



## REALISTIC PULMONARY DELIVERY SYSTEM TRAINERS: BENEFITS FOR PATIENTS, PHYSICIANS AND DRUG MANUFACTURERS

The use of training devices has been shown to improve correct inhalation device technique in patients. In this article, Craig Baker, Executive Vice-President, Noble, discusses the prevalence of improper use and how addressing this issue via training devices is of benefit to manufacturers, healthcare providers and patients.

*Based on the article that previously appeared in ONdrugDelivery Magazine, Issue 85 (April 2018), pp 28-31.*

Many treatments for respiratory conditions, such as chronic obstructive pulmonary disease (COPD) and severe asthma, are self-administered through pulmonary delivery systems, including nebulisers, metered-dose inhalers (MDIs), dry-powder inhalers (DPIs) and soft-mist inhalers (SMIs). As this form of targeted drug delivery continues to grow, so too does our understanding of the complexities and challenges associated with this route of administration, particularly those that can result from improper use by patients.<sup>1</sup> The most common failings are

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related to inhalation timing and force, but this is compounded by the fact that patients are often unaware when they are using improper technique, thus not realising they are not receiving the proper drug dose. This incorrect usage and subsequent under-dosing inevitably has detrimental consequences for patient health.<sup>2</sup>

Understanding the need for innovation in patient onboarding and training, Noble has developed a wide range of patented technological advancements to design training devices for pulmonary delivery systems, mimicking the look, feel and operation of the prescribed product and user experience (Figure 1). These training products afford patients a hyper-realistic experience during the onboarding period (defined as the initial 30, 60 or 90 days of delivery system usage), boosting patient confidence and encouraging proper device use, which may ultimately enhance patient health.

Numerous studies suggest the use of realistic trainers in familiarising patients with the operation of pulmonary delivery systems could help ensure that they are being utilised properly. Additionally, the impact of comprehensive onboarding and training can offer benefits to healthcare professionals (HCPs) and drug manufacturers.



**Craig Baker**  
Executive Vice-President  
T: +1 888 933 5646  
E: cbaker@gonoble.com

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

[www.gonoble.com](http://www.gonoble.com)



Figure 1: MDI training device designed to replicate an actual MDI's form factor and operation while providing the user with multisensory feedback.

### ENHANCING PATIENT CONFIDENCE AND HEALTH

While there is no question that pulmonary delivery systems can help save lives, patient error is still a concern because it is crucial that actuation and inhalation are performed by the patient in proper sequence with correct timing. This issue is more prevalent than one might expect.

For example, according to a widely reported study published in the *Annals of Allergy, Asthma & Immunology*, only 7% of inhaler patients follow proper technique when using their device.<sup>3</sup> Additionally, a pair of studies from Rice University (Houston, TX, US) concluded that the users of MDIs may be limiting their medication's effectiveness by getting only half the medication they need, again as the result of device misuse. The vast majority of the time, between 70–90%, patients commit errors resulting in only a fraction of the medication, usually less than 40%, actually reaching their lungs, as reported in *COPD News Today*.<sup>4</sup>

A solution to this problem lies in the latest generation of pulmonary delivery system trainers, incorporating an array of both mechanical and “smart” features, such as realistic actuation simulation. To ensure proper sequencing, calibrated whistles have been incorporated as well. As long as the patient is inhaling at the proper rate, a whistle will sound during the process but will stop sounding if the drug intake is occurring improperly.

Additionally, “smart” features on

Noble's pulmonary delivery system trainers are designed to monitor the key steps involved in usage of these devices and can give the user feedback in real time. If the patient does not perform the proper sequence of steps or is not inhaling at the proper rate, these errors can be detected immediately and reported to the patient through the use of light or sound effects. Depending on the specific configuration requested by a drug manufacturer, this feedback can be conveyed both via the trainers themselves and in tandem with an app that runs on a smart device, such as a smartphone or tablet. The latter configuration allows the use of interactive videos that can further educate patients on proper use of the trainers.

### HELPING HCPs PROVIDE BETTER INSTRUCTION TO PULMONARY PATIENTS

Enhancing patient confidence may also help HCPs to ensure a prescribed treatment is working as intended for a patient, thereby mitigating complications and resulting in an overall better quality of care.

Part of the problem in the pulmonary space is that studies have indicated that only a minority of HCPs are familiar with the proper way to use aerosol devices.<sup>5</sup> At the same time, studies have shown a

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strong correlation between poor adherence to prescribed inhaled medications and risk of hospital admission due to exacerbations, as well as increased healthcare costs. These studies also spotlight the importance of HCPs taking extra steps to promote patient adherence to these medications, including improving patient education on how to use these medications properly. Studies suggest it is important for HCPs to demonstrate proper use of pulmonary delivery systems to improve the effectiveness of therapy.<sup>5</sup>

The use of realistic trainers can play a role here by allowing an improvement in the quality of individualised medication self-management programmes initiated by HCPs, which have been shown to increase a patient's medication adherence.<sup>5</sup> For example, in one randomised, controlled study of subjects with moderate-to-severe asthma, researchers reviewed the effect of an individualised self-management education programme on medication adherence and markers of asthma control over a 24-week period. It was concluded that subjects who

received such individualised sessions had higher medication adherence compared with a control group.<sup>5</sup>

It is evident that the patient onboarding process is just an initial concern for HCPs. Because whether or not a patient is using their pulmonary delivery systems properly is such a critical factor in the efficacy of a treatment, it becomes a challenge for the HCP to evaluate the drug's effectiveness once the patient is sent home, leading to reliance on patient self-reporting. If patients believe they are utilising their pulmonary delivery systems correctly when in fact they are not, this can throw off the analysis of the medication and disease management. Evidence suggests this is a substantial and current issue. In one study, 94 patients with COPD were observed using a pulmonary delivery system; although 96% self-reported that they utilised the proper inhalation technique, a successful first inhalation attempt was performed by only 30% of patients<sup>6</sup> (Figure 2).

