

Specific Conditions of Home Use Medical Devices: A Study on CPAP Devices

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ABSTRACT

Recent developments in medical and healthcare technologies have resulted in longer life expectancy, along with an increase in chronic conditions and related medical costs. This trend is being mitigated through the integration of empowering technologies into everyday life, which improve tracking and effectiveness in preventive healthcare, thereby enhancing quality of life and lowering expenses. Digital technologies, especially smart wearables, have become widely adopted, addressing a variety of user needs beyond just health and wellness. Their multifunctionality facilitates their incorporation into daily routines, allowing users to monitor exercises, steps, calories burned, sleep patterns, heart rate, blood pressure, diet, and hydration—key components for preventive health. Conversely, while medical devices are becoming more compact and user-friendly for non-professionals, their development is progressing more slowly and conservatively than digital products. The differences between these markets stem from variations in regulations, research and development capabilities, financial limitations, and legal obligations. Nevertheless, medical technologies in healthcare are increasingly integrating with consumer technologies, highlighting the need for product designers to be aware of the specific requirements for medical devices. This paper reports on findings from a field study with 30 users of Continuous Positive Airway Pressure (CPAP) devices for Obstructive Sleep Apnea (OSA), selected as a successful home-use medical device for a common chronic condition. The findings are categorized by factors affecting product choice, ease of use, and user perceptions of CPAP therapy.

Keywords: Medical device design, Home use medical devices, CPAP

INTRODUCTION

The recent statistical reports of the Turkish Statistical Institute (2024) have supported the aging population trend resulting from both increased life expectancy and lowered birth rates. The report mentions that the ratio of elderly in the population has reached 10% for the first time in history and projections show the elderly population will exceed 15% in 2035 and 23% in 2050. Although 25 years may seem long, the sudden increase in the age distribution will affect the economics of future generations. In addition, Covid19 pandemic has shown the capacity of healthcare services should be

improved in case higher margins of the population are in need. Japan, where the elderly population has reached 30%, is a good case for studying the strategies for adaptation to aging population. The government institutions are developing a future scenario called as ‘the Community-based Integrated Care System’ which aims to diffuse the long term healthcare services into communities where people will have a more active and healthy living in the population supported by creating a population with higher awareness on dementia with volunteers training on different levels such as schools, offices, and communities (Japan Ministry of Health, Labour and Welfare, 2016).

As mentioned above, healthcare organizations are increasingly supporting the decentralization of healthcare, transitioning many activities outside traditional healthcare facilities to address the current challenges. This model is expected to shift the financial responsibility for healthcare from governments and private entities to individuals. Additionally, transferring specific tasks to non-professional users is anticipated to generate significant cost savings. Alongside this shift, medical devices turning into consumer healthcare products will evolve to meet the needs of patients and other relevant stakeholders. Compact and mobile healthcare products are expected to become more widespread with emerging technologies. The mobility of medical technologies also influences the environments in which these devices are used. Data sharing and continuous monitoring enables the transformation of healthcare environments. The concept of telemedicine draws attention of healthcare providers. In addition to smart home applications, outdoor spaces, workplaces, and entertainment venues are increasingly becoming spaces where medical feedback is provided through remote monitoring systems.

FIELD STUDY

The research centers on home-use medical devices intended for non-professional users, such as patients, relatives, and caregivers, within the scope of homecare. These products, which include both devices and disposables, are categorized according to their specific applications. The primary goal of home-use medical products is to meet patient needs, with categories such as bedding, respiratory support, mobility, hygiene, and monitoring. Through an examination of these products, medical device manufacturers in the Ankara region were identified, and the focus was narrowed to those producing devices used in the home setting. Given that the lack of prototypes or product samples has been identified as a barrier to user studies in healthcare (Money et al., 2011; NHS, 2010; Shah, Farrow, & Robinson, 2009), priority was given to devices available for purchase in Turkey and reimbursed by the Social Security Institution (SGK). In addition to availability, the feasibility of fieldwork also depends on proper maintenance and companies with sufficient technical expertise. Consequently, the product offerings of these companies were reassessed. In line with the earlier analysis of home-use medical devices, respiratory assistive devices (such as CPAP, BPAP, nebulizers, and ventilators) were identified as a common product category among manufacturers and service providers in the Ankara region. Therefore, CPAP devices were selected for the case study due to their long-term use by people with sleep apnea.

Participant Selection

The field study participants are selected from a diverse group of CPAP users, representing various ages, education levels, and backgrounds. The participants' experience with CPAP devices ranges from those in the early stages of use (less than six months) to those who have been using the devices for over five years and have successfully adhered to the treatment. The decision to include participants with varying levels of experience is based on two key reasons. First, having users at different stages allows for comparisons of their perceptions and attitudes toward the treatment. Second, long-term users are able to compare devices and components based on their experiences with other products and can provide insights into issues arising from prolonged use, such as maintenance and cleaning challenges.

