TRAINING DEVICE OPPORTUNITIES AND SOLUTIONS FOR A CHANGING RESPIRATORY MARKET

Building on his previous articles in ONdrugDelivery on training devices and drug delivery device education, here, Joe Reynolds, Research Manager at Noble, outlines the increasing range of options available for helping patients learn how to use their devices correctly and maximise the effectiveness of their treatments.

Pulmonary drug delivery is one of the most common routes of administration for chronic and acute conditions, such as chronic obstructive pulmonary disease (COPD) and severe asthma. As with any device-delivered therapy, the successful use of pulmonary delivery systems depends on a number of intrinsic and extrinsic variables, including the properties of the lung, breathing patterns and delivery techniques.

To realise the full therapeutic benefits of these treatments, patients must first understand how to use their drug delivery devices properly to administer the correct nominal dosage. According to the US National Institutes of Health (NIH), a nominal dose is defined as "the total prescribed dose" of an inhalable therapeutic. When commonly observed, actual deposition rates (amount of medicament effectively reaching the lung) range from 6-60% of the nominal dose. Such incomplete doses can pose safety risks to patients and reduce the overall efficacy of treatments.

IMPROVING PATIENTS' USE OF DELIVERY DEVICES

To understand how to improve patient performance and outcomes, it is important first to understand common treatment barriers and the process patients go through when learning how to use delivery devices.

By definition, autonomous patients are those able to administer a prescribed dose free of error consistently and effectively. In order to reach this level of autonomy, patients progress through a number of learning stage where motor and muscle skills are acquired and confidence is built.

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The early stages of this learning process, known as onboarding, is characterised by highly variable outcomes due to patient errors and improper administration techniques. Errors experienced during the onboarding process, or the first 30–90 days of treatment, are frequent in nature but can often be avoided through proper education and training.

Without proper training and support during onboarding, many studies suggest that patients are more likely to incorrectly use delivery systems or discontinue therapy. According to a recent study conducted by the University of Texas Medical Branch in Galveston, 93% of patients who use an inhaler failed to follow proper administration techniques. In addition, only 7% of users demonstrated perfect technique and 63% failed to complete three or more steps correctly (Figures 1 and 2).[1]

