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### Authors

Fung, Constance

Igodan, Uyi

Alessi, Cathy

et al.

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## Human Factors/Usability Barriers to Home Medical Devices Among Individuals with Disabling Conditions: In-depth Interviews with Positive Airway Pressure Device Users

Constance H. Fung, MD, MSHS<sup>1,2</sup>, Uyi Igodan, BA<sup>2</sup>, Cathy Alessi, MD<sup>1,2</sup>, Jennifer L. Martin, PhD<sup>1,2</sup>, Joseph M. Dzierzewski, PhD<sup>1,2</sup>, Karen Josephson, MPH<sup>2</sup>, and B. Josea Kramer, PhD<sup>1,2</sup>

<sup>1</sup>David Geffen School of Medicine at University of California, Los Angeles, 16111 Plummer Street (11E), North Hills, California, 91343, United States of America

<sup>2</sup>Department of Veterans Affairs (VA) Greater Los Angeles Healthcare System, 16111 Plummer Street (11E), North Hills, California, 91343, United States of America

### Abstract

**Background**—Evidence suggests that medical equipment often fails to accommodate the needs of individuals with disabling conditions. Few studies have focused on the accessibility of home medical devices such as positive airway pressure (PAP), which is a type of home medical equipment prescribed for long-term therapy.

**Objective**—The purpose of this study was to explore in detail the types of difficulties experienced by patients with physical/sensory impairments who use PAP devices, as an initial step in designing a questionnaire to survey users about this topic.

**Methods**—In this descriptive study, in-depth interviews were conducted with 19 participants (9 patients with physical/sensory impairment and 10 healthcare providers). Interviews were coded and analyzed for major topics.

**Results**—Participants detailed the numerous ways in which current PAP devices fail to meet the needs of individuals with physical/sensory impairments (e.g., tremor, poor depth perception, paresis), by requiring patients to perform manually difficult tasks, such as inserting PAP parts through small apertures, attaching parts using a twisting motion, and lifting arms overhead to apply PAP headgear. These demands contributed to patients' frustration with and reduced usage of the home medical device.

**Conclusions**—Our findings suggest that home medical devices such as PAP may not be currently designed to meet the needs of some users with physical/sensory impairments. Additional

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Address correspondence to: Constance H. Fung, M.D., M.S.H.S., GRECC (11E), VA Greater Los Angeles Healthcare System, 16111 Plummer Street, North Hills, CA 91343, Tel: (818) 895-9311; Fax: (818) 895-9519; Connie.Fung@va.gov.

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studies are needed to measure the prevalence and impact of impairment-related barriers on PAP adherence for this common medical equipment.

## Keywords

Sleep apnea syndromes; continuous positive airway pressure; disabled persons; equipment design

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## Introduction

Approximately 16% of adults in the United States have difficulty with physical functioning, and 15% of the world's population has a disability.(1;2) An increasing number of individuals with health conditions and disabilities are expected to use home medical devices, which are a type of medical equipment, to monitor and treat their chronic health conditions.(3) Yet studies of medical equipment users with disabilities have found that the equipment may be difficult to use or even hazardous for some patients.(4-6)

Obstructive sleep apnea (OSA), which is prevalent among adults with disabilities (e.g., chronic spinal cord injury, stroke) (7;8), is the prototypical health condition treated with a home medical device—namely, positive airway pressure (PAP). PAP devices keep the airway open, thereby ensuring adequate airflow and blood oxygen levels and reducing cardiovascular morbidity and mortality.(9) These devices are comprised of a machine, tubing, mask, and straps. They require individuals to engage in nightly set-up and maintenance tasks, which involve gross and fine motor movements and sensory input. Optimizing PAP design has the potential to increase access to PAP therapy, improve adherence to this lifesaving medical therapy, and minimize disability.

Human factors directly affect individuals' interactions with their home medical devices(10;11) and are a target for optimizing home medical devices. The Food and Drug Administration has issued documents to help manufacturers apply human factors engineering to improve the safety and effectiveness of home medical devices.(10) The Association for the Advancement of Medical Instrumentation (AAMI) recommends addressing human factors when designing equipment, to help users with a range of abilities. (11) For example, tactile cues on equipment controls can make the equipment easier to operate for users with impaired vision.

