



DEVELOPING DEMONSTRATORS TO INCREASE PATIENT CONFIDENCE & REDUCE ANXIETY

Using Noble's recent partnership with BD to develop trainers for BD's UltraSafe™ needle safety technology as an example, Joe Reynolds, Research Manager, Noble, discusses the importance of training devices for the successful onboarding of patients beginning to use self-injected therapeutics, and how Noble's training devices are designed to be faithful to the look and feel of the real product.

According to recent research, the global prefilled syringe market is estimated to reach US\$22.5 billion (£16.8 billion) by 2025. Drivers in the market's expansion include technological advancements in drug delivery and the growing use of prefilled syringes for delivering biologic and large molecule medications.¹

Whilst these medications can significantly improve patients' quality of life, the WHO estimates that 50% of patients diagnosed with chronic conditions do not take their medications as prescribed.² While myriad factors influence patient adherence and outcomes, demonstrators and education can positively influence patient acceptance of, and adherence to, treatments using prefilled syringes, safety systems and other forms of drug delivery.

Through advancements in usability and human factors engineering, the overall understanding of patient adherence and the value of both device demonstrators and onboarding education has greatly improved. While Instructions for Use (IFU), package inserts and other content-based collateral are effective, it is estimated that only 12% of patients have the health literacy needed to understand and manage their treatment using these materials alone, resulting in training gaps that can adversely affect the use of prefilled and safety syringes by patients and other stakeholders.³

Through experience, Noble has found that confidence and anxiety are two

"All device demonstrators are tested to guarantee that needle simulation and plunger speeds accurately mimic those of real drug delivery devices."

key variables that influence a patient's perception toward drug delivery devices and their overall therapy. The onboarding period (or the first 30, 60, 90 days of treatment) is where these attitudes and usage behaviours are first established, and become key predictors of long term adherence and outcomes (Figure 1). During the onboarding phase 45% of patients skip or avoid injections due to needle anxiety or fear,⁴ which can lead to avoidance behaviours and, ultimately, the discontinuation of treatment.

DEVICE DEMONSTRATORS REDUCING NEEDLE ANXIETY

Needle anxiety is a common adherence barrier for patients who use prefilled syringes and other injection-based delivery systems. To help patients overcome the emotional barriers of self-injection, novel needle simulation technologies have been developed to fully mimic the deformation, puncture and insertion force characteristics



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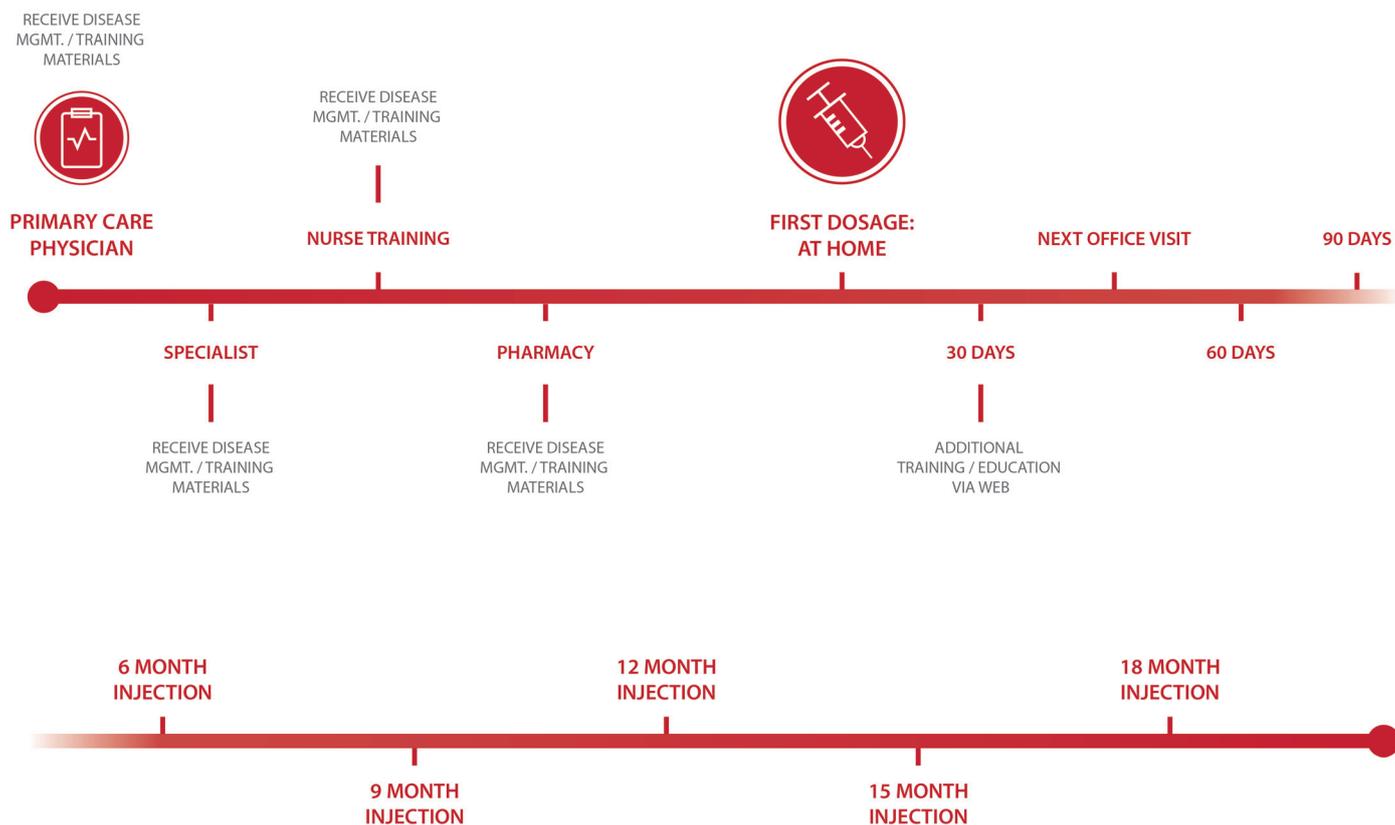