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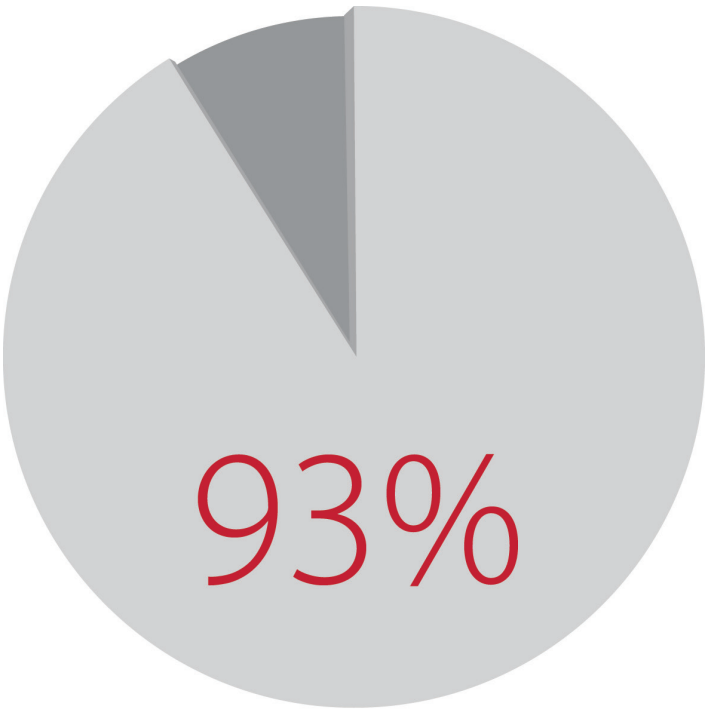
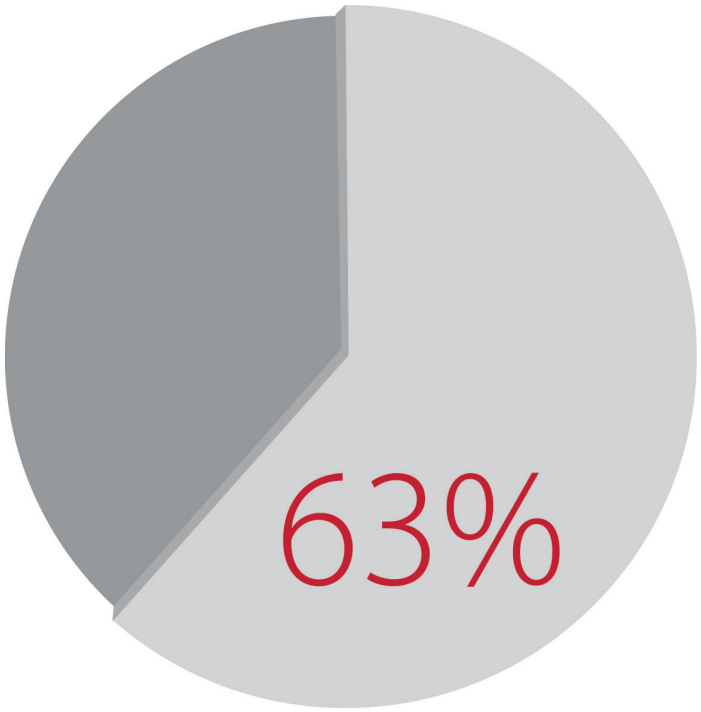


of patients use their inhaler incorrectly

Figure 1: Percentage of users who failed to demonstrate proper administration technique.



of patients failed to correctly complete three or more steps

Figure 2: Percentage of users who failed to correctly complete three of more steps.

TRAINING DEVICES

As with any form of drug delivery, providing patients with access to proper training and education is often the first step in successfully onboarding them to pulmonary treatments. In recent years the use of training devices that mimic the form, function and behaviours of pulmonary delivery devices have become effective resources for patients when learning how to administer their treatments properly.

These novel training devices are reusable and allow patients to learn how to handle and operate drug delivery devices. For pulmonary systems, this often includes priming, cleaning, actuating and inhaling procedures. Historically, many pulmonary devices require a high degree of hand-lung co-ordination and proper flow rates for medication to reach and deposit in the proper area of the lungs effectively.

Failure to complete these steps successfully can decrease the effectiveness of treatments and result in a number of unintended consequences. To address these risks, pulmonary training devices incorporate novel technologies such as air-flow sensors and calibrated mechanical features to teach patients the proper sequence and flow rates required to administer their treatments successfully. Providing this level of education and training to patients promotes the proper use of drug delivery systems and is an effective strategy to improve outcomes and maximise the value of pulmonary therapies.

Multisensory Technology

Developing optimal pulmonary training devices requires the effective application of human factors considerations and other cognitive methodologies. Modern neurological research suggests that information perception, encoding, decoding and retrieval is influenced by the strength and uniqueness of educational stimuli.

Thus, device-training solutions incorporating multisensory technologies, such as audio, visual and tactile feedback, have been proven to strengthen neurological connectivity between semantic networks of the brain, a principle referred to as cross-modal processing. As a result, training devices that incorporate multisensory technologies can be used to enhance patient training further and create a consistent onboarding experience for all users.

INHALED DRUG DELIVERY DEVICE OPTIONS

Currently, there are a variety of drug delivery device options available to patients with respiratory or related indications. Many of these conditions are characterised by inflammation, constriction or obstruction of airways and the lung. Such factors can

Figure 3: MDI training device designed to be true to form and function of an actual MDI.