Given the evidence of disparities between patient self-reporting and actual pulmonary delivery system use, advanced training technology can serve a twofold benefit for HCPs. Firstly, a patient who practices with realistic trainers is more likely to adopt proper technique from the start of their treatment and continue to do so when self-administering at home, ensuring more effective drug delivery. Second, certain advanced trainers are capable of generating feedback that patients can share with their physicians and other HCPs in order to verify that the devices are actually being used in the proper manner.

#### WHY PHARMACEUTICAL & DEVICE MANUFACTURERS TURN TO TRAINING

Finally, manufacturers stand to benefit from the new generation of realistic pulmonary delivery system trainers, as proper administration resulting from training may positively impact the device's perceived effectiveness. This can be the case not only when starting a new therapy, but also when switching to a new brand or class of treatment. Additionally, manufacturers should realise that patients and their physicians, given a choice between competing therapeutics, might select a brand that can be simulated by a realistic trainer over a competing brand for which no realistic trainer is available.

Of additional interest to manufacturers, whilst Instructions for Use (IFU) have

Only **30%** of patients performed a successful first inhalation

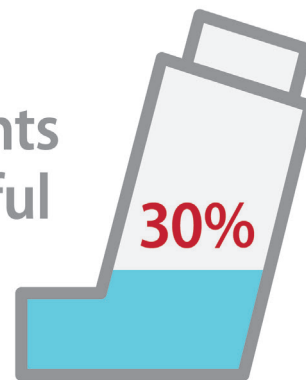
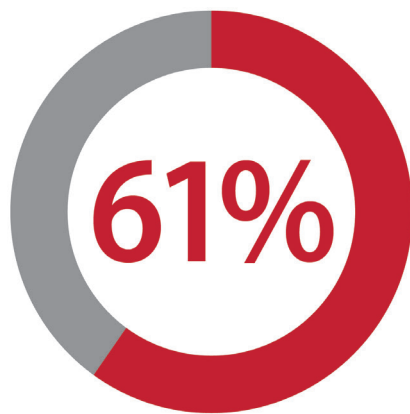


Figure 2: Study finding – 96% of patients self-reported correct inhalation technique, although observations revealed only 30% of participants actually performed a successful first inhalation attempt.

“Given the level of precision built into Noble’s production process, manufacturers can be assured that the finished product will precisely simulate their actual device.”



of patients don't read the IFU

Figure 3: Study finding – IFU alone may be insufficient for patients to learn correct administration technique.

traditionally been included with devices, research suggests that these are not always effective in conveying proper pulmonary delivery system technique to patients. Research demonstrates that many patients who self-administer medication do not fully understand, or even read in some instances, the IFU that accompanies their device (Figure 3). A study conducted by Noble and researchers from Auburn University (Auburn, AL, US) surveyed more than 700 patients and found more than half did not read their device's IFU prior to beginning treatment.<sup>7</sup> Noble has the capability of working with manufacturers to produce training IFUs specifically for pulmonary delivery system trainers, incorporating user-friendly literacy level messaging, multiple language options and simple, step-by-step written and visual instructions. While still an important part of the device package

for manufacturers in this area, IFUs can be usefully supplemented with realistic trainers. Noble can work with manufacturers to simulate the attributes of real MDIs, DPIs and SMIs; these are available both as off-the-shelf and customised platforms.

Aside from pioneering the technology behind the trainers themselves, Noble has developed processes and systems to optimise the development and commercialisation of training devices. Given the level of precision built into Noble's production process, manufacturers can be assured that the finished product will precisely simulate their actual device. Noble can also work with a drug manufacturer during the global launch of a specific pulmonary delivery system to ensure that trainers are made available in the necessary quantities at locations worldwide in a timely manner.

It is clear there is a multitude of benefits



that pulmonary delivery system trainers can provide to patients, HCPs and drug manufacturers. Especially compelling are the studies illustrating the need for these training devices, which might be able to raise the percentage of users who correctly utilise their devices up from the 7% noted in the *Annals of Allergy, Asthma & Immunology* study, and consequently raise the amount of medication that is actually inhaled above the average of less than 40% noted by *COPD News Today*. As a result, the innovative design and production of Noble's sophisticated, patient-centric trainers may have an impact on the overall quality of healthcare administration.

#### ABOUT THE COMPANY

Noble® works closely with the world's leading pharmaceutical and biotechnology companies to develop respiratory device, autoinjector and prefilled syringe training solutions designed to provide positive patient onboarding experiences, reduce errors and improve patient outcomes. Cross-disciplinary designers and engineers provide fully customised solutions from the first concept sketch through to production, in both regulated and non-regulated environments.

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#### ABOUT THE AUTHOR

Craig Baker is Executive Vice-President at Noble, a product development company with a focus in designing and manufacturing drug delivery training and patient onboarding solutions. Joining the company just a few years after its creation, Craig holds an undergraduate degree from the University of Iowa and a Masters degree from the University of South Carolina. In addition, he has 10 years of management experience in the marketing industry and the pharmaceutical & healthcare field. This insight into both industries is an important advantage for the future growth of Noble.

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