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InnoSpire Go

Portable mesh nebulizer

InnoSpire Go usability and human factors evaluation

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There are a number of factors that should be taken into account when designing a new nebulizer for delivery of aerosolized medication, such as the efficiency of nebulization, the time required to deliver the drug, and ease of use for the patient.[1] Ease of use is an important requirement, as nebulizers that are difficult to use may result in a higher incidence of mistakes during nebulizer use, potentially resulting in lower drug delivery to the patient and reducing adherence to the prescribed treatment regimen.[2]

Background

Chronic respiratory diseases, of which asthma and chronic obstructive pulmonary disease (COPD) are the most common, are among the leading causes of mortality and morbidity worldwide.[3]

The management for COPD recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) includes non-pharmacological interventions and pharmacological treatment.[4] Since the pulmonary route of administration has proven to be effective to treat pulmonary diseases, most of the drugs are inhaled.[5]

- Common prescribed devices for the treatment of COPD patients include nebulizers, pressurized metered dose inhalers (pMDIs), slow-mist inhalers (SMIs), and single-dose and multi-dose dry powder inhalers (DPIs).[6]
- In general, pMDIs generate aerosol faster than the patient can inhale, which has proven to be a challenge for children and elderly patients.
- Dry powder inhalers (DPIs), are breath-actuated devices that require the patient to generate a high inspiratory flow rate, which may be problematic, for patients with severe COPD.[7]
- Traditional jet nebulizers or small volume nebulizers (SVN's) do not require patient coordination or high inspiratory flow rates.[7,8] They are commonly prescribed for pediatric, elderly patients with cognitive impairment and those who are unable to use other types of inhaler therapy, and severe COPD patients.[7] Patients have reported benefits of symptom relief, ease of use and an increase in quality of life and a preference for SVN's.[8] Physicians have indicated SVN's are effective in the management of severe COPD and more effective than inhalers in the management of exacerbations.[9]

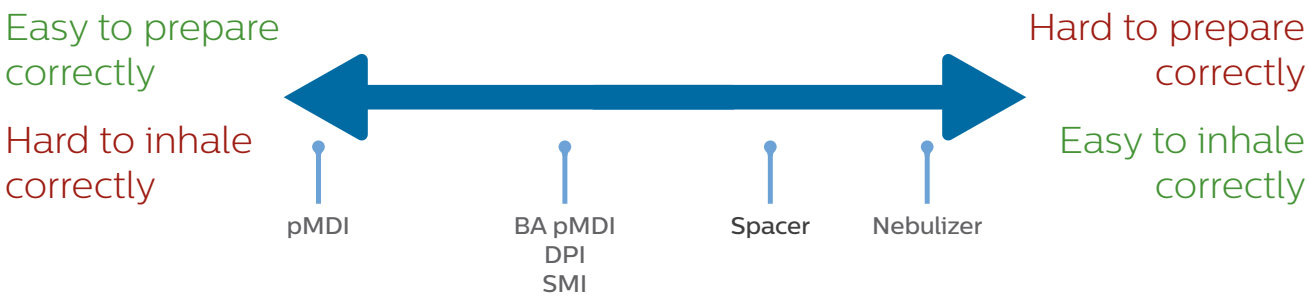


Figure 1 **Ease of use vs. ease of preparation comparison, among common respiratory medication delivery systems. pMDI: pressurised metered-dose inhaler; BA pMDI: breath-actuated pMDI; DPI: dry powder inhaler; SMI: slow-mist inhaler.** Adapted from Newman SP Eur Respir Rev 2005; 14: 96, 102–108.[10]

Problems associated with use of nebulizers by COPD patients

It is well known that the success of the inhalation therapy is dependent on the patient's ability to properly use the drug delivery devices.[4,8] The following issues are likely to reduce the amount of drug being inhaled and therefore may negatively affect outcomes.