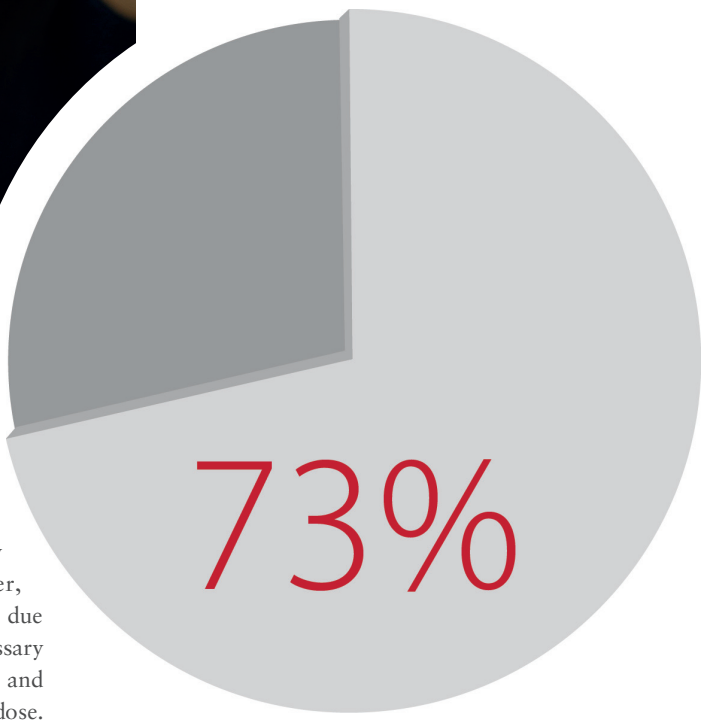
adversely affect the functions of the lung and are commonly treated with targeted therapies such as anticholinergics, beta-agonists or corticosteroids.

The efficiencies of targeted therapies that treat these conditions lie in the localisation and rapid uptake in the lungs. The absorption of medications for systemic delivery has also become an attractive option for future treatments and pipeline molecules due to properties of the lungs and proximity to the cardiovascular system.

The following are drug delivery options that are available for the majority of currently marketed pulmonary treatments.

- Nebuliser – converts liquid medications into a mist to help treat patient conditions. To use the nebuliser, patients inhale the mist through an attached mouthpiece or mask. Nebulisers are historically used by patients at home, limiting the flexibility of their treatment and dosing schedules.
- Metered dose inhaler (MDI) – delivers medication through a pressurised handheld device. Patients use an MDI by pressing on the device while simultaneously inhaling the medication, depositing the medication directly into the lungs. While MDIs are small and easily transportable, patients often fail to inhale the nominal dosage due to a number of issues, including hand/lung co-ordination, confusion in steps, and inspiratory flow or rate of inhalation. An MDI training device is shown in Figure 3.
- Dry powder inhaler (DPI) – also small and compact, making it easily transportable. However, patients often misuse DPIs due to the amount of steps necessary to actuate the medication and administer the nominal dose. DPIs rely on the force of patient inhalation to deposit the medication into the lungs. For this reason, insufficient inhalation flow may cause the patient to receive too little medication. Patients must also properly close the cap in order to prevent the medication from hardening.
- Soft mist inhaler (SMI) – combines the size and portability of MDIs and DPIs with the benefits of a nebuliser. Although SMIs disperse medication through a mist, allowing patients to inhale at their own rate, there are a number of components in the device that can cause confusion for patients and result in preventable errors.

> "Smart technologies provide the opportunity to maximise training value by incorporating sensors, algorithms and multisensory feedback to monitor real-time patient behaviour and detect errors."



of patients reported increased anxiety around injectable treatment therapies when relying on an instruction manual as their only form of training

Figure 4: Percentage of users who reported needle anxiety when relying on only the IFU.

