

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

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- 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^(a).
- This poster 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**

Generally, spacers (VHC) have mixed reviews from users:

PROS



- VHCs have been shown to improve asthma control ^(b).
- They are prescribed for use with pressurized metered dose inhalers (pMDIs) ^(c):
 - To retain the aerosol emitted upon inhaler actuation,
 - To remove the need for perfect patient-inhaler coordination,
 - To remove the large droplet/particle size component of the aerosol

CONS



- Their size and appearance as medical devices can lead to infrequent use outside of the home ^(d)

a. GINA – Global Strategy for Asthma Management and Prevention 2019. Available at URL: <https://ginasthma.org/> visited: November 16, 2019.

b. British Thoracic Society/Scottish Intercollegiate Guidance Network (SIGN): British guideline on the management of asthma. Publication 158. September 2019. Available at URL: <https://www.sign.ac.uk/asbbsets/sign158.pdf>, visited: November 16, 2019.

c. Corr D, et al, *Design and characteristics of a portable breath actuated, particle size selective medical aerosol inhaler*. J Aerosol Sci. 1982;13:1–7.

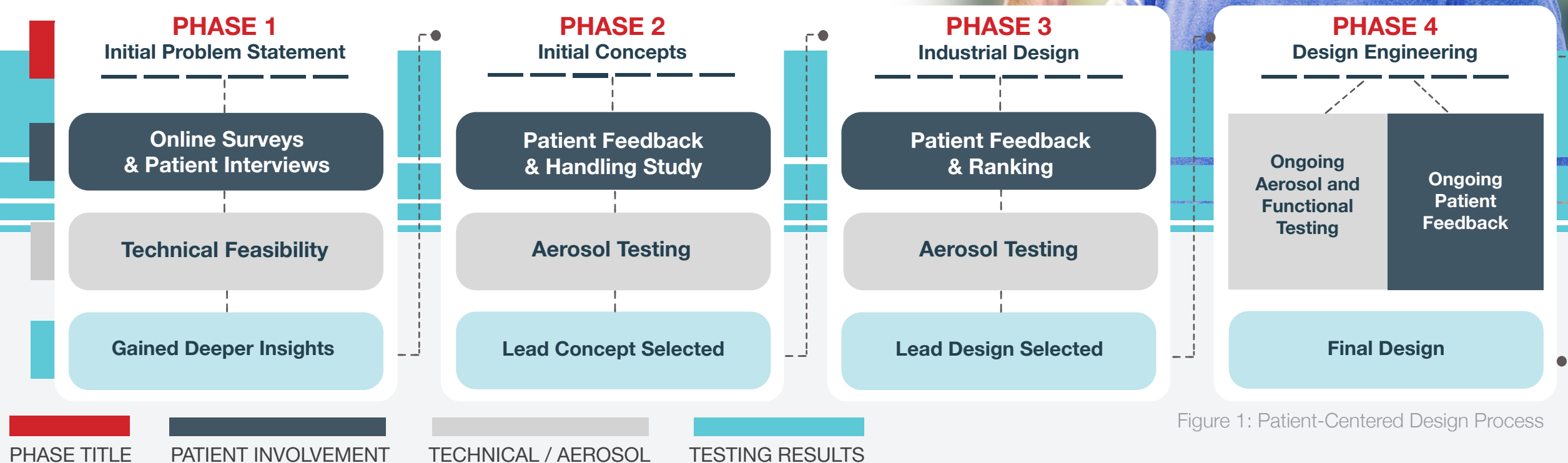
d. Holley S, et al, *Barriers and facilitators to asthma self-management in adolescents: A systematic review of qualitative and quantitative studies*. Pediatr Pulmonol. 2017;52(4):430-442.

Methodology

Initial Problem Statement Defined

- Life-saving metered dose inhaler medication can be difficult to inhale in an emergency^(e)
- A new VHC would need to maintain the core values of the **AeroChamber®** VHC family, 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

Patient-Centered Design Process



Aerosol Testing

- Medication delivery performance of the prototypes was evaluated throughout the process (Figure 1).
- 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.
- The *in vitro* aerosol performance of the prototype VHCs (n = 5) was verified using the adult Aerosol Delivery to Anatomical Model (ADAM)^(f) for the delivery of albuterol sulfate (90 mg/actuation albuterol; Ventolin) as a representative short-acting beta2 agonist widely used in emergency care.

^e Keeley D, Partridge MR. *Emergency MDI and spacer packs for asthma and COPD*. Lancet Respir Med. 2019;7(5):380-382

^f Nagel MW, Suggett JA, Coppola DP, Mitchell JP: *Development and evaluation of a family of human face and upper airway models for the laboratory testing of orally inhaled products*. AAPS PharmSciTech 2017,18(8): 3182–3197.

