]Clinical Outcomes Solutions, Folkestone, UK; [2]Patient-Reported Outcome (PRO) Consortium, Critical Path Institute, Tucson, AZ, USA; [3]Clinical Outcomes Solutions, Tucson, AZ, USA; [4]Electronic Patient-Reported Outcome (ePRO) Consortium, Critical Path Institute, Tucson, AZ, USA; [5]Ironwood Pharmaceuticals, Cambridge, MA, USA; [6]CRF Bracket, London, UK; [7]Medidata Solutions, London, UK; [8]MedAvante-ProPhase, Hamilton, NJ, USA

INTRODUCTION

- Capture of patient-reported outcome (PRO) data electronically has historically been completed with provisioned devices (PD).
- The desire to reduce drug development costs and ease patient burden, combined with better access to handheld devices (e.g., smartphones and tablets), has led to increasing interest in having participants use their own devices ('bring your own device' [BYOD]) in clinical trials and other research studies.
- This approach is now even more viable because:
  - A growing body of evidence supporting migration equivalence of paper to a variety of electronic formats, supports the hypothesis that small format changes between devices may be inconsequential.[1]
  - Availability of new technologies that can adaptively present the screen content to allow questions to be displayed in a similar format on different devices.
- In previous studies assessing the feasibility of using a BYOD approach for PRO data collection, high compliance was found where most participants did not find the process of completing daily items burdensome.[2-5]

OBJECTIVES

- To qualitatively evaluate, using longitudinal PRO data collection, participants' experience using a PD versus BYOD to complete PRO measures.

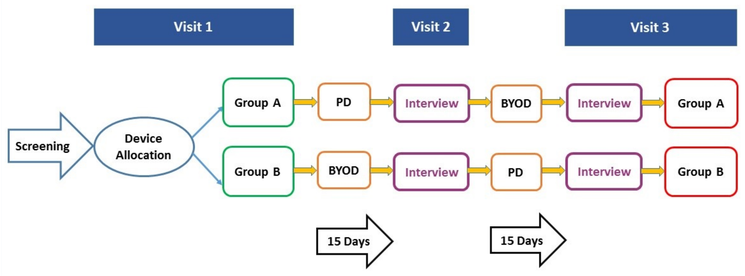
METHODS

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

Methods – Continued

- Participants were asked to complete three study visits. Participants who met the inclusion criteria were allocated to receive a PD (Group A) or instructed to use their own device (BYOD; Group B), for collection of PRO data. Group A were supplied 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 period of this study, participants completed the 14-item EXAcerbations of Chronic pulmonary disease Tool (EXACT®) every day for 15 days and the 8-item Chronic Obstructive Pulmonary Disease (COPD) Assessment Test™ (CAT) and the Patient Global Impression of Severity (PGIS) question on Days 1, 8, and 15.
- 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 he or she was assigned.

Figure 1. Study Design Flow Diagram



BYOD - bring your own device, **PD** - provisioned device

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 EXACT® every day for an additional 15 days and CAT and PGIS 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 for a second interview about the experience of completing the PRO measures using the alternate device type and their preference, if any, for PD or BYOD.
- The interviewer, assisted by a semi-structured interview guide, asked participants to discuss the following aspects of using each device type:
  - Ease of use/overall experience (also assessed quantitatively using an 11-point numeric rating scale where 1=very difficult/poor and 10=very easy/good)
  - Capacity to complete PRO measures as intended
  - Reasons for non-compliance with completion of PRO measures
  - Problems with devices not functioning correctly
  - Usefulness of training and training materials (referred to as the 'Quick Reference Guide' [QRG])
  - Interruptions while completing measures on BYOD (e.g., due to telephone calls, messages, notifications from other apps)
  - Perceptions of security of responses to the PRO measures
  - Preference between PD and BYOD (at second interview - Visit 3 - only)

Analytic Approach

- Transcribed data from the qualitative interviews were entered into ATLAS.ti (version 7.1), a software package that is designed to facilitate the storage, coding, and analysis of qualitative data.
- The interview data were analyzed by grouping discrete thematic codes into concepts and then further collating them into domains. Coding was completed by three researchers. To assess the reliability of the codes, the first three transcripts were independently coded, reviewed, and revised as appropriate.

RESULTS

Demographic and Clinical Characteristics

- In terms of non-participation, a total of 59 candidates were unable to be enrolled into the study. The most common reason for non-participation was a lack of FEV_1 data available in the potential participant's medical record (n=25, 42.4%). BYOD-related reasons (either not owning a smartphone or not wanting to use it in this 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 [10.55]; 65.6% female; 51.6% Black/African American) (Table 1).

