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# TRAINING DEVICES AND PATIENT EDUCATION PLAY A CRUCIAL ROLE IN THE SELF-INJECTION DRUG DELIVERY MARKET

In this article, Joe Reynolds, Senior Manager, Strategy and Patient Insights at Noble, discusses the role training devices and patient education play with regard to self-injection therapies.

## BIOPHARMACEUTICALS: AN INDUSTRY MARKED BY GROWTH AND INNOVATION

The biopharmaceutical industry has experienced incredible exponential growth in recent decades. Annual revenues have increased from US\$4.4 billion (£3.4 billion) in 1990 to \$275 billion (£213 billion) in 2018 (a 6,250% increase) and now represent more than 25% of the total pharmaceutical market.<sup>1</sup>

"The rising number of parenteral medications has prompted drug and packaging manufacturers to continue seeking more sophisticated delivery systems. By 2017, there were over 100 injectable drug products available in prefilled syringes and an ever-rising number of pipeline drugs targeted for delivery by this method."

A primary driver of this rapid expansion is the pioneering pursuit of biologics to treat the growing rate of chronic diseases.<sup>2</sup> Other factors fuelling the industry's robust economic growth are technological advancements, such as the use of smart data, machine learning and wireless connectivity, and the ongoing progress towards developing new products and services to better meet patients' needs and the challenges they confront in the daily use of their prescribed therapeutics.<sup>3</sup>

### The Evolution of Injection Devices and Prefilled Syringes

Injectable drug delivery systems have come a long way from conventional syringes packaged with simple vials to include prefilled syringes, autoinjectors, pen injectors and needle-free systems. The origin of prefilled syringes dates back to the 1950s when they were introduced in a polio vaccination campaign.<sup>4</sup>

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## OPPORTUNITIES AND CHALLENGES FOR SELF-INJECTION DRUG DEVICES

The expanding development of biologic drugs to address chronic diseases, from diabetes and multiple sclerosis to Crohn's disease and rheumatoid arthritis, has resulted in an increasing cohort of patients who rely on self-injection devices to administer their medications at home. Supporting this trend are advances in the design of patient-centric devices, driven by usability and intuitiveness, which are transforming biologic drug delivery.<sup>6</sup> The involvement of training devices and patient education could be essential to the success of this transformation.

But with opportunity comes challenges; nearly half of health care professionals (HCPs) who prescribe self-injecting drug delivery devices do not train patients on how to self-inject correctly.<sup>6\*</sup>

The covid-19 pandemic has helped to bring telemedicine into the mainstream as a safe and convenient alternative to traditional in-person medical care. Nearly 60% of respondents to a survey conducted in mid-March 2020 indicated that covid-19 made them more likely to consider using telehealth services in the future, yet over 40% expressed concerns about the ability to be properly diagnosed or treated in a virtual setting.<sup>7</sup> For those patients who lack hands-on access to an HCP, robust patient training and proper onboarding can further support them in adhering to their therapeutic treatments (Figure 1).

### The Benefits of Training Devices Combined with Patient Education

Noble, an Aptar Pharma company, first saw the need for better self-injection training at the beginning of the 2010s. Since then, it has become a global leader in the development and delivery of medical device training solutions, patient onboarding

Figure 1: For patients who lack hands-on access to an HCP, robust patient training and proper onboarding can further support them during this uptick in telemedicine appointments.



strategies and multisensory products for patients and HCPs that aim to improve patient adherence and, ultimately, healthy outcomes.

And yet, the need for ongoing patient training persists. While biologic and drug delivery advancements are giving more patients with chronic conditions greater access to therapeutic medications, some patients are non-adherent due to lack of training, improper use and recall erosion.

- 49% of HCPs do not train patients to correctly use their self-injection devices.<sup>6\*</sup>
- 84% of patients do not use an autoinjector correctly.<sup>8\*\*</sup>
- 90% of treatment information is forgotten in a week if patients do not practice at home, a phenomenon attributable to the “forgetting curve” theory that, without practice and repetition, retention and recall degrade over time.<sup>9</sup>

### An Empirical Look at Patient Training

In 2018, Noble conducted a survey to understand better how patients learn, retain and recall information. This longitudinal study explored whether the use of injection training devices and other stimuli to help reinforce memory could, over a period of time, lead to decreased memory decay, fewer device errors and improvements in the onboarding experience for patients who self-inject.

To begin the study, participants across three cohorts – nine participants per cohort – attended an introductory session where they received self-injection training, just as they would in a doctor's office if they were prescribed a self-injection course of therapy.

During this first session, researchers replicated an optimal introductory in-office

learning experience between an HCP and a patient. This session focused on introducing participants to the drug delivery device and then training them on how to use it with a demonstration device that did not include medication or a needle.

Afterwards, participants could practice on themselves with a training device, with researchers present. Participants were also given feedback and recommendations for improvement, as would occur during training with an HCP. After the 45-minute training session, they were sent home.

To understand the effects of having access to a training device in-office only, cohort A – the control group – was sent home with only the instructions for use (IFU). This cohort was not intended to represent the minimum amount of training a patient may receive, but to set a baseline for evaluating the effects of having additional support, such as training materials, at home.

Cohort B was sent home with both an IFU and a training device that mimicked the actual device they would self-inject with later in the study, and Cohort C was given both the IFU and the training device, as well as an interactive training video to use at home.