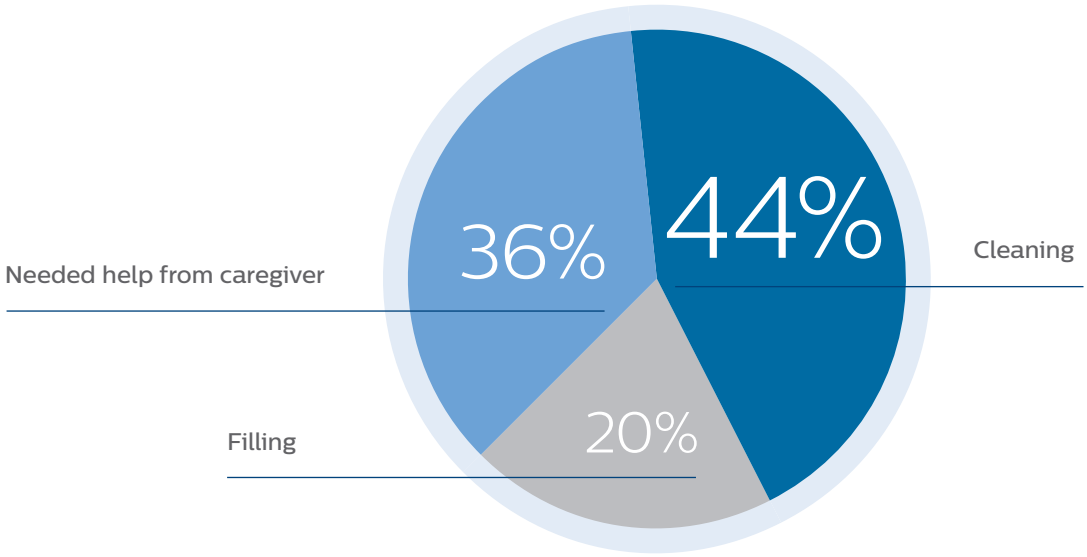


Figure 2 **Most common problems encountered by COPD patients using nebulizer therapy.** Adapted from Teale C et al, 1995.[11]

The most common problem encountered by COPD patients, as reported by Alhadad B and colleagues in a 2015 study related to an in-home use of jet nebulizers, included assembly of the device and cleaning.[12]

In addition to the problems related to misuse, jet nebulizers are relatively inefficient,[13] have significant inter-device variability with respect to particle distribution and output,[14] require an external pressurized gas source to operate, and there is limited control of the dose delivered to the patient.[1]

Therefore, there was a need to develop technology that could provide a more reliable and faster delivery of the drugs, while also combining characteristics to attend patients and caregivers demand for a higher quality, smaller, lighter, quieter and easier to use device.[8]

Vibrating mesh nebulizers have yielded improvements, such as compact design, portability, shorter treatment duration, and quiet operation. Mesh nebulizers generate aerosols with a high fine particle fraction and the aerosol particles are most likely to reach deeper in the respiratory tract.[15]

InnoSpire Go – designed with the patient in mind

The InnoSpire Go is a portable, general-purpose mesh nebulizer, with a built-in battery. It employs Aerogen's clinically proven Vibronic vibrating mesh technology that can be used to nebulize commonly prescribed liquid inhaled drugs for respiratory diseases. The device operates continuously once initiated until the medication has been delivered, at which point the device will automatically switch off and provide an audible alert to signal end of treatment. The InnoSpire Go was designed with a minimal number of parts and an ergonomic design to make the device easy to use and comfortable for an adult or child to hold for the duration of a treatment. In addition, considerations for users with dexterity issues were made (Figure 3).

The InnoSpire Go design has been proven through extensive testing, including both Usability (human factors) testing and bench performance testing.

Figure 3 InnoSpire Go (2-part assembly)

Human Factors Evaluation (HFE)

Taking into consideration the fact that the success of the inhalation therapy is dependent on a patient's ability to follow the device's instructions and properly use the device, human factors engineering and usability principles were applied during the development of the InnoSpire Go. This type of testing is used in order to eliminate or reduce risks related to user error and to ensure that the device can be used, cleaned and disinfected safely and effectively.