Table 1. Baseline Demographic and Clinical Information (FAS)

Demographic	Group A PD 1st N = 23	Group B BYOD 1st N = 41*	Overall N = 64
Age			
Mean (SD), years Min–Max	57.5 (11.33) 40–75	59.8 (10.13) 40–77	59.0 (10.55) 40–77
Gender			
Female	14 (60.9%)	28 (68.3%)	42 (65.6%)
Male	9 (39.1%)	13 (31.7%)	22 (34.4%)
Race			
White	13 (56.5%)	13 (31.7%)	26 (40.6%)
Black/African American	6 (26.1%)	27 (65.9%)	33 (51.6%)
Other	4 (17.4%)	1 (2.4%)	5 (7.8%)
Education			
Did not complete high school	0	5 (12.2%)	5 (7.8%)
High school diploma	8 (34.8%)	12 (29.3%)	20 (31.3%)
Some college or certificate program	6 (26.1%)	13 (31.7%)	19 (29.7%)
College or university degree	9 (39.1%)	8 (19.5%)	17 (26.6%)
Graduate degree	0	3 (7.3%)	3 (4.7%)
Work Status			
Employed Full-Time	15 (65.2%)	11 (26.8%)	26 (40.6%)
COPD Severity			
Very mild	0	1 (2.4%)	1 (1.6%)
Mild	0	13 (31.7%)	13 (20.3%)
Moderate	18 (78.3%)	18 (43.9%)	36 (56.3%)
Severe	5 (21.7%)	8 (19.5%)	13 (20.3%)
Very severe	0	1 (2.4%)	1 (1.6%)

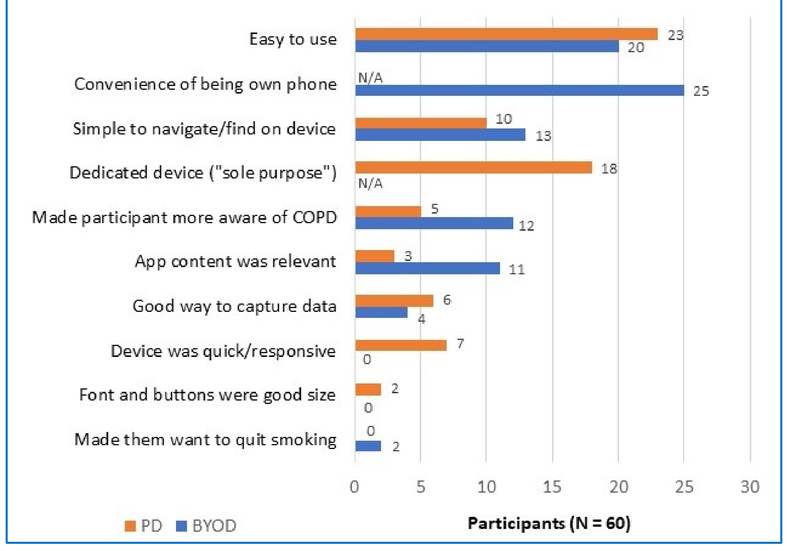
BYOD = bring your own device, **FAS** = full analysis set, **PD** = provisioned device, **SD** = standard deviation
*Although every effort was made to ensure that sample sizes for both groups were equivalent, an issue occurred during recruitment where nine participants who were supposed to start on PD were unable to do so because of device issues and, instead, had to start on BYOD.

- The two allocation groups (Group A or B) were of similar mean (SD) ages (Group A=57.5 years [11.33]; Group B=59.8 years [10.13]) and gender split was similar to the overall study population (Group A n=14 female, 60.9%; Group B n=28 female, 68.3%).
- Race distributions amongst the two allocation groups did not reflect the overall population. Group A participants were more likely to be White (n=13, 56.5%) whereas Group B participants were more likely to be Black or African American (n=27, 65.9%). Other demographic characteristics are summarized in Table 1.
- Sixty-one participants completed the first interview (v2) and 60 participants completed the second interview (v3). Fifty-seven participants completed both interviews, two completed only the first interview, and one completed only the second interview.
- The overall study population was diagnosed with COPD for an average of 7.2 years prior to enrollment, and half of the study population had no prior exacerbations (n=32, 50.0%), with around a third of the study population reporting a single previous exacerbation (n=20, 31.3%).

Qualitative Findings

- Ease of use and overall experience were rated equally positively across device types (Group A mean score: PD=9.4, BYOD=9.5; Group B mean score: PD=9.7, BYOD=9.5).
- Overall, participants had a positive impression of their experience using both the PD and BYOD. The ease of using the device application and completing the PRO measures on both the PD and BYOD was frequently mentioned by participants (Figure 2).

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



- When asked to identify their preferred device type for completing PRO measures after using both device types in the study, approximately half of the study population selected the PD (n=26) and half of the study population selected BYOD (n=29); two participants had no preference.
  - The most common reason for preferring PD was that it was "dedicated" to the study (n=17). Another prominent reason for preferring the PD was the lack of interruptions from messages/calls (n=7) (Figure 3).
  - The "convenience" of carrying a single device was the main reason for preferring BYOD (n=25). Those who preferred BYOD also reported that it was because they were more familiar with their own device than the PD (n=13) (Figure 4).

