PATIENT PREFERENCE IN RESPIRATORY DEVICE TRAINING & EDUCATIONAL TOOLS

Here, Paul Sullivan, Associate Director, Business Development, and Craig Baker, Executive Vice-President, both of Noble, provide data from recent patient studies to emphasise the importance of training devices in improving adherence to, and compliance with, inhaled therapeutics.

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 formulation with active pharmaceutical ingredients, and drug delivery devices.

When properly used by patients, inhalers administer the prescribed dose to the lungs. 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 or 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, Associate Clinical Professor at UCSF School of Medicine (San Francisco, CA, US). "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 for recognising 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 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. Another study was conducted to understand the impact of various forms of training materials and devices on patient performance.

Identifying 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 was 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

Paul Sullivan
Associate Director,
Business Development
T: +1 888 933 5646

Craig Baker
Executive Vice-President

Noble
121 South Orange Avenue
Suite 1070 North
Orlando
FL 32801
United States

the senses to enhance memory recall through audio, visual and tactile features.

In one study, five training methods were analysed:

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

As shown in Figure 2, the study found that users are most confident when training and on-boarding 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 on-boarding, 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 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 systems," said Chris Evans, Vice-President, Research & Innovation, West Pharmaceutical Services (Exton, PA, US). "By instilling confidence with good training, fear or anxiety is diminished … It also minimises 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 participant feedback, 76% of users prefer error detection technologies to overcome anxiety when on-boarding to device-delivered therapies. Patient anxiety decreased by 18% across all training methods evaluated during this study (Figure 3).

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 coordinate 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.

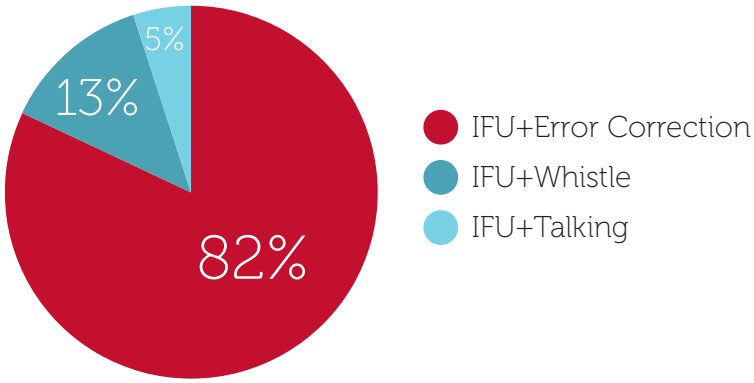

Figure 2: Preference (%) related to confidence when on-boarding with specific training device configurations.

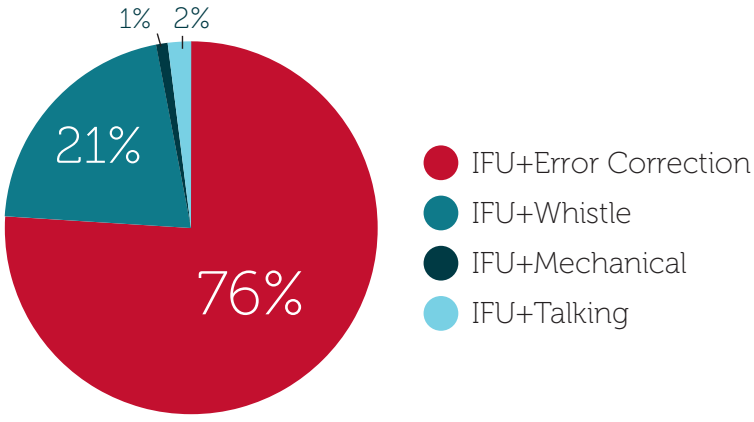

Figure 3: Preference (%) related to anxiety when on-boarding with specific training device configurations.

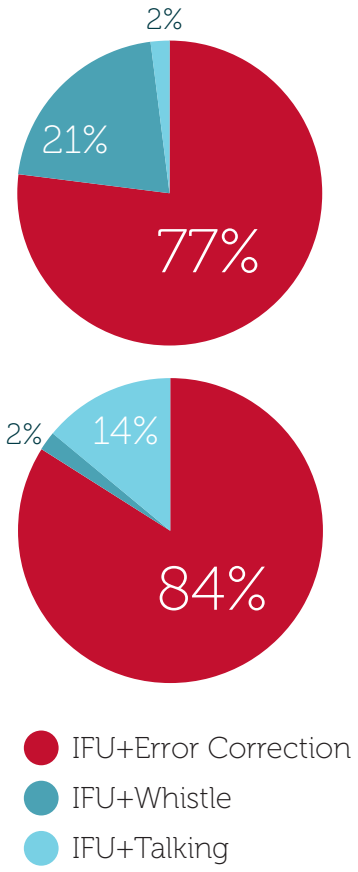

Figure 4: Top: Users would make the fewest errors after being trained with error-detecting technologies. Bottom: Users prefer error-correcting training when on-boarding to pulmonary delivery devices.

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 safely and effectively use a pulmonary delivery device. 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.

> "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"

Based on a review of secondary literature, errors and technique are significant adherence barriers for patients 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 the effect of 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 system is only effective if the patient delivers the dose correctly, and in accordance with the appropriate treatment regimen," explained Graham Reynolds, Vice-President of Marketing and Communications, Pharmaceutical Delivery Systems, at West. "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 on-boarding for patients – with the aim of improving patient adherence and outcomes over the long run." What Mr Reynolds says in the context of injectables here also holds true for inhaled medications of course, as these are even more commonly self-administered.

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 fulfil such needs and support patients in the successful management of their treatments.

ABOUT THE AUTHORS

Paul Sullivan
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, Paul 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 honours from the University of Western Ontario.

Craig Baker
Joining Noble® just a few years after its creation, Craig is the company's Executive Vice-President. He holds an undergraduate degree from the University of Iowa and a masters degree from University of South Carolina. In addition, he has ten years of management experience in the marketing industry, and the pharmaceutical and healthcare fields. This unique insight into both industries is an important advantage for the future growth of Noble.