Figure 1: Timeline showing onboarding, including initial and subsequent injections at different dosing frequencies.

“A study announced by Noble revealed that demonstration devices that incorporate needle simulation technologies result in a greater reduction in patient anxiety compared with traditional training.”

of syringe needles. When applied to prefilled syringe training, these proprietary technologies allow patients to learn the force and technique required to insert a needle into subcutaneous tissue safely. A study announced by Noble revealed that demonstration devices that incorporate needle simulation technologies result in a greater reduction in patient anxiety compared with traditional training.

COLLABORATIONS THAT FOCUS ON PATIENT SUCCESS

As the pharmaceutical market continues to grow, so too does the need for injection devices that support both the complex properties of molecules and the needs of the end-user performing the injection. By providing a best-in-class user experience, pharmaceutical manufacturers can ensure that patients have access to resources that promote meaningful outcomes and build confidence in their ability to self-manage treatments and use drug delivery devices.

Noble recently announced its collaboration with BD to provide advanced patient onboarding solutions, including demonstration devices. Through the ongoing collaboration, Noble will

leverage its onboarding solutions to develop novel demonstrators based on the BD UltraSafe™ technology (Figure 2), thereby improving the patient experience and confidence. Noble’s market expertise and BD’s passive needlestick safety devices allow for the full customisation of drug delivery devices and access to dedicated onboarding systems. BD has been an early innovator in developing safety-engineered solutions for the market, partnering with numerous customers to ensure product success.⁵



Figure 2: Noble is collaborating with BD to develop novel demonstrators based on the BD UltraSafe™ technology.

Partnerships and collaborations like this one provide the expertise needed to develop optimal treatments from start to finish. In a recent market survey conducted by Noble, 89% of patients reported that it was “very important” to have the most realistic demonstrating device possible. By having a deep understanding of complex device engineering and patient needs, companies are better able to create positive and impactful onboarding solutions for patients. User-centric companies, like BD and Noble, have the patient in mind from when they begin the onboarding process all the way to the end with administration of treatment.

One example of how this collaboration benefits patients is the BD UltraSafe Plus™ passive needle guard. The overall design of the product was validated by performing handling studies with both nurses and self-injecting patients. The user study confirmed that the BD UltraSafe Plus™ passive needle guard was intuitive and easy to use with a 100% activation success rate for all 500 injections.⁶ Noble’s device demonstrators will compliment BD’s prefillable syringe safety systems and help instil another level of confidence during

the onboarding process by providing hands-on experience that fully mimics the actual device. Demonstration devices, like those produced by Noble, have become the foundation of effective education and onboarding strategies by allowing patients and healthcare professionals to safely learn how to use prefilled syringes and other forms of drug delivery.

