



PATIENT PREFERENCE OF RESPIRATORY DEVICE TRAINING & EDUCATIONAL TOOLS

Although pulmonary delivery is a popular and growing method of drug delivery, evidence shows that most patients with asthma do not use their inhaler properly. Paul Sullivan, Associate Director, Business Development, and Craig Baker, Executive Vice-President, from Noble, review the evidence from a trial of five different methods and conclude that training devices could be effective tools to increase patient confidence and reduce anxiety.

Pulmonary drug delivery is an effective route of administration for localised and systematic uptake of pharmaceutical products. As a result, pulmonary administration is a viable alternative to more invasive routes, with future growth potential across new therapeutic areas. These products are often marketed as combination therapies, consisting of active pharmaceutical ingredients and drug delivery devices. When properly used by patients, these devices administer a prescribed dose to the lungs.

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Over the years, the use of pulmonary drug administration has continued to grow, with more patients being introduced to pulmonary delivery devices such as metered dose inhalers (MDIs), dry powder

inhalers (DPIs) and nebulisers. Healthcare professionals receive professional training on the correct ways to use delivery devices, but when the patient, who has limited to no experience, receives in-office training on how to use the device, it's often not memorable or fully understood, resulting in misuse at home. According to a recent study published by the American College of Allergy, Asthma and Immunology, only 7% of inhaler patients follow the proper technique when using their devices.

“Recent publications have confirmed that most patients with asthma do not use their inhaler properly. In addition to only 7% of users demonstrating perfect technique, 63% failed to complete three or more steps. This is a good reason for much needed education, both verbally and visually, to be administered by physicians and asthma educators,” said Dr Sam Pejham, Assistant Clinical Professor at University of California at San Francisco (UCSF) School of Medicine.

“Also the availability of trainers for patients to demonstrate in front of their provider how they use their inhaler is crucial to ensure proper technique. Currently, asthma patients' poor inhaler technique is causing them to have diminished drug delivery which could lead to poor asthma management.”

One important factor in recognising



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“Improving the training process for pulmonary drug administration is a key opportunity for pharmaceutical brands.”

patient centricity is the first 30, 60, or 90 days after diagnosis, commonly called onboarding – this is the time when patients are first introduced and trained on how to use drug delivery devices. In-office training is undoubtedly vital and beneficial. However, inconsistencies in training technique and various environmental conditions can affect this training and cause deviations within patient groups.

Improving the training process for pulmonary drug administration is a key opportunity for pharmaceutical brands. Noble, the leader in design and

manufacturing of multisensory drug delivery training devices, identified deviations and inconsistencies as an unmet clinical and market need. The company conducted an in-depth analysis of secondary literature to understand causes of product misuse and developed strategies that could be implemented to improve patient adherence and outcomes. A study was also conducted to understand the impact of various forms of training materials and devices on patient performance.

Having identified user error as a significant risk factor, a review of commercial device platforms and instructions for use (IFU) was conducted to understand common usage steps and the source of errors during the administration sequence. Figure 1 is a summary of common tasks associated with the use of an MDI. Included is a preliminary risk level assessment correlating the severity, detectability and probability of errors in common usage steps.

Through this analysis and initial review, training and education were identified as a significant treatment barrier and control for preventing errors and improving technique. Multisensory training technology has the potential for major impact as it stimulates the senses to enhance memory recall through audio, visual and tactile features.

In a study, five training methods were analysed:

- **Instructions for use (IFU) document:** this is a traditional 12-step IFU, based on common themes and steps of currently marketed respiratory devices.
- **Mechanical training device and IFU:** a mechanical simulator of a currently marketed respiratory device was used. All forces, feedback and behaviour were accurately simulated.
- **Training device calibrated whistle and IFU:** the training device has a mechanical whistle calibrated to respiratory flow rate requirements of common inhalers.
- **Training device with auditory instructions and IFU:** a training device with auditory instructions walks patients through the IFU in a predetermined sequence.
- **Smart training device for detecting errors and IFU:** a training device with sensors and adaptive algorithms is used to detect and teach patients how to prevent errors (see Figure 2).

The study found that users are most confident when training and onboarding with smart training devices that detect and teach them how to prevent errors. Patient confidence is a significant driver of compliance and patient adherence. In light of the importance of confidence during onboarding, training device configurations were evaluated to determine how each affected patient confidence. Based on participants' feedback, 82% of users would feel most confident when training with a device that detects and corrects errors. Across all configurations, training devices

STEP	DESCRIPTION	RISK OF ERROR	FREQUENCY OF ERROR
1	Prepare device	Low	Low
2	Remove mouthpiece	Low	Low
3	Inspect mouthpiece and device	Medium	High
4	Prepare device and dose (i.e. shake, prime, etc.)	High	High
5	Exhale fully	High	High
6	Place and properly orient device in mouth	Medium	Medium
7	Actuate device to deliver medication	High	Medium
8	Inhale with the appropriate force	High	High
9	Inhale at the appropriate sequence and duration	High	High
10	Hold breath for appropriate duration	High	Medium
11	Repeat as prescribed	High	Medium
12	Clean and store device as prescribed	Low	Medium

Figure 1: Common MDI instructions for use (IFU) steps. The most common errors are failure to prime, exhale and co-ordinate actuation with the necessary timing, force, and duration of the patient's inhalation. These factors commonly correlate with successful delivery, deposition and absorption of medication.