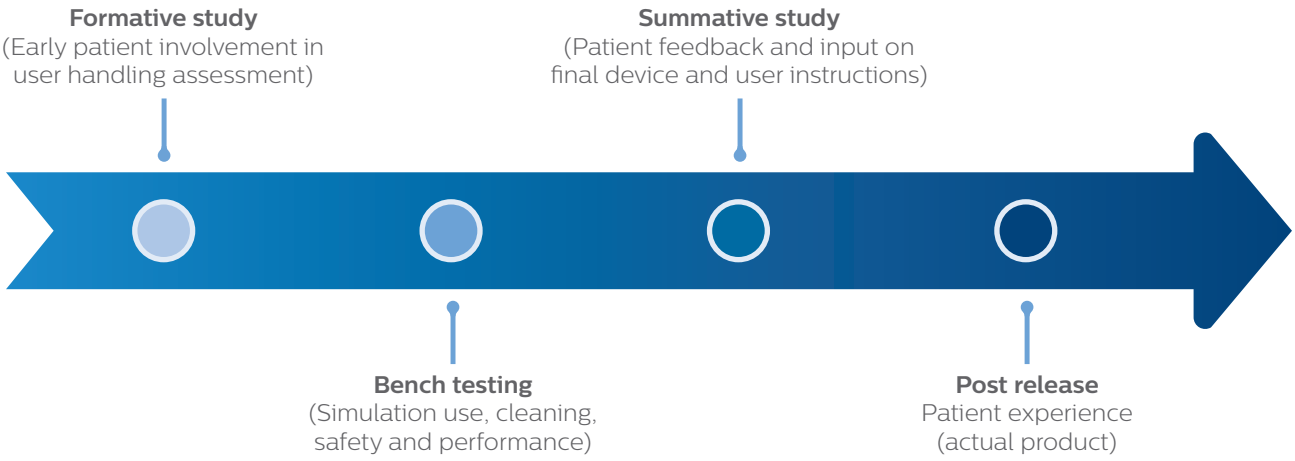


Figure 4 Feedback progression on the development of InnoSpire Go

Formative – patient observational handling assessment

HFE includes formative testing which is a supportive tool that is completed early with the device in the design process in which the end user completes certain tasks under observations. The objective of the formative testing with the InnoSpire Go was to evaluate the ease of use and user satisfaction against three commercially marketed nebulizers. After an introduction, but no training, the participants were asked to use four different nebulizers. During this assessment, participants did not receive any medication. A saline solution was used as 'medication' and the participants were asked to demonstrate how to fill with medication, power on the unit and hold the nebulizer in the proper position, simulate breathing but to not place the mouthpiece in their mouth. The purpose of this exercise was to evaluate, if the participants understood the correct orientation of the device. Correct orientation is critical in delivery of a dose of medication with several commercially available nebulizers.

The subjective user's feedback collected during this initial evaluation provided important insights for the development of the InnoSpire Go, and its design was refined.

Methods

Reported potential misuse techniques historically associated with nebulizers include: loading medications into devices, assembling devices, inhaling properly, activating the device to release the medication, and keeping devices clean for future use.[12]

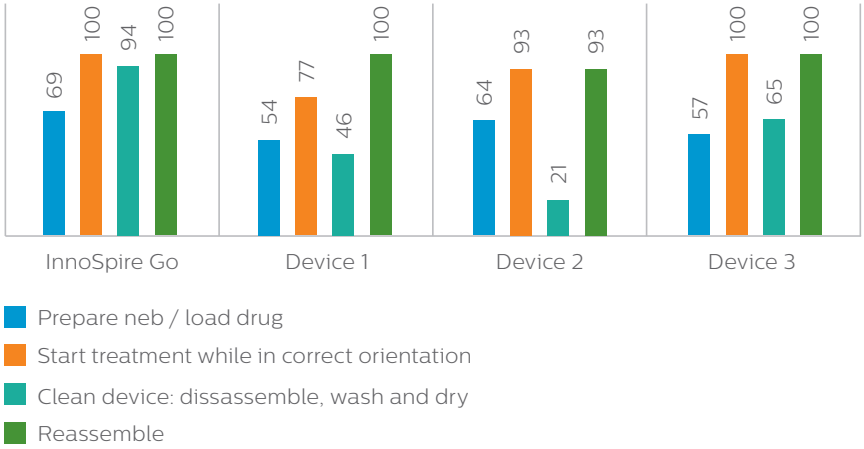
Therefore, during this test, participants were asked to perform the following tasks: prepare the device, load the drug, simulate starting the treatment while holding device in correct orientation, clean and reassemble each nebulizer.

In addition, participants provided subjective feedback regarding ease of use, perceived treatment burden, comfort of holding the device, and satisfaction with device appearance.

Results

Sixteen participants (9 females, 7 males), age range 5 to 73 years, were included in the testing. Four out of 16 had previous nebulizer experience.

Table 1 – Tasks success rate (% combined attempts 1 and 2)



Results of study show that preparation was the most difficult task observed in attempted success rate with all devices. Cleaning of the device had the greatest variation 0-69% during the first attempt, with **the InnoSpire Go being the device with the highest success rate (69%).**

Figure 5 Formative study - user handling assessment

Summative – patient use and written instruction understanding test

Summative testing is part of the development process of medical devices to ensure compliance to regulatory requirements. It is conducted before the product is released to the end-user. The goal of the summative test was to examine the usability and acceptability of the final device, accessories, and User Instructions (packaged in box) among patients with COPD, asthma, or patients who had both conditions.

Methods

This evaluation was conducted in a controlled environment representative of a typical home setting. Staging involved setting-up an initial home use environment with the participant sitting at a table, as well as a cleaning environment with the participant standing at a sink. Participants were asked to perform the following tasks without assistance: prepare the device, load the drug, start the treatment (simulated), clean and reassemble each nebulizer. Data was collected by visual observation and video recording of the participants. In addition, verbal and written questionnaires were completed.