Few studies have examined barriers related to human factors among PAP users with physical/sensory impairments.(12-16) No studies have examined in detail the extent to which the design of current PAP devices (i.e., human factors) meets the needs of patients with physical or sensory impairments. One reason for the scarcity of data on this topic is an absence of self-administered questionnaires for measuring human factors associated with PAP devices among populations at risk for physical/sensory impairment.

In this study, we conducted in-depth interviews to identify ways in which the design of home medical devices for OSA treatment supports or impedes use among individuals with physical and/or sensory impairment. As a recommended initial step in questionnaire development (17), in-depth interviews were designed to gather information that would

inform development of questionnaire items about human factors associated with PAP devices.

## Materials and Methods

### Setting, Recruitment, and Sample Selection

The setting was one United States Department of Veterans Affairs (VA) Healthcare System, which includes an accredited sleep center. The center issues PAP machines from one major manufacturer and PAP parts (e.g., masks) from a variety of manufacturers.

We recruited both patients and healthcare providers. We felt that patients could provide rich descriptions of the types of impairments that impact PAP use and the amount of support from the healthcare system and their family. We felt that providers could offer a broad perspective on the types of individuals who have experienced discordant person-device interactions and would have in-depth knowledge of the healthcare environment (i.e., features of PAP equipment and healthcare systems that enable patients to use their equipment).

We posted recruitment flyers in clinics and offices and sent email invitations to providers listed in our center's online directory. Individuals who were interested in participating contacted our research office. Staff informed prospective participants about the study, including plans to digitally record each interview, and screened individuals for eligibility. Patients aged  $\geq 50$  years who were current or past users of PAP equipment for OSA and reported difficulty using PAP equipment related to sensory or physical impairments were considered eligible. We focused on older adults because of the increased prevalence of disability associated with advanced age. We excluded patients with a self-reported diagnosis of dementia or Alzheimer's disease, because interview data from these patients may not be valid or reliable. Providers who self-identified as clinical staff (e.g., physician, nurse, respiratory therapist, physical therapist, occupational therapist) of the pulmonary, sleep medicine, geriatrics, or physical medicine and rehabilitation divisions at our local VA were eligible. All participants were compensated with a \$50 gift card (VA employees conducted the interviews outside their tours-of-duty).

### Conducting the Interviews

Different interview guides were used for patients and for providers. Both guides were framed by the theoretical construct of the Enabling-Disabling Model, which describes disability as the product of an interaction between an individual and his/her environment, rather than a characteristic inherent to an individual with impairments.(18) All interviews were completed between October 2012 and May 2013. One field staff moderated each session while another recorded notes and asked follow up questions.

To focus our patient interviews on previously unidentified barriers to PAP therapy, we began each patient interview by displaying a list of 24 problems commonly known to contribute to difficulty using PAP equipment (see Appendix).(16;19) Patients were asked to identify which problems caused "trouble using [their] sleep apnea equipment" and then were asked about barriers that were not listed. Focusing on these newly identified barriers, respondents described in detail their experiences using their PAP equipment (see Table 1).

We delved into these difficulties by asking additional open-ended questions and probes to encourage patients to describe their health, their impairment(s), their functional limitation(s), their environment including PAP design/features, family support, and healthcare provider support, and any discordant interactions between themselves and their current treatment environment. We also asked about supportive factors that could reduce this discordance, such as therapies directed at the physical/sensory impairment and improvements in PAP design/features. We asked each patient to identify his/her race/ethnicity and living arrangement (e.g., lives alone).

Our open-ended interview queries with providers encouraged providers to describe their experience treating patients with physical/sensory impairment and impressions about how the availability of caregiver/family involvement enables or impedes patients' use of their PAP equipment. When providers identified human factors, we probed for ways PAP equipment may be difficult for patients with specific types of physical/sensory impairments. We also asked providers to describe ways that their patients or colleagues have recommended to diminish discordance, such as improvements in PAP design/features. We asked providers to identify their clinical divisions/departments.

We conducted interviews with participants until participants were no longer providing unique information about the types of difficulties patients with physical and/or sensory impairment have with their PAP devices, which occurred after nine patients and ten providers were interviewed.

Institutional review boards at our institutions approved all study procedures.