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increased confidence by 41%, which is consistent with other device-related studies.

“For us, usability and human factors go hand-in-hand with effectively training patients to use our drug delivery devices,” says Chris Evans, Vice-President of Research and Innovation at West Pharmaceutical Services (Exton, PA, US). “By instilling confidence with good training, fear or anxiety is eliminated when someone is injecting themselves or a loved one. It also eradicates some major barriers to adherence and compliance.”

Similar to confidence, anxiety can result in stress and avoidance behaviours that adversely affect patients’ adherence to therapy. Based on participants’ feedback, 76% of users prefer error detection technologies to overcome anxiety when onboarding to device-delivered therapies. Patient anxiety decreased by 18% across all training methods evaluated during this study (Figure 3). Smart training devices with error-detecting technologies are preferred methods in overcoming anxiety and preventing errors.

In addition to evaluating the effects of training on confidence and anxiety, the study sought to understand the patients’ overall training preferences and how these factors would relate to their ability to use a pulmonary delivery device safely and effectively. Figure 4 is a summary of these findings related to overall preferences and expected delivery outcomes. Users trained with smart, error-detecting technologies would make the fewest errors when administering with pulmonary delivery devices.

Based on a review of secondary literature, errors and technique are significant adherence barriers for patients

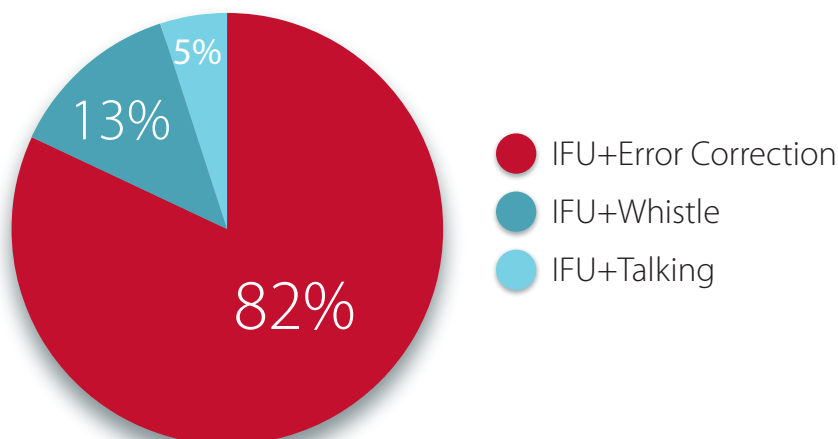


Figure 2: Preference (%) related to confidence when onboarding with specific training device configurations.

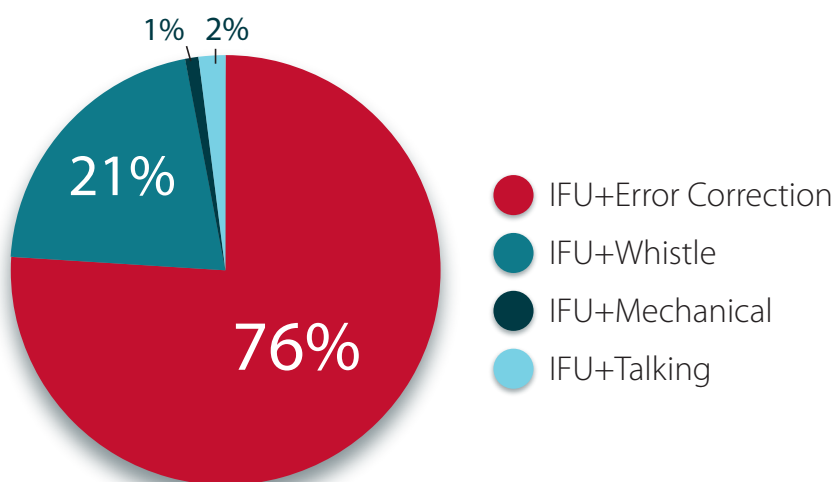


Figure 3: Preference (%) related to anxiety when onboarding with specific training device configurations.

using pulmonary delivery devices. The findings of this user study suggest that training devices could be effective tools to increase patient confidence and decrease anxiety – two variables that are closely associated with adherence and patient outcomes. Though the findings were

robust and insightful, follow-up research is recommended to evaluate device training on actual patient errors and long-term outcomes further.