Figure 3. Reasons for Preferring PD – Example Quotes

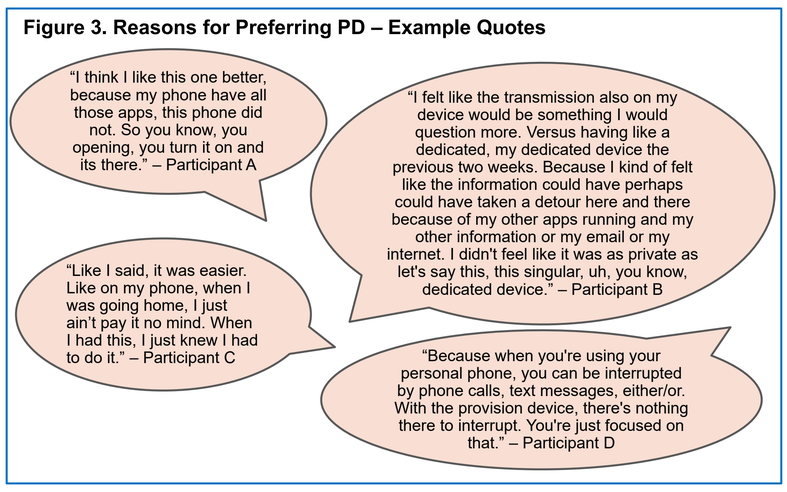
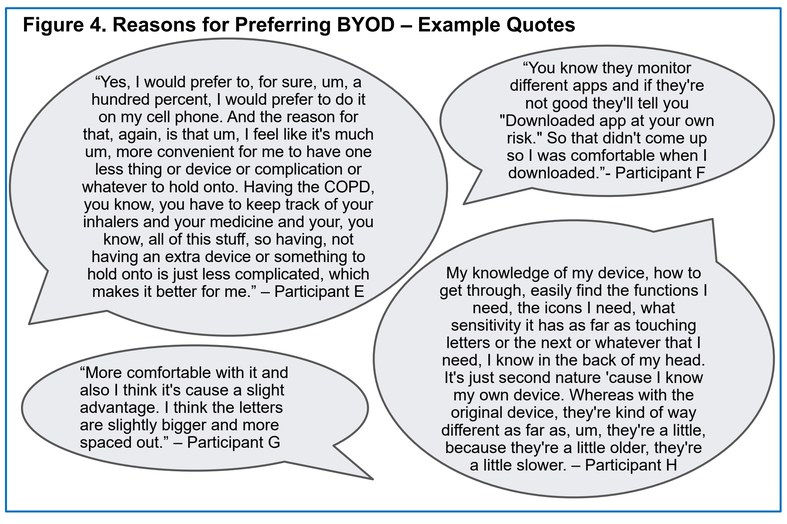


Figure 4. Reasons for Preferring BYOD – Example Quotes



- Most participants described the training on the PD and BYOD as good and sufficient to show them how to complete study procedures, with few suggestions for improvement. A small number of participants (on both PD and BYOD) reported that they were essentially unaware that there would be multiple questionnaires to complete on some days but not others.
- In addition, the QRG was also generally considered easy to understand and helpful across device types, although a large number of participants (PD n=18, BYOD n=21) reported not needing to consult it during the study because they were sufficiently prepared by the training received.
- Twenty participants (33%) reported missing the diary on at least one day when using the PD, and 24 (40%) reported missing at least one day when using their BYOD; eight participants commented that they missed a day when using both devices.
  - 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)
    - tiredness/falling asleep (n=11)
    - poor health (n=11)
    - forgetting (n=10)
- Overall, just over half of participants reported receiving the reminder notifications and finding them a useful aid to completing the PRO measures on the PD (n=36) and BYOD (n=37).
  - Many participants reported that they set their own reminder, in addition to the programmed notification (PD [n=15]; 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, setting an alarm clock, having physical reminders (such as written notes), or asking a family member to remind them.
- Seventeen participants reported that while completing the diary on their BYOD they received a phone call (n=11), a text message (n=2), a phone call and a text message (n=3), 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 there was a general acceptance of some risk when doing any online activity.

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 50.9% (n=29) preferring BYOD (n=2 had no preference).
- Although many of the same features were endorsed across both device types, some participants specifically liked the "dedicated" purpose of the PD, whereas others liked the "convenience" of BYOD.
- More missing days were reported when using the BYOD (40% vs 33%) but the reasons for missing days were similar across devices.
  - Device-related reasons were primarily due to the battery running out on the PD and BYOD, and not being able to access the App.
  - When using BYOD, there were slightly more technical issues than when using PD including issues with data transfer and PIN related issues.
- On BYOD, being interrupted did not appear to be a major issue and when participants were interrupted, it did not impact their ability to finish the diary questions on their BYOD.
- This study supports the use of BYOD as a potential complement to PD for collecting PRO data in COPD studies, and contributes evidence that BYOD may be employed to collect PRO data in diverse patient populations.

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For further information, please contact: Louise Newton (louise.newton@clinoutsolutions.com)

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