The Survey Study

The survey for this study is designed as a semi-structured interview that incorporates a mix of open-ended questions, multiple-choice items, and established scales to assess CPAP usage experiences. To capture the full scope of CPAP users' experiences throughout the product's lifecycle, the survey is organized into six sections: participant demographics, purchase process, early learning phase, CPAP usage experience, daily life impacts of CPAP use, and adherence to treatment.

Common demographic details are collected, along with information on the brands and usage duration of current and previous CPAP devices. The interview begins by determining whether participants have a refurbished CPAP from the Social Security Institution or a brand-new device. For those with new devices, they are asked to describe the purchase process and the factors that influenced their decision.

Next, the interview explores how participants learned to use the device. Given the importance of the learning curve for both safety and adherence to medical devices, it is crucial to understand how users address challenges such as confusion during use, maintenance, and device setup.

In the following section, users' overall experiences with the CPAP device are evaluated using the User Experience Questionnaire (UEQ). The UEQ assesses user experience across six domains: traditional usability factors such as attractiveness, perspicuity, efficiency, and dependability, as well as hedonic qualities like stimulation and novelty (Laugwitz, Held, & Schrepp, 2008). These domains are rated using a seven-point Likert scale with 26 items expressed through pairs of opposite adjectives.

The impact of CPAP use on daily life is explored through two established scales followed by open-ended questions. The scales used in this section include the Self-Efficacy Measure for Sleep Apnea (SEMSA) (Weaver et al., 2003) and the Attitudes to CPAP Treatment Inventory (ACTI) (Broström et al., 2011). During this part of the interview, participants are asked how CPAP treatment has affected their social relationships and the privacy of their use.

The survey concludes with questions about the frequency and duration of CPAP use, which are critical for understanding adherence levels, as there

is no objective measure for what constitutes ‘regular use’ among patients. For example, two patients may both consider their use ‘regular,’ but one might use the device nightly, while the other might use it only every few days. The environment in which the device is used is also explored, as side effects like noise from the motor can impact daily use, potentially leading to separation of sleeping arrangements for couples. The final topic addresses how users store their devices, providing insights into patients’ habits. In addition to the interview, the CPAP Habit Index-5 (Broström et al., 2014) is utilized to evaluate the alignment of usage habits with other measures of CPAP adherence.

FINDINGS

The study’s findings are based on data collected from 30 participants using a range of CPAP devices, each with diverse demographic backgrounds. In addition to variations in education levels and technological proficiency, the participants are at different stages of the learning curve, with usage durations ranging from one month to 15 years. These differences influence their attitudes and experiences with the devices. Key findings related to product selection, ease of use, and user perceptions were identified.

Product Selection

Product selection and learning experiences are shaped by the Social Security Institution’s (SGK) reimbursement policies. In the study, five participants acquired refurbished CPAP devices returned to the SGK headquarters, while the remaining 25 purchased brand-new devices. One participant shared that they purposely delayed their purchase for a week to avoid acquiring a refurbished device. When a refurbished device is available through SGK, patients are expected to use it instead of purchasing a new one, as doing so would prevent them from receiving reimbursements, which cover a significant portion of the product’s cost. The reimbursement policy thus limits patients’ ability to select their preferred devices unless they receive written confirmation that no refurbished devices are available. Hygiene concerns were the most frequently cited reason for opting for new devices, with 19 out of 30 participants mentioning this factor. Although users can purchase new masks and hoses for used devices, many participants expressed discomfort with the idea of using pre-owned devices. In addition to hygiene concerns, one participant mentioned the negative perception of using a device previously owned by a deceased individual. Refurbished devices are returned to SGK either when a patient no longer uses the device or when they belonged to someone who has passed away. While it may seem rational to reuse these devices if they are in good condition, users often struggle to accept this, particularly due to the lack of transparency regarding the former owner’s health, which raises concerns about potential infections.

In addition to reimbursement policies, several other factors influence product selection, such as recommendations from doctors, salespeople, and family members. Participants noted that doctors typically offered general guidance, advising them to select high-quality products with certain

features, but they often sought more specific recommendations, such as a particular brand or model. Doctors, however, were generally hesitant to make specific brand recommendations, as it could create a perception that they were endorsing certain products over others. Three participants mentioned receiving clear guidance from their doctors, but these doctors were either family members or friends, suggesting that personal relationships could lead to more direct advice than professional consultations.

All participants identified salespeople as significant influencers in the product selection process, with opinions on their role ranging from positive to negative. Many participants praised salespeople for their support with training and maintenance. Salespeople played a key role not only in the initial product purchase but also in ongoing support, including examinations, maintenance, and the replacement of device components. Through messaging and social media platforms, users could receive instant assistance from sales representatives, even when they were in different cities or on vacation. However, a common negative remark was that salespeople tended to overly promote their own products, which led to concerns about their objectivity.