## Data analysis

Data analysis of semi-structured interviews occurred in three phases.<sup>(20)</sup> During phase 1, which occurred immediately after each interview, field staff identified and recorded major topics of the interview in the field notes. During phase 2, which began before all interviews were completed, two team members independently read through five interviews and labeled the text with codes that reflected topics discussed. Then they met with a third team member to discuss how different codes were interpreted and applied. Codes were refined iteratively and expanded until all relevant interview topics were represented in a coding tree. Through this process, we also refined our interview guide (e.g., added additional probes). In phase 3, we applied the final coding scheme to all of the transcripts using NVivo10 software (QSR International, Burlington, MA). We tested hypotheses about relationships and compared interviews from groups with different perspectives (e.g., patients versus providers). Finally, we generated kappa statistics for each code (number of codes = 38), and iteratively revised codes until intercoder reliability (kappa) 0.85 was achieved for each transcript.

Throughout data analysis, we explicitly acknowledged the need to safeguard against imposing preconceived notions derived from clinical experience rather than research data, by staffing this project with two team members who have no direct clinical experience with OSA patients and openly discussing whether analyses were being unduly influenced by clinical experiences.

## Results

### Participant characteristics

Eight of our nine patient participants (89%) were male, and five (55%) were Caucasian. All patient participants described active/current attempts to use their PAP device. Three (33%) lived alone. Six of our ten provider participants (60%) were male, and the following clinical divisions/departments were represented: five physical medicine and rehabilitation providers (50%), four pulmonary and/or sleep medicine providers (40%), and one geriatrics provider (10%).

### Types of Impairments Associated with Difficulty Using PAP Devices

Patients and providers identified a variety of health conditions that caused functional limitations. In the context of current PAP devices and home environment (described in the next section), the following impairments were associated with disability (associated health condition in parentheses): tremor (e.g., Parkinson's Disease), weakness (e.g., carpal tunnel syndrome, stroke), decreased range of motion (e.g., rotator cuff injury, osteoarthritis, rheumatoid arthritis), loss of digits (e.g., amputation), numbness (e.g., diabetic neuropathy), and visual impairment (e.g., impaired depth perception).

### Description of Discordant Interactions

**Overall**—Participants identified a discrete number of person-device interactions, which shared the common thread of discordance between what was needed to set-up, use, and maintain/clean PAP devices and what the patient could perform in the context of physical/sensory limitations within their current home environment (i.e., caregiver/family). One provider described PAP equipment use by patients with physical and/or sensory impairment in following manner:

“Well...anyone that has had a stroke and limited use of their upper extremity, arthritic changes...all those things would probably limit their abilities to use it, care for it.”

**PAP Headgear**—Most participants focused on their difficulties applying and securing the PAP headgear. One barrier, as described by the following patient, was the need for adequate range of motion of the shoulder and upper extremity muscle strength to lift and lower the headgear from the head:

“I have a shoulder I can't really go up with much. That makes it hard for me to ... get the straps off and set right to put it on my head...”

Another barrier was the fine motor movement and sensory input necessary to connect or adjust the straps. The following quote demonstrates the difficulties with fastening headgear encountered by a patient who has finger numbness:

“It does seem like it's not...between my fingertips and my brain. It's not clear what I'm trying to do, reinserting that snap [between my mask and straps]. It just strikes me that sometimes it's really kind of frustrating and it's not something I can see.”

One provider identified lack of digits (e.g., due to amputation of a finger) as a barrier to applying headgear:

“I’ve seen a couple of patients that have lost a finger... They have a hard time with some of the masks because of the straps: you have to strap it here [on the face] and adjust the mask on the bridge of the nose. There are a lot of technical parts of the mask that they have difficulty putting together.”

These results suggest that strategies to facilitate lifting the headgear overhead or fastening straps would be helpful.

**Water Chamber**—Reduced motor strength led to difficulty removing and opening the water chamber, and poor vision negatively impacted patients' ability to pour water into the water chamber:

“Some [very old veterans] don't even have the strength to pull the humidifier out or open [the water chamber] up.”

“The challenge is when you have no depth perception, then pouring [water into the water chamber] is very hard... That's a challenge because it's a small hole.”

These comments suggest that reducing the motor strength required to remove and open the water chamber could facilitate use of the water chamber, as would increasing the diameter of the hole or providing alternative ways of filling the water chamber.