Results and Discussion

Phase 1: INITIAL SURVEY

To validate the problem statement and obtain deeper insights:

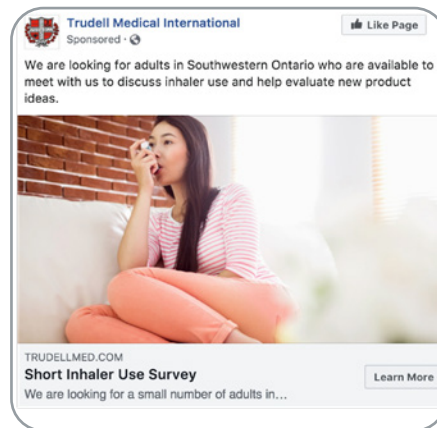
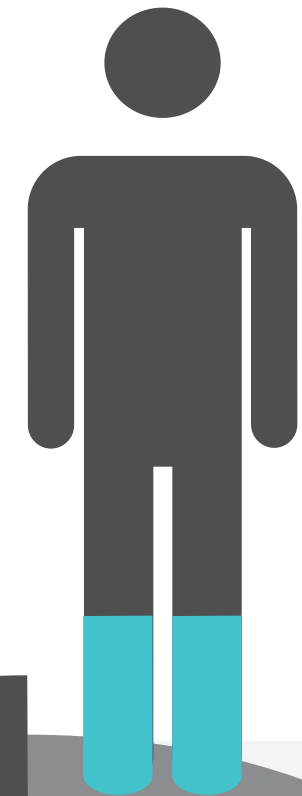


Figure 2: Patient Surveys

- 715 asthmatic and COPD patients recruited through social media
- Face-to-face interviews with a subset of over 50 patients aged from 14-77 years



- **55%** Never used a VHC with their inhaler
- **32%** Occasionally making use of one
- **13%** Always use pMDI-delivered medication via a VHC