Participants were instructed to practise at home as little or as often as they preferred and were told to keep track of how many times they used their materials. Participants then did not hear from researchers for 14 days, allowing them to practise with the various materials as frequently or infrequently as they preferred. The purpose of this was to uncover the correlation between successful and unsuccessful self-injections and the participants' access to training materials.

“The covid-19 pandemic has helped to bring telemedicine into the mainstream as a safe and convenient alternative to traditional in-person medical care.”

### COHORT A MEDICATION IFU

Only had access to Medication IFU during the 14-day decay period.

### COHORT B TRAINING DEVICE

- 100% practiced at least 3 times.
- 56% practiced 5-9 times.
- 33% practiced 10 or more times.

### COHORT C TRAINING DEVICE & INTERACTIVE VIDEO

- 100% practiced at least 3 times.
- 83% practiced 5-9 times.
- 33% practiced 10 or more times.

Figure 2: Research found participants with additional training resources were more engaged during the decay period.

The study confirmed that when patients are provided with materials to practise with at home, engagement in their therapy increases (Figure 2).

- 100% of participants practiced at least three times
- 70% of participants with demonstration devices (cohorts B and C), on average, practiced five-to-nine times
- 33% of subjects practiced 10 times or more
- 92% of participants indicated they prefer to receive a training device to take home and practice (Figure 3).

Moreover, the study concluded that 100% of cohorts B and C completed all critical steps for a successful self-injection, while only 44% did so from cohort A.

# 92%

of the participants would prefer to receive a training device to take home and practice with prior to conducting their self-injection.

Figure 3: The majority of participants stated how important a training device would be to have in the home for practice.

### Noble's Training Solutions Aim to Address the Needs of Today's Patients

Human behaviour and user experience are critical elements of a patient-centric training solution. Noble's training devices – including autoinjectors, prefilled syringes, on-body and respiratory devices – are calculated to mimic the feel, force and function of the actual drug delivery device so that patients can practise at home; potentially resulting in less error and increased device familiarity.

Noble also provides IFU for its training devices to help guide patients through proper administration prior to using the true drug delivery device. Specifically designed to complement the actual device, the training IFUs address human factors such as literacy-level messaging, multiple language options and simple step-by-step instructions.

### Partnering with Biopharma to Advance Healthy Outcomes

To achieve the goal of fostering healthy outcomes for patients who self-administer their drug therapies, Noble partners with leading biopharmaceutical companies and original equipment manufacturers (OEMs) to develop and launch innovative training platforms and holistic solutions.

One such partnership is with BD. Noble's robust programme for the BD UltraSafe™ passive needle guard portfolio involves designing and manufacturing demonstration and onboarding devices, as well as supporting materials, with the aim of strengthening pharma's commercial launches and improving patient adherence.

The newest addition to Noble's line of demonstrators for the BD UltraSafe™ needle guard portfolio is the BD UltraSafe Plus™ 2.25 mL. Proprietary features of Noble demonstration devices include a resettable locking needle guard that simulates the safety systems with the ability to reset the device for multiple training sessions, and an encased faux needle designed to simulate the forces and feel of an injection.

From clinical trials through to post-launch, Noble's integrated approach includes human factors studies and patient experience mapping; launch strategy and pre-launch training summits; training device distribution and fulfillment; and patient and HCP engagement programmes. This combined comprehensive approach benefits not only the patient, but also Noble's partners, with improved speed to market, lower cost of entry and the ability to customise training devices to brand specifications.

### CONCLUSION

Biopharma manufacturing is expected to continue evolving and adopting new and improved technologies, contributing to a global biotechnology market that is expected to surpass \$775 billion (£601 billion) by 2024.<sup>1</sup> When it comes to the rising number of self-injection therapies, Noble recommends that patient training and education be part of the standard of care for biopharmaceutical companies and OEMs to help build more confident, healthy – and ultimately, adherent – patients who self-administer.

### ABOUT THE COMPANY

Noble, an Aptar Pharma company, is focused on fostering healthy patient outcomes for those who self-administer drug therapies, through the development of robust training devices and onboarding solutions for the world's top pharma brands and biotech companies. Noble manufactures and commercialises training devices that mimic the exact feel, force and function of drug delivery devices such as autoinjectors,

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prefilled syringes, and on-body, nasal and pulmonary devices in order to increase patient adherence and confidence and decrease usage errors.

\*Data obtained via online survey of 1,166 physicians practicing in the US, of which 733 prescribed self-injection devices.

\*\*Study of 146 patients receiving allergy and immunology treatment, of which 102 patients were prescribed an epinephrine autoinjector.

BD UltraSafe and BD UltraSafe Plus are registered trademarks of Becton, Dickinson and Company.

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## ABOUT THE AUTHOR

Joe Reynolds is the Senior Manager, Strategy & Patient Insights 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, pharmaceutical and biopharmaceutical manufacturers. Mr Reynolds earned his BSc in Business Administration from the University of Central Florida, an MSc in Business from the University of South Florida, and a MSc in Pharmacy and Master Certificate in Drug Regulatory Affairs from the University of Florida.

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#### B: How to pass a Human Factors Validation study

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Demonstration devices aim to help patients worldwide build the confidence to self-inject, properly engage with their therapies and live longer, healthier lives.

Noble's platform solutions—including demonstrators of BD UltraSafe Plus™ passive needle guards—also boost speed to market, low development costs and customization to meet brand needs.

Contact us at **[GoNoble.com/pfs](https://GoNoble.com/pfs)**

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