**Machine Controls**—Several participants described a need for intact vision and touch to operate machine controls:

“At night when I go to sleep, it is hard to see what numbers [on the controls] you're supposed to be on.”

“I'm doing things with [the machine controls] that I'm not clear about because of the numbness in my hands.”

These comments suggest that information about machine settings and position of controls is being provided in only visual or tactile formats, which may pose a problem to patients who have low vision or numbness.

**Filter**—Replacing the filter can also be challenging, because of the small aperture of the space where the filter is placed and the mechanics needed to place the filter into this space. One patient who has a tremor described his experience replacing the filter:

“Shaking of my right hand ... So when I try to hold something like that, it's shaking and it'll get the adjustment off... Changing the filter... I try to pinch it and then... the filter will fall out.”

This description suggests that the source of difficulty may be related to the small size of the filter and manner in which filters must be replaced.

**Tubing**—Connecting and disconnecting tubing also can be challenging when patients have severe arthritis, as described by the following patient.

“Sometimes my hands get pain [from severe arthritis] when I try to work with the machine, connecting [the hose] or something... and sometimes it makes it difficult to do that.”

**Caregiver/Family Assistance**—When we asked participants about caregiver or family involvement in setting up or maintaining PAP devices, some patients told us that they receive no assistance or minimal assistance (“No. I mostly try to do it myself.”). Yet some providers described a need for caregiver or family assistance to set up or maintain devices.

“If they have something like a stroke where they are plegic on one side, that would obviously affect them from washing, cleaning, or putting them on properly...If they have a caretaker, or help, or a family member there to help them put them on, [the equipment would be cared for].”

### Description of Concordant Interactions

Not all participants described the current state of PAP therapy as one of discordant interactions. One provider said that some patients with impairment can use their headgear without difficulty, suggesting that current PAP devices meet the needs of some patients.

“But... there are a few spinal cord patients who obviously can use, operate, and maintain it without family help.

Another provider said that some patients with impaired sensory modalities (e.g., blindness) are able to operate the device (possibly because of increased capabilities and altered organization of spared modalities such as enhanced tactile sensation).

“There really isn't a whole lot to see in the actual machine, even though I have patients that are legally blind that I set up because they have such great touch and feel thing.”

### Consequences of Discordant Interactions

Several patients described increased effort or time required to set up or maintain their devices. One patient had reduced the amount of time needed to set up the equipment over time, but was still, cumulatively, spending a couple hours per week setting up the equipment:

“Yeah,[at first] [getting PAP equipment ready for use] took a while. It was about 40 minutes and then I broke it down in about 20 minutes.”

Both patients and providers described how more effort, frustration, or fear about insurmountable usability barriers may contribute to PAP nonadherence.

“[Putting the mask on] might take me twice, three times, four times as long. It just gets really frustrating; I'll just put it down and say, ‘Not tonight...I'll suffer as a result of it, but it just doesn't work.’”

“I think when people have the fear that they can't take their mask off because they've had a stroke, it becomes a matter of just not using it or looking for other options.”



## Suggestions for Making Interactions More Concordant For Individuals with Physical/Sensory Impairment

**Change the mechanisms for attaching or positioning parts**—A few patients recommended modifying the headgear and changing the mechanism for connecting the tubing. These improvements might include attachment mechanisms that do not rely on either a positive grasp to keep the tubing in place or the simultaneous need to exert and maintain force on the tubing, as described by the following patient.

“[I would like] snaps on [the ends of the tubing] or vice versa a snap on the machine. Instead of...one of those rubber hoses you have to squeeze in there...If you have a snap, you can just snap right off.”

Participants also recommended minimizing the number of attachments or adjustments needed.

**Change the layout of machine controls**—A few patients recommended changes in the layout of their machine's controls to improve access to the controls. These suggestions included placing the controls or displays in the front of the machine so that they are more accessible when patients are supine, as described by the following patient:

“I have to turn the light on to find it...Actually, if it wasn't on top, [and instead] was on the front, I'd probably be able to [find it]...But I've been trying to memorize where it is so I can get it by feel.”