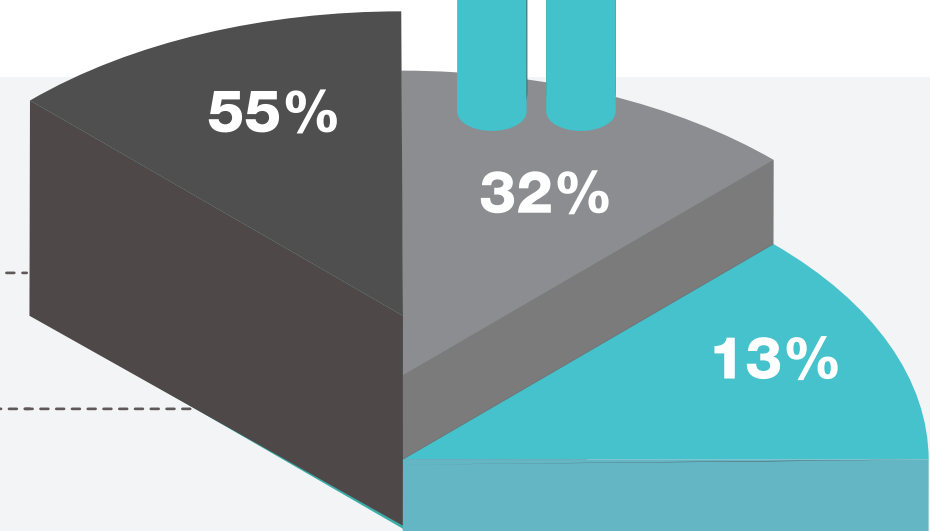


Figure 3: Patient Survey Results

■ • **87%** Do not always use ■ • **13%** Always use

Results and Discussion

Reasons For Not Using a VHC with their pMDI

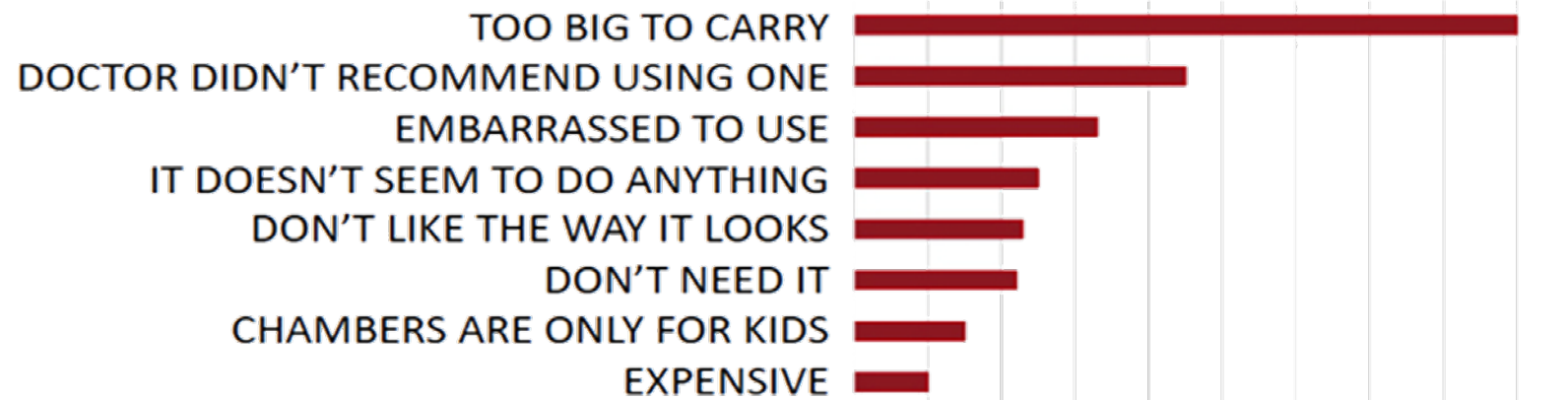


Figure 4: Reasons for not using a VHC with their pMDI

Patient Feedback Insights:

- Portability, lack of clinician recommended use, and embarrassment highlighted as major factors for not using a spacer (VHC)
- Patient feedback validated the initial problem statement
- 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
- Preference for a 2 in 1 spacer and protective case for pMDI to smaller or collapsible spacers carried separate to the pMDI

Phase 2: DEVELOP TWO PROTOTYPE DESIGNS (Figure 5)

- To execute on the new project focus (from Phase 1 patient insights) of a portable, 2 in 1 chamber/case, two designs were developed
- A handling study was performed to evaluate the form-factors

Findings:

- 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**

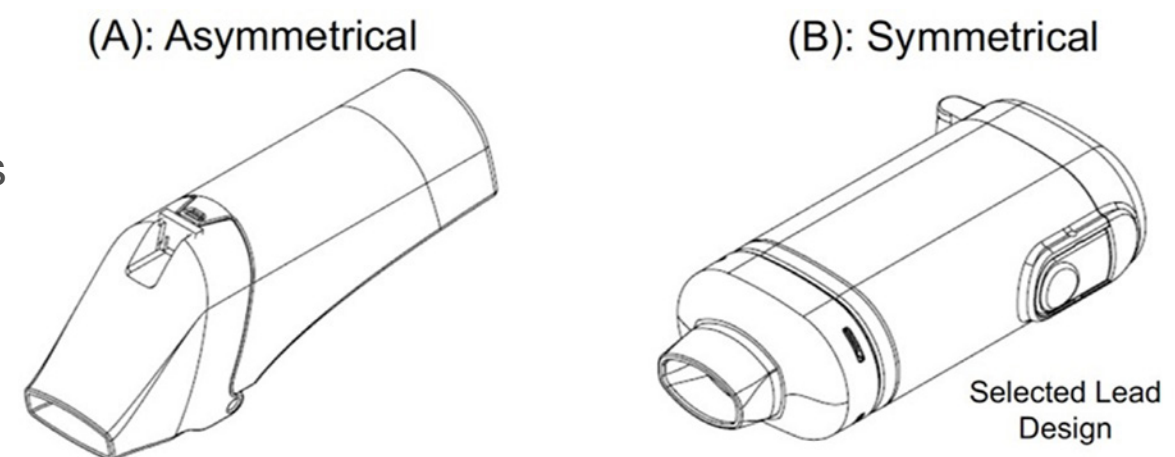


Figure 5: Two Prototype Designs

Results and Discussion

Phase 3: DEVELOP INDUSTRIAL DESIGN



Figure 6: Selected Prototype (yin/yang concept)

- The industrial design phase explored the design language, improving usability and aesthetics
 - 10 unique designs developed
- Three designs were selected to prototype
- Patient feedback was an overwhelming preference for the 'yin/yang' pivot variant shown in Figure 6



Aesthetics

The intuitive way the device opened to present the pMDI

Phase 4: FEEDBACK AND PERFORMANCE EVALUATION

Feedback from Patients:

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



Figure 7: Patient Evaluation

Results and Discussion

Performance Evaluation in the Laboratory:

- Medication delivery performance of the prototype was evaluated throughout the process (Figure 1), using the adult Aerosol Delivery to Anatomical Model (ADAM) adult oropharynx:
 - Albuterol sulfate (90 µg/actuation albuterol; Ventolin[®]) as a representative short-acting beta2 agonist widely used in emergency care
 - 30 L/min 'inhalation' flow rate, with different delay intervals following inhaler actuation, and compared to pMDI alone (Figure 8)^(g)

