



## IMPROVING PATIENT EXPERIENCE WITH PREFILLED SYRINGES AND NEW ONBOARDING TECHNIQUES

In this article, Paul Sullivan, Associate Director of Business Development, Noble, outlines how the growing trend towards patient self-injection, outside of the clinical setting, places an ever greater emphasis on quality training and onboarding. Mr Sullivan specifically explains how such training can help overcome the issue of patient needle fear or anxiety.

The rapid growth of innovative biologic therapies, currently 20% of the pharma market and the fastest growing part of the industry,<sup>1</sup> has fostered the need for innovative drug delivery systems. This, combined with a strong trend towards patient self-administration

using prefilled syringes (PFS), has led to the growth of the PFS market, projected to reach global sales of \$7.9 billion by 2024.<sup>2</sup>

For some patients diagnosed with chronic medical conditions, self-administration using drug delivery devices is often a necessary component of a successful treatment programme. Every year, more patients are introduced to injection devices for home treatment. With self-injection comes a variety of emotional and environmental factors, potentially causing inconsistencies in treatment. Recent studies have shown that many patients are struggling to follow all of the required steps outlined in instructions for use (IFU) documents.<sup>3</sup>

### THE VALUE OF PROPER ONBOARDING

As the preference remains to self-administer therapy, pharmaceutical manufacturers, physicians, patient advocates, payers and

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other industry stakeholders have come to realise the importance of training programmes designed to help patients properly self-administer treatments in order to promote positive patient outcomes and effective disease management. Many studies suggest that without proper training during the onboarding process, defined as the first 30 to 90 days of treatment (Figure 1), patients are more likely to drop off from therapy or incorrectly use drug delivery devices, such as PFS and other forms of self-administration.<sup>4</sup>

A focus on the human factors at work here is crucial. Classical conditioning studies have shown that experience and familiarity reinforce patient behaviour. In contrast, uncertainty leads to a lack of adherence. All patients are aware of the long-term benefits of pharmacotherapy, however, although specific medications are effective in combating disease, their full benefits are often not realised because a substantial subset of patients do not take their medications as prescribed.



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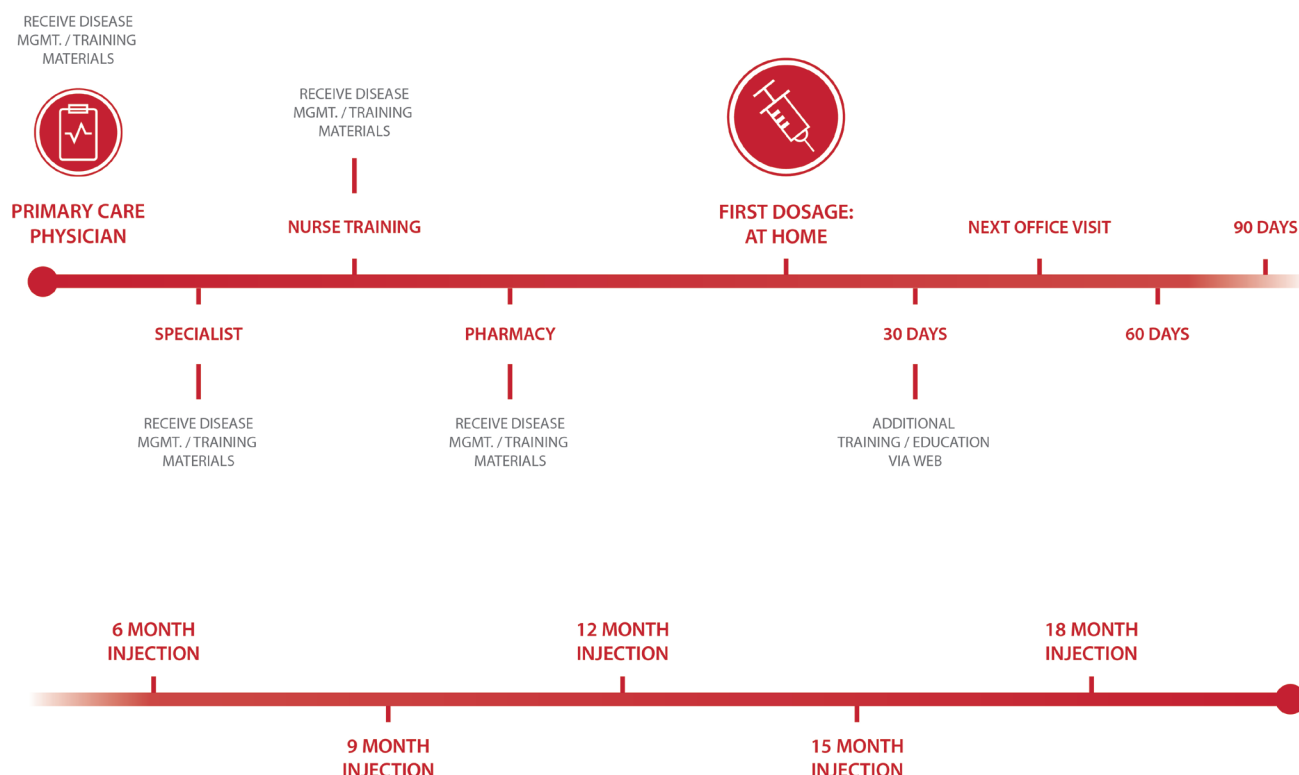