DEMONSTRATORS FOR PREFILLED SYRINGE SYSTEMS

Noble’s prefilled syringe demonstrators simulate the attributes of real prefilled syringes and are available off-the-shelf or as customised platforms that include proprietary technologies. With the ability to be customised, brands can include capabilities like audio, tactile feedback, sensors, syncing and error detection. They also offer customisable options for syringe angle training that can be custom-fit to shape and design, colour, and 45° or 90° angularity.

These demonstrators are custom developed to mimic both standard prefilled syringes and those with safety systems. A few key features (also shown in Figure 3) include:

- Plunger speed simulation – Noble’s device demonstrators replicate viscosity and volume, and are designed to help patients become familiar with break-loose and glide forces.
- Resettable Safety Mechanisms – Designed for repeated use, demonstrators are intended to replicate the device safety and shielding systems with the capability for users to reset the mechanisms for repeated use.
- Replication – Demonstrators should be designed true to form and function and able to simulate all aspects of the patient experience including design form, colour adjustments, window size and actuation force.
- Needle Tip Simulation Option – Demonstrators should also offer the option to exhibit realistic injection simulation designed to simulate the “feel” and “forces” involved with an injection.

PLUNGER FORCE SIMULATION*

Replicate viscosity and plunger forces

RESETTABLE SAFETY MECHANISMS*

Designed for repeated use

NEEDLE TIP SIMULATION OPTIONS*

Realistic injection simulation



AGITATOR

ENCASED

BALL TIP

Magnified to reveal detail

DEVICE REPLICATION

True to form and function

NEEDLE SHIELD OPTIONS

- Rigid
- Soft

Figure 3: Noble offers a variety of innovative features designed to simulate BD UltraSafe™ with the goal of familiarising and preparing patients to self-inject.

BEST PRACTICES IN QUALITY

Noble adheres to a strict quality control process to ensure patients are provided with best-in-class demonstration devices. All device demonstrators are tested to guarantee that needle simulation and plunger speeds accurately mimic those of real drug delivery devices. By setting high quality standards when designing medical demonstrator devices, companies are able to prioritise user needs and translate those needs into effective onboarding solutions.

The industry will continue to evolve, giving patients opportunities to gain confidence in their treatments, overcome adherence barriers and, ultimately, achieve an improved quality of life. Through partnerships and collaborations that put the patient at the centre, like the relationship between Noble and BD, patients will have a better onboarding experience for treatment all the way to the last step when they administer their own medication. Industry leaders and partners who know the power of incorporating human factors into engineering and experiential training inspire the industry to innovate in design and onboarding practices, providing patients with better overall treatment options.

ABOUT THE COMPANY

Noble is a full-service, user-centric, advanced drug delivery training device and patient onboarding company. Noble works closely with the world's leading drug delivery device original

equipment manufacturers and pharmaceutical companies to develop educational and training solutions designed to provide positive patient onboarding experiences, reduce errors and improve patient outcomes.

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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, pharmaceutical and biopharmaceutical manufacturers. Mr Reynolds earned his Bachelor of Science in Business Administration from the University of Central Florida, a Master of Science in Marketing from the University of South Florida, and a Master of Science in Pharmacy and Master Certificate in Drug Regulatory Affairs from the University of Florida.

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BD has chosen Noble as its official partner to offer *true to form and function* prefillable syringe onboarding devices.

Enhance the patient onboarding experience with proprietary Noble technologies

Noble's Available Capabilities:



Customizable



Ergonomics



Packaging



User Guide



Travel Kit



AGITATOR



ENCASED



BALL TIP



1 mL Onboarding Device



1 mL BD UltraSafe
Passive™ Needle Guard

True to Form and Function™ Onboarding Devices Pre-configured for Speed-to-Market

Noble's prefillable syringe onboarding devices are custom-developed to match BD UltraSafe™ line of products customization and can also include proprietary needle simulation technology options.

Noble's best-in-class training program services include:

- Platform Evaluation and Development
- User Guide Development
- Launch Strategy Development
- Commercial Packaging Development
- Global Launch Preparation
- "Train-the-Trainer" Program
- Competitive Intelligence
- User Preference Research

*Noble Patents Pending



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