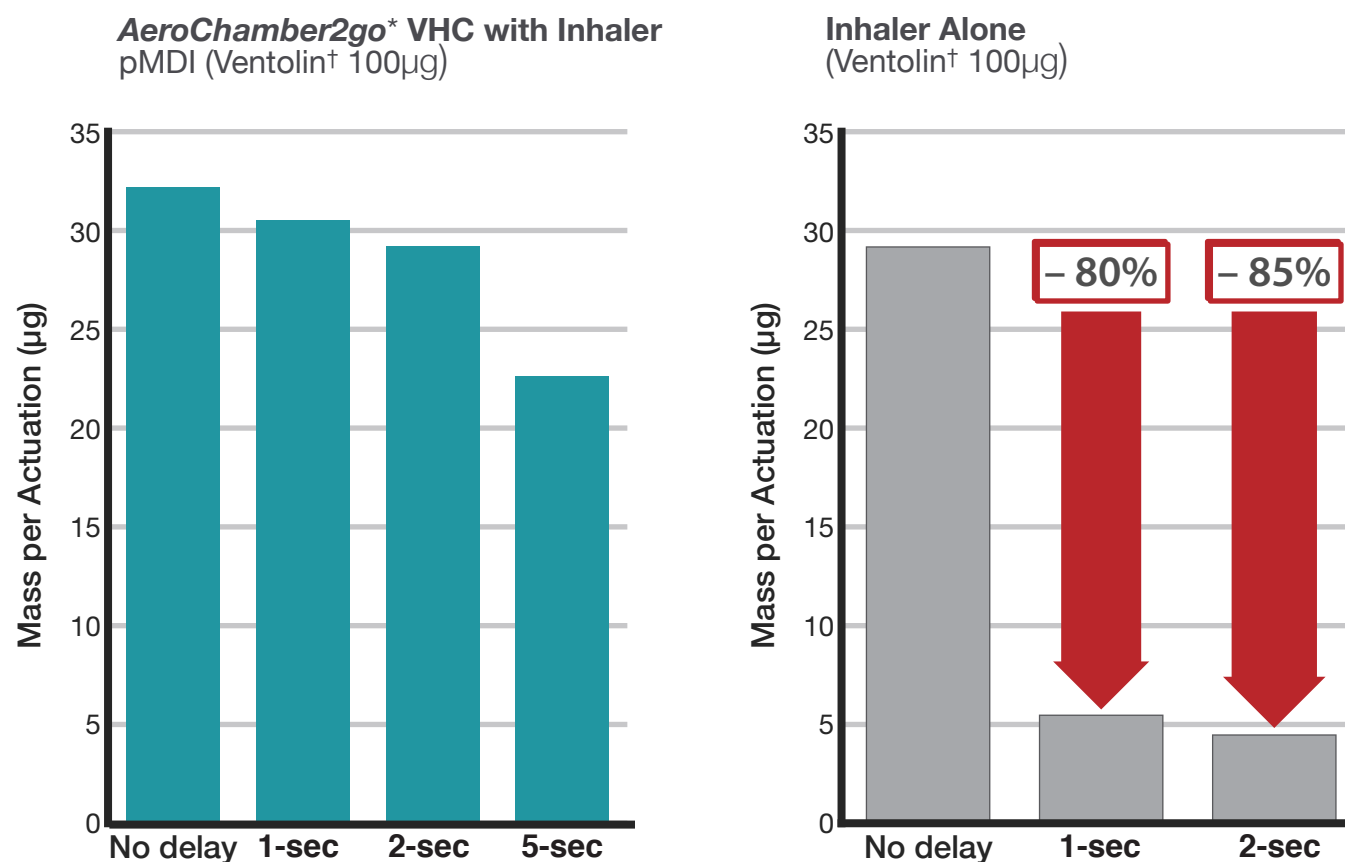


Figure 8: In Vitro Performance Measures

- 29.5 ± 1.3 µg/actuation of albuterol from the final design (**AeroChamber2go* VHC**) for potential availability for lung deposition after a delay of 2-s following inhaler actuation
- 29.0 ± 4.8 µg/actuation delivered from the pMDI alone with no delay, representing the optimum, if perfect coordination was achieved

Conclusion

Design experience, using patients from the outset, provided valuable learning opportunities, helping to:

- Refine and reframe the problem statement
- Establish the critical design features for the target patient
- Realize the value of repeated usability (carrying and using) studies involving designers and patients

As a result, reliance on “assumptions” was minimized; therefore, hopefully avoiding the risk of forgetting what the patient really needs and cares about.



Figure 9: Final Device

<https://www.trudellmed.com/rdd-2020-eposter-1>