NEW DELIVERY METHODS

Indications such as COPD affect an estimated 11 million patients and is the third leading cause of death in the US.[2] For nearly two decades, the pharmaceutical industry has been evaluating next-generation pulmonary treatments to help in the management of symptoms and to improve patients' quality of life. Many of these pipeline treatments leverage modern science to target and block inflammation through novel mechanisms of action and delivery technologies.

Due to the clinical profile and properties of these treatments, many of them will be administered as subcutaneous injections using prefilled syringes, auto injectors or other parenteral methods. While these injectable compounds will mitigate patient barriers associated with traditional pulmonary devices, they will also introduce new behaviours and training considerations into patients' treatment and onboarding experiences.

Research demonstrates that many patients who self-inject therapies do not read or fully understand the instructions for use (IFU) that accompany their drug delivery device. A study conducted by Noble and researchers from Auburn University surveyed more than 700 patients and found more than half did not read their instructions for use (IFU) document prior to beginning treatment.

In addition to traditional instructions and package inserts, healthcare professionals are often leveraged as learned intermediaries to onboard patients and provide access to training and education. However, patients are often new to medical terminology and therefore do not fully understand medical instructions. Similar to pulmonary devices, patients' inability to recall and utilise information effectively may lead to a higher probability of incorrect administration techniques and errors when using injection devices.

Injection Training Devices

To address the common gaps in patient onboarding for injection systems, training devices are often used to create consistent onboarding experiences for patients through the use of multisensory technologies and mechanisms that fully simulate the mechanical aspects of the injection experience.

In a study conducted by Noble, 73% of patients reported increased anxiety around injectable treatment therapies when relying on an instruction manual as their only form of training (Figure 4). The research also found that providing these patients with training devices that simulate the look and feel of real injection devices and allowing them to practice self-injection prior to beginning helps to decrease anxiety and fear.

CONCLUSION

As the pulmonary market continues to evolve and new injectable treatments are introduced, patients will need to familiarise themselves with using auto injectors, syringes and other forms of injectable delivery. This market need will create opportunities for pharmaceutical manufacturers to establish differentiation through superior onboarding tactics in order to avoid barriers associated to adherence and acceptance.

Due to the success of multisensory device training, smart technologies are now augmenting the training device market. Smart technologies provide the opportunity to maximise training value by incorporating sensors, algorithms and multisensory feedback to monitor real-time patient behaviour and detect errors. This direct feedback further accelerates the learning and onboarding process.

At its core, the ultimate goal of device training is to create value for industry stakeholders by enhancing the patient experience and improving safety. As new products continue to launch and augment markets, brands will continue looking for strategies to differentiate themselves and improve patients' quality of life.

In the modern era of patient-centric care, those able to provide superior product and educational experiences will continue to benefit from the value and utility that they create for patients and society.

ABOUT THE COMPANY

Noble, the leader in patient onboarding and drug delivery device training, develops "True to Form and Function" auto injector, prefilled syringe, wearable and respiratory training platforms to provide biopharmaceutical companies improvements in patient onboarding and adherence. These training platforms are built to brand specifications and are available as off-the-shelf, pre-configured ready-for-launch solutions.

Noble's offerings range from mechanical training devices to smart error-correcting training platforms, which replicate a brand's shape, design and tactile feedback, operational forces and steps needed to administer the drug. These devices have been designed to simulate actual drug delivery devices while being a low-cost reusable solution to onboard users safely and effectively.

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ABOUT THE AUTHOR

Joe Reynolds is Research Manager at Noble, where he leverages his knowledge and experience to develop and implement strategies that improve the patient experience and maximise value for stakeholders. His experiences include commercial, managed care and product development initiatives with leading medical device, pharma and biopharma brands.

Mr Reynolds holds a BS in Business Administration from the University of Central Florida, an MS in Marketing from the University of South Florida and an MS in Pharmacy and Master Certificate in Drug Regulatory Affairs from the University of Florida.

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 IFU[1] and 12% of patients have proficient health literacy.[2]

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