The primary factors affecting product selection were the product's origin and price. Nineteen out of 30 participants mentioned that their doctors recommended internationally recognized brands, which could be verified online. The country of origin was also an important consideration for some participants. One noted that they preferred devices made in the EU or USA for their perceived higher build quality, while another participant argued that local brands were often similar to products from Far Eastern countries, as most components are sourced from the same regions. Twelve participants raised concerns about the price, although they generally viewed it as a secondary issue to product quality. Nevertheless, availability remained an important factor in the decision-making process.

Ease of Use

Ease of use is a critical aspect to address in the design of medical devices. The findings related to ease of use are grouped into two main themes: comfort of use and digital interaction. The comfort of use refers to how well the device aligns with the user's needs, taking into account anthropometric measurements and the characteristics of the environment in which the device is used.

Designers must consider the user's body measurements and reach when developing medical devices. Many participants in the study highlighted the importance of device components that contribute to sleep comfort, particularly focusing on two key elements: the hose and the mask. The length of the hose was frequently mentioned, as it impacts the user's range of movement while sleeping. If the hose is too short, it restricts the movement. In addition to length, moisture buildup in the hose is another issue that needs attention. Participants use third-party straps or clips to secure the hose and prevent water from leaking into the mask. The mask itself also plays a significant role in sleep comfort, with the most common issue being air leaks. These leaks typically occur due to gaps between the mask and the user's face.

While users can try on masks in stores, they often purchase both the device and mask together, with limited options available at the point of sale. Another concern raised by participants is the rigidity of the mask, which is closely linked to air leaks. There is no consensus on whether more flexible masks are better at creating a seal, as some users prefer them, while others find that firmer masks work better. The type of mask, either full-face or nasal, also impacts comfort, with nasal masks being more comfortable for some, while full-face masks are more suitable for mouth-breathers. Therefore, the ability to trial these components in healthcare settings, where users can receive more tailored guidance, is crucial for ensuring a better fit.

The environment in which CPAP devices are used also affects the user experience, and this can be broken down into two broad categories: the device's location and the conditions of the surrounding environment. The first category involves the positioning of the device relative to the user and other elements in the environment. The second category focuses on environmental factors that can influence both the device's performance and the user's experience. Regarding the device's location, visibility is an important factor tied to the user's privacy. Users may prefer to keep their CPAP devices out of sight, often storing them in drawers or positioning them in places where they are not visible to others. Another concern related to location is the proximity of the device to an electrical outlet. If the device is not near a plug, users must rely on extension cords, which is particularly common in unpredictable settings such as sleepovers or vacations. Other environmental factors worth mentioning are noise, temperature, and humidity. Noise created by the device, often amplified by vibrations through the mask, is a major concern for sleep comfort, both for the user and their bed partner. Temperature and humidity also play a significant role, as improper air humidity can lead to issues such as dry nasal passages or bleeding. Devices are designed to manage these environmental factors to prevent discomfort, which, in turn, supports patient adherence. Another environmental consideration is the illumination from the CPAP device's interface. Since CPAPs are used during sleep, the brightness and direction of the display are designed to minimize disruption to both the user's and their bed partner's sleep. Finally, the airflow and air quality in the user's environment are important. The space around the device should be kept free of dust and contaminants, as this can affect the filtration system, requiring more frequent maintenance and ensuring healthy air intake.

Perceptions Towards CPAP Therapy

Users' reactions to a chronic illness and the adoption of a new medical device are critical considerations for designers aiming to foster motivation for continued device use. Without addressing these factors, patient adherence will largely depend on the expectation that patients will follow their doctor's advice during treatment.

A chronic diagnosis significantly impacts a patient's lifestyle, employment, and aspirations (Turner & Kelly, 2000). Participants in the study frequently mentioned the emotional challenges faced at the time of diagnosis, describing the experience as saddening and distressing. The prospect of using a medical

device for the rest of one's life affects not only the user but also their close family members. Alongside distress, participants also noted the anxiety that arises from using a CPAP device in the home environment, especially in the presence of others. This highlights the connection between the privacy of the user's health condition and their desire to share this information with family members. The emotional effects of the diagnosis, such as distress, can also manifest as physical symptoms, including fatigue, disrupted sleep, and changes in appetite. These symptoms may not always be directly linked to the emotional state, as they can also stem from the underlying illness (Williamson, 2010). Despite this, designers can devise strategies to address these negative emotional responses, which can hinder patient adherence and acceptance of their condition.