Another patient recommended positioning the controls to provide tactile variation cues so that patients can more accurately select a control without needing to read the label on the machine control:

“Put [the controls] in a different spot. There's like three switches on top. So at night you lean over [and ask yourself], so which one is it and stuff like that. So if one was maybe higher or a little bit bigger or set back or stuff like that, I think that would help also.”

**Add additional mechanical or contour features**—Although patients and providers both identified ways to improve PAP devices overall, patients provided the majority of strategies for reducing impairment-related barriers to PAP devices. For example, several patients suggested that machine controls incorporate more mechanical or contour features to allow for more ease of use for patients with upper extremity physical and/or visual impairment. Detent controls and larger, key-shaped controls were specifically identified as strategies:

“I seem to find myself looking at what the machine is doing and I say, “How did that happen?” Go from a 2 to a 0 [setting]...or whatever. It might be that some kind of detent [a device to mechanically resist movement] control would be helpful... That in order to turn it, you'd actually have to depress it before it would turn.”

“Put some other kind of adjustment that would be more design friendly to users. Perhaps a...large key so that they could turn it with their hands, rather than just a knob.”

Another patient described a strategy for improving the way the power is turned on and off:

“I [would] have a...junction box with a switch on it. If you plug the...machine into the box, and then you plug the box into the wall, then all you'd have to do is flip on the switch because [currently] there is no switch in line from the wall receptacle to the machine.”

**Make the filter larger and provide more indication about how it should be inserted**—A few participants described ways in which the filter could be designed better. For example, the size of the filter and aperture of the filter chamber could be increased to reduce the demand for fine motor control, as described by the following patient:

“The filter is so small and you have to pinch it on both sides just right. It would be a little bit easier if it was a little bit bigger and easier to get to because it's always in the back and on the bottom and in a corner type...”

The filter could have multimodality sensory cues (i.e., mixture of tactile, visual, and audio modes) to enable patients with sensory impairment to accurately identify the proper orientation of the filter:

“Filters could probably be designed a little bit better for the patient to know which is up, which is down, which is left, which is right.”

## Additional Analyses

We did not identify differences in responses based upon race/ethnicity or provider clinical divisions/departments. The only differences between patients and providers were related to perceptions of availability of family/caregiver support. Patients tended to identify a lack of family/caregiver support in the home (and a concomitant increase in patient effort/frustration with PAP devices), while providers did not.

## Discussion

We explored physical (e.g., tremor, decreased range of motion) and/or sensory (e.g., low vision) impairment-related obstacles to one of the most common types of home medical devices, PAP. All of the patients and most of the providers described ways in which physical and/or sensory impairments, in the context of current device design, contribute to difficulty setting up and using home medical devices. These barriers increased the amount of effort and time spent on these devices and increased frustration levels. The Enabling-Disabling Model suggests that these barriers and their consequences are not inherent to patients(18); rather, they result from a mismatch between the needs of the patients and their unsupportive environment and therefore, could be overcome through modifications of the equipment, assistive devices, or additional support from family or caregivers. The descriptions of nonadherence, frustration, and fear of using the devices suggest a need to survey patients about the accessibility of home medical devices and the adverse effects of unaddressed human factors/usability barriers.

Our findings add to the limited number of studies that have examined barriers to use of PAP equipment, the relationship between equipment acceptance and disability, or medical

equipment usability among patients with a range of impairments.(4;5) In one study of PAP barriers, nearly one-fifth of patients experience minor skin lesions from their PAP masks, and similar to our study, participants suggested making straps adjustable and masks easy to assemble.(12) A study of patients undergoing geriatric rehabilitation found that individuals who accepted PAP therapy were less disabled (13), a finding echoed by our participants. Although not specific to PAP equipment, a survey found a high percentage of participants with visual, hearing, speech, mobility and/or cardiopulmonary impairment who had “moderate” or “extreme” difficulty with medical equipment use such as exam tables, rehabilitation equipment, communication aids, and some patients who found medical equipment “impossible” to use.(5) On that survey, nearly half who responded to items about oxygen delivery (N=95) reported at least a little difficulty with the oxygen delivery equipment (47%).(5) In a study that used video task analysis, participants had difficulty transferring to medical equipment (e.g., weight scales) and had postural instability associated with use of medical equipment.(4)