“With increasing self-administration of injectable medications, it is critical that we recognise the best drug and delivery

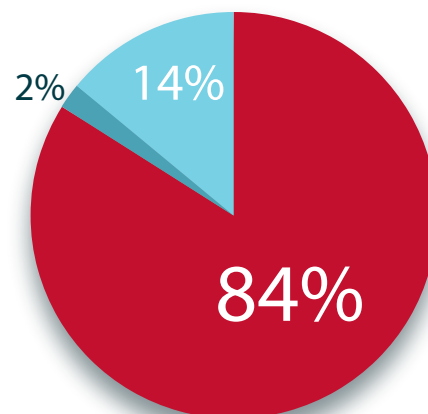
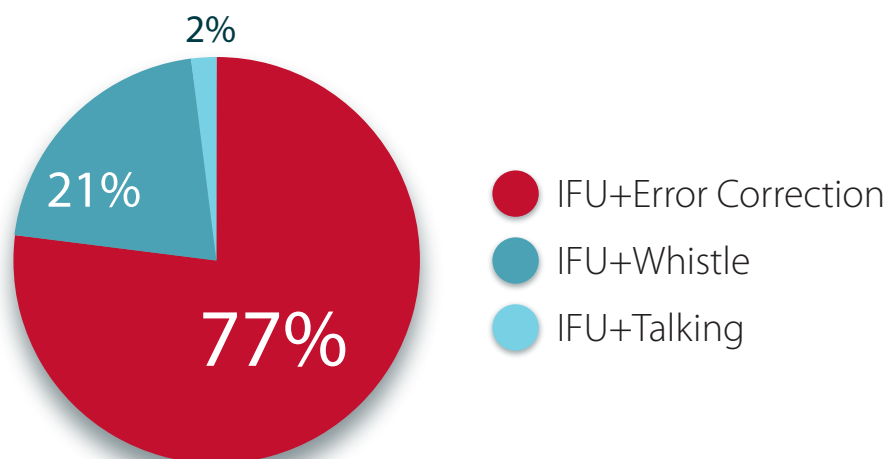


Figure 4: Users would make the fewest errors after being trained with error-detecting technologies (left). Users prefer error-correcting training when onboarding to pulmonary delivery devices (right).

system is only effective if the patient delivers the dose correctly, and in accordance with the appropriate treatment regimen,” says Graham Reynolds, Vice-President, Marketing and Communications, Pharmaceutical Delivery Systems at West Pharmaceutical Services.

“While manufacturers continually work to better understand user needs and design drug delivery systems for affinity, it is also imperative that we spend more time on effective training and onboarding for patients – with the aim of improving patient adherence and outcomes over the long run.”

As pulmonary delivery markets continue to evolve, patients and industry stakeholders will continue searching for value and differentiation. At its core, the goal of device training is to fulfill such needs and support patients in the successful management of their treatments.

ABOUT THE AUTHORS

Paul Sullivan is the Associate Director of Business Development at Noble®, a product development company with a focus in designing and manufacturing drug delivery training and patient on-boarding solutions. Prior to Noble, Mr Sullivan worked at Informed Medical Communications, as a Director of Business Development and Client Service. His primary role was to train physician and nurse key opinion leaders on the skills of peer-to-peer influence and round-table moderating. In 2003, started his career in the pharmaceutical industry as a pharmaceutical sales representative with Procter & Gamble Pharmaceuticals and holds a Kinesiology degree with honors from the University of Western Ontario (Canada) and resides in Cincinnati, OH, US.

Craig Baker joined the company just a few years after its creation. Mr Baker holds an undergraduate degree from the University of Iowa and a Masters degree from University of South Carolina. In addition, he has 10 years of management experience in the marketing industry and the pharmaceutical & healthcare field. This unique insight into both industries is an important advantage for the future growth of Noble.



2017 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
Jan 2017	Ophthalmic Drug Delivery	EXTENDED
Feb 2017	Prefilled Syringes	Dec 19th
March 2017	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Jan 23rd
April 2017	Pulmonary & Nasal Drug Delivery	Feb 20th
May 2017	Injectable Drug Delivery: Devices Focus	March 20th
June 2017	Connected Drug Delivery Systems	April 17th
July 2017	Novel Oral Delivery Systems	May 22nd
Sept 2017	Wearable Injectors	July 24th
Oct 2017	Prefilled Syringes	Aug 21st
Nov 2017	Pulmonary & Nasal Drug Delivery	Sept 25th

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Device training happens here.

There's life beyond chronic conditions. Distractions, anxiety and understanding correct administration technique can all affect compliance. Studies suggest 61% of patients don't completely read the IFU¹ and 12% of patients have proficient health literacy.²

Will your patients correctly administer their drug delivery device?



Onboarding and Device Training