A potential design strategy is the use of positive reinforcement methods, commonly applied in other products aimed at behavior change. To effectively implement this, the interaction between the user and the device should be carefully examined and enhanced. Mobile apps, as a medium for interaction, offer designers an opportunity to improve user engagement and feedback. With mobile phones offering advanced graphics and data management capabilities, these apps provide a more sophisticated platform than medical devices, which often rely on simpler components. Additionally, for devices that are worn throughout the day, such as insulin pumps, the use of mobile apps can provide an added benefit of privacy, allowing users to manage their condition discreetly, even around people they prefer not to share their health status with.

The visual design of the device is another important consideration for designers. Most medical devices are built with a focus on functionality, leading to a more utilitarian design approach that doesn't align with contemporary consumer trends. Participants in the study expressed dissatisfaction with this outdated design approach. Beyond being considered outdated, the visual appearance of medical devices—especially respiratory devices—can contribute to negative emotional reactions. The mask and hose of CPAP devices, in particular, resemble equipment used in more severe medical conditions, such as ventilators in intensive care settings. This visual similarity can cause significant anxiety and distress among family members, especially children. Although obstructive sleep apnea (OSA) is a serious health concern requiring treatment, it is not classified as a high-risk medical condition. Therefore, the association with more intensive medical devices can be unsettling. Furthermore, the appearance of medical devices in general is often conventional, with a focus on plastic or metal bodies and minimal controls, which are typically positioned on nightstands next to the bed. Some devices even resemble alarm clocks, helping them blend into the environment. However, this approach is less effective when considering components like the hose and mask, which remain highly visible and disrupt the overall attempt to make the device less conspicuous.

CONCLUSION

The findings presented in this paper highlight several critical factors that product designers should consider to enhance the adherence of home-use medical devices, particularly in the context of CPAP treatment for non-professional user groups. Key themes identified include: reimbursement policies, product origin, the need for improved training services from healthcare professionals, and price considerations during the product purchase phase; enhancing sleep comfort through the redesign of device components that come into direct contact with users, as well as optimizing the use environment to improve sleep quality and reduce side effects; addressing the emotional responses of users and their families during the early stages of use; leveraging mobile apps and technologies to provide positive reinforcement and foster adherence; and finally, rethinking the visual form of these devices to improve both aesthetics and their perceived invisibility in everyday settings.

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REFERENCES

- Broström, A., Ulander, M., Nilsen, P., Svanborg, E. and ÅRestedt, K. F., 2011. The attitudes to CPAP treatment inventory: Development and initial validation of a new tool for measuring attitudes to CPAP treatment. *Journal of Sleep Research*, 20(3), pp. 460–471.
- Broström, A., Nilsen, P., Gardner, B., Johansson, P., Ulander, M., Fridlund, B. and ÅRestedt, K., 2014. Validation of the CPAP habit index-5: A tool to understand adherence to CPAP treatment in patients with obstructive sleep apnea. *Sleep disorders*, 2014(1), p. 929057.
- Japan Ministry of Health, Labour and Welfare, 2016. *Long-Term Care Insurance System of Japan*. Available at: https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/ltcisj_e.pdf [Accessed 23 October 2024].
- Laugwitz, B., Held, T. and Schrepp, M., 2008. Construction and evaluation of a user experience questionnaire. In *HCI and Usability for Education and Work: 4th Symposium of the Workgroup Human-Computer Interaction and Usability Engineering of the Austrian Computer Society, USAB 2008, Graz, Austria, November 20-21, 2008. Proceedings 4* (pp. 63–76). Springer Berlin Heidelberg.
- Money, A. G., Barnett, J., Kuljis, J., Craven, M. P., Martin, J. L. and Young, T., 2011. The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC medical informatics and decision making*, 11, pp. 1–12.
- Martin, J. L., Norris, B., Murphy, E. and Crowe, J., 2010. Design for patient safety: User testing in the development of medical devices. *London, UK: National Patient Safety Agency*.
- Shah, S. G. S., Farrow, A. and Robinson, I., 2009. The representation of healthcare end users' perspectives by surrogates in healthcare decisions: A literature review. *Scandinavian Journal of Caring Sciences*, 23(4), pp. 809–819.

- Turkish Statistical Institute, 2024. *Population Projections: 2023-2100*. [Online] Available at: <https://data.tuik.gov.tr/Bulten/Index?p=Population-Projections-2023-2100-53699> [Accessed 14 November 2024].
- Turner, J. and Kelly, B., 2000. Emotional dimensions of chronic disease. *Western journal of medicine*, 172(2), p. 124.
- Weaver, T. E., Maislin, G., Dinges, D. F., Younger, J., Cantor, C., McCloskey, S. and Pack, A. I., 2003. Self-efficacy in sleep apnea: Instrument development and patient perceptions of obstructive sleep apnea risk, treatment benefit, and volition to use continuous positive airway pressure. *Sleep*, 26(6), pp. 727–732.
- Williamson, C., 2010. *Towards the emancipation of patients: Patients' experiences and the patient movement*. Policy Press.