The overall acceptance criteria adopted was the following: steps that impact effectiveness or safety with a no risk of permanent injury (non-crucial) require an 80% passing rate with a 95% confidence level: six failures were acceptable, seven were not.

Results

Fifteen participants were involved in this test, age range 40-76 years (average 64 years), majority women (77%).

Table 2 – Participants' characteristics

	COPD (n=7)	Asthma (n=4)	COPD + Asthma (n=4)
Age, years	69 ± 5	55 ± 15	64 ± 12
Female, n	2	4	4
Nebulizer user, n	3	3	3
Instruction time, min	8	6.5	8

Sixteen tasks were completed by the participants, and the results showed an improvement in the tasks related to the preparation and cleaning of the device. Unexpectedly participants found it difficult to understand some of the charging/battery conditions as shown in Figure 6 below. This is not unusual considering the age group of most of the participants. The elderly often need help adapting to the use of new gadgets and understand user interfaces.

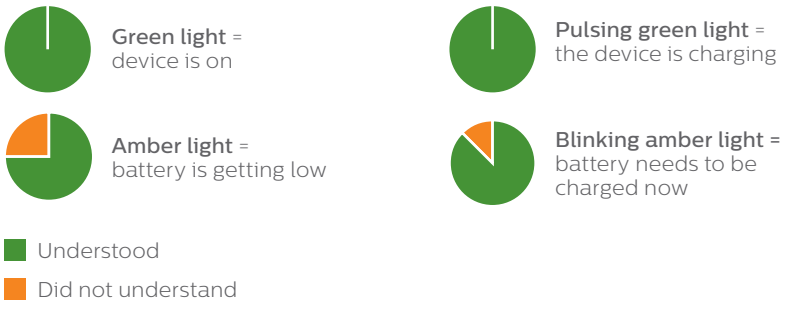


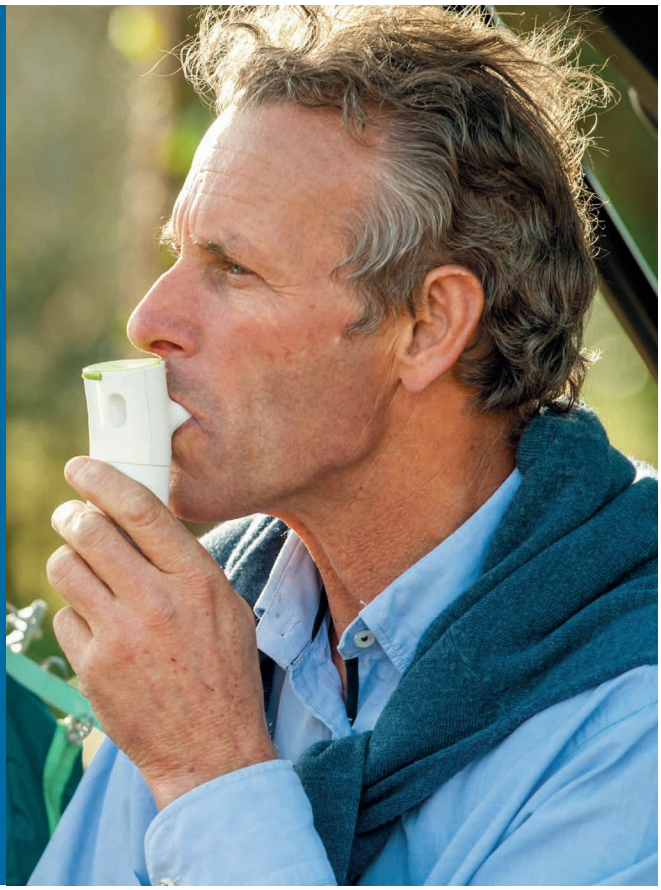
Figure 6 Summative study – understanding charging/battery feedback. Participants were asked to explain the following different light signals around the on/off button.

Overall, the test participants evaluated the InnoSpire Go favorably, and results of this usability test were considered acceptable, since the level of risk associated with performance by representative users would be acceptable.

Several aspects of the user interface were identified as areas that could be simplified. Thus, the results were considered acceptable with the condition that improvements will be made to the commercially available User Instructions and Quick Start Guide.

Conclusion

The results from the formative test during the development process led to improvements to design of the InnoSpire Go. The results from the summative test confirmed that the implemented changes have addressed user errors and that the final design of the device can be properly used by patients even without prior training.



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