Our results suggest that strategies are needed to facilitate device use among individuals with impairment. The Enabling-Disabling Model (18) suggests that individuals with impairment might not experience barriers, if devices were designed to enable the patient to set up, use, and maintain the devices. Design strategies, in general, should account for high rates of upper extremity impairment (e.g., decreased range of motion due to arthritis, paresis due to stroke) and visual, tactile, and auditory impairment, as described by the AAMI and several of our study's participants.(11) A multimodal presentation of information (e.g., tactile cues) could help patients with visual impairment use their equipment more efficiently and effectively.(11) Device controls that regulate continuous functions (e.g., humidifier setting) could use a sliding interface operable with the side of a hand or a dowel pointer, instead of an interface that requires a twisting movement. These types of interfaces might be easier to operate for users with arthritis or carpal tunnel syndrome.(11)

Our study has both strengths and limitations. Our qualitative methods enabled us to identify a range of perspectives and to begin a line of inquiry into home medical device use, but do not permit estimation of the prevalence of usability barriers or generalization of findings. All of our patient participants described impairment-related difficulty with their PAP devices because we specifically recruited for patients who have had this type of difficulty so that we could obtain more detailed descriptions of impairment-related obstacles.

## Conclusion

Participants with physical and/or sensory impairment described obstacles to home medical devices that were related to the design of the devices. Research is needed to implement strategies to help these patients use their home medical devices. More studies are needed to determine whether patients with physical and/or sensory impairment encounter impairment-related barriers to other types of home medical devices.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Table 1**  
**Interview Guide Topics**

<p>“The Person”</p> <ul style="list-style-type: none"> <li>Description of medical conditions, physical/sensory impairment, functional limitations</li> </ul> <p>Sample probe: “Can you tell me a little bit more about what kind of physical or sensory condition you have?”</p>
<p>“The Person-Environment Interaction” (Current and Ideal)</p> <ul style="list-style-type: none"> <li>A description of current PAP equipment and how physical/sensory impairment impacts set up, use, or maintenance of PAP equipment.</li> </ul> <p>Sample question: “Please tell me about your experience setting up PAP equipment, CPAP, APAP, or BIPAP for older veterans who are newly diagnosed with sleep apnea.</p> <p>What’s your experience with that? Are there any models of equipment, or are there certain ones, that are easier or harder?”</p>
<ul style="list-style-type: none"> <li>A description of how PAP equipment is issued to patients/set up</li> </ul> <p>Sample question: “Let’s talk about when you first received your CPAP equipment and you met with the person who gave you your equipment. Can you briefly describe what happened during that encounter?”</p>
<ul style="list-style-type: none"> <li>The amount of actual or perceived assistance from family or caregivers with PAP equipment</li> </ul> <p>Sample probe: “You mentioned that you received help once or so putting the straps on. Do you receive regular help from family and friends?”</p>
<ul style="list-style-type: none"> <li>Identification of strategies that patients or providers have developed to improve use of PAP equipment, including equipment modifications or therapies directed at reducing the physical/sensory impairment:</li> </ul> <p>Sample question: “Some patients we’ve spoken with have developed some home remedies to make their equipment easier for them to use. Have you encountered anything that makes it easier?”</p>
<ul style="list-style-type: none"> <li>A wish list for improving PAP equipment to make it easier to use</li> </ul> <p>Sample question: “What would you like me to tell the designers of PAP equipment that might make it easier for patients to use it, if anything?”</p>
<p>Impact of Discordant Person-Environment Interactions</p>
<ul style="list-style-type: none"> <li>Effort required and accuracy setting up and maintaining equipment (patients only)</li> </ul> <p>Sample probe: “How many minutes or hours does it take to set up your equipment each night?”</p>
<ul style="list-style-type: none"> <li>Attempts to adhere to PAP therapy and self-confidence in ability to use PAP equipment (patients only)</li> </ul> <p>Sample question: “Can you tell me what the doctors told you about the number of hours to use the machine each night? Can you use it that many hours each night?”</p> <p>Sample question: “How confident are you/were you in your ability to use your CPAP equipment?”</p>

PAP = positive airway pressure. This table lists the topics that the field team aimed to discuss with research participants during each interview. The “Modified Institute of Medicine’s Enabling-Disabling Model” (18) and our research team’s clinical experience provided the framework for developing the guide.