Patient-Centered Device Development of a New Portable Spacer (Valved Holding Chamber – VHC)

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INTRODUCTION

The 2019 Global Strategy for Asthma Management and Prevention (GINA) report identified that the majority of patients are not able to use their inhalers (all types) correctly, and most people with incorrect technique are unaware of the negative effects this can have on the efficacy of drug delivery [1]. VHCs have been shown to improve asthma control [2] and are widely prescribed for use with pMDIs to retain the aerosol emitted upon inhaler actuation, remove the need for perfect coordination of inhalation and pMDI actuation, and remove the large droplet/particle size component of the aerosol [3]. However, their size and appearance as medical devices can lead to infrequent use outside of the home [4]. This article describes the generative, patient-centered, design process used in the development of a prototype VHC intended primarily for use ‘on the go’ by adults with persistent asthma or newly diagnosed COPD.

METHODOLOGY

The initial problem statement was internally defined as: ‘Life-saving metered dose inhaler medication can be difficult to inhale in an emergency’, supported by the observations of Keeley and Partridge of exacerbated asthmatic patients in an Emergency Room setting [5]. Although VHCs have been shown to minimize problems of poor inhalation technique and target pMDI delivery to the lungs, they are often left at home. Based on experience, a new VHC would need to maintain the core values of the AeroChamber® VHCs, while also being compact and portable. Involving patients in the design process is essential in order to ensure the product will be useful for consumers. The graphic below highlights the involvement of patients throughout the design process and how these learnings informed the design.
Medication delivery performance of the prototypes was evaluated throughout the process (Figure 1). The in vitro aerosol performance of the prototype VHCs (n = 5) were verified using the adult Aerosol Delivery to Anatomical Model (ADAM) [6] for the delivery of albuterol sulfate (90 μg/actuation albuterol ex mouthpiece; Ventolin®) as a representative short-acting beta2 agonist widely used in emergency care. The total mass of albuterol that reached the model carina was determined, sampling at 30 L/min, and with different delay intervals following inhaler actuation, compared to pMDI alone.

RESULTS AND DISCUSSION

Phase 1

An initial inhaler-use survey of 715 asthma and COPD patients recruited through social media was undertaken, followed by face-to-face interviews with a subset of over 50 patients aged from 14–77 years, with the objectives of validating the problem statement and obtaining deeper insights. The survey indicated that a slight majority (55%) of patients never used a VHC with their inhaler, with 32% occasionally making use of one, leaving only 13% who reported always inhaling pMDI-delivered medication via a VHC. The 87% who were not consistent or never used a VHC were asked for a reason why not (Figure 2). Portability, lack of clinician recommended use, and embarrassment were highlighted as major factors.

The patient interviews involved a generative process using collaborative exercises through which they were encouraged to create a physical representation of their ideal device. Patient feedback validated the initial problem statement and also provided a new insight that debris was sometimes inhaled since many people misplaced pMDI caps. Patients also preferred pocket size spacers that were discrete and did not look like medical devices. A critical learning point was that patients preferred a 2-in-1 spacer and protective case for pMDI to smaller or collapsible spacers carried separate to the pMDI. The insights and learnings from Phase 1 shifted the project focus to: ‘a portable, 2 in 1 chamber/case that keeps the inhaler clean and secure and enables patients to easily inhale their life saving rescue inhaler medication while on the go’.
Phase 2

Two prototypes were developed, using asymmetrical and symmetrical profiles (Figure 3) to execute on the new project focus (from Phase 1) of a portable, 2 in 1 chamber/case, and a handling study was performed to evaluate the form-factor. Although the symmetrical shape had a larger size than the asymmetrical, the participants strongly preferred the symmetrical design as it felt more comfortable in their pocket.

Phase 3

The industrial design phase explored the design language, improving usability and aesthetics, and thus evolved into the evaluation of 10 unique designs. The development team selected three designs (based on desirability and viability) to prototype and obtain patient feedback. Patients had an overwhelming preference for the 'yin/yang' pivot variant shown in Figure 4, citing aesthetics and the way the device opened to present the pMDI, as major reasons.
Results from an evaluation comparing this version of the design to the pMDI alone and an alternative ‘portable’ commercially available VHC showed a preference for the prototype in all aspects, including aesthetics, comfort in pocket and ease of use.

Phase 4

The ability to have rapid and easy access to the pMDI was seen by interviewed patients as highly desirable. Intuitiveness, visual cues, and ability to open the prototype device were evaluated in multiple rounds of usability testing with patients.

Results from the in vitro aerosol performance testing of the selected prototype showed that it functioned to the design intent, delivering 29.5 ± 1.3 μg/actuation of albuterol for potential availability for lung deposition after a delay of 2 s following inhaler actuation. This output was similar to the 29.0 ± 4.8 μg/actuation delivered from the pMDI alone with no delay, representing the optimum, if perfect coordination was achieved [7].

CONCLUSIONS

This design experience involving patients from the outset resulted in important learning opportunities that helped realize the new functioning VHC concept. These included (a) refining and reframing the problem statement as more needs are highlighted from the patients throughout the design process, (b) establishing the critical design features for the target patient; e.g. using the VHC as the carrying case for the pMDI, and (c) the value of repeated usability (carrying and using) studies involving designers and patients. As a result, the reliance on ‘assumptions’ was minimized and therefore hopefully avoiding the risk of forgetting about what the patient really needs.

REFERENCES