Figure 1: Timeline showing onboarding including initial and subsequent injections at different dosing frequencies.

“One specific form in which poor adherence can manifest itself is needle/injection anxiety, also known as belonephobia. Many people fear needle-sticks to some extent, but when this fear becomes persistent, excessive and unreasonable, the fear becomes a phobia.”

Factors contributing to poor medication adherence are myriad,<sup>5</sup> including but not limited to:

- Patient related:
  - Suboptimal health literacy
  - Lack of involvement in the treatment decision making process.
- Physician related:
  - Prescription of complex drug regimens
  - Communication barriers
  - Ineffective communication of information about adverse effects
  - Provision of care by multiple physicians.
- Healthcare system related:
  - Office visit time limitations
  - Limited access to care
  - Lack of health information technology.

### NEEDLE/INJECTION ANXIETY

One specific form in which poor adherence can manifest itself is needle/injection anxiety, also known as belonephobia. Many people fear needlestick injury to

some extent, but when this fear becomes persistent, excessive and unreasonable, the fear becomes a phobia. The problem arising from such phobia is exponentially exacerbated in patients who are called upon to perform self-injection using PFS devices.

Patients with needle anxiety require reassurance about the prevalence of needle fear and clarification about methods available to counter their reactions. Healthcare practitioners can communicate empathy and respect for the patient's feelings, and institute a number of potentially useful strategies to reduce the level of fear they are experiencing. Steps that have been proposed include recognition and relaxation techniques such as cognitive behavioural therapy; adoption of control and preparation strategies such as having a support person present during injection; and graded exposure.<sup>6</sup> The utilisation of innovative onboarding programmes can clearly serve as an integral component to successful patient compliance.

The benefits of innovation in PFS devices can be appreciated by assessing research undertaken to gauge the relationship between anxiety, injections and device training. According to a study published by Elsevier Science Ireland, injection anxiety could result in decreased compliance, leading to 45% of patients skipping or avoiding injections due to anxiety or fear.<sup>7</sup> Based on a literature review and R&D activities to develop the most effective PFS trainers (including a needle insertion force profile analysis, using cadavers and 18, 25 and 30 gauge PFS, performed at a Florida hospital), a study conducted by Noble further explored the relationship between anxiety, injections and PFS training devices that simulate real device characteristics.<sup>8</sup>

The aim of the study was to investigate whether needle-naïve participants using a PFS training device demonstrated decreased anxiety compared with users who did not utilise a training device. A total of 45 respondents were randomly assigned to one of three groups: participants receiving no training; participants receiving ‘traditional’ training (i.e. in-office training and IFU); and participants receiving traditional training plus a PFS training device. In addition, the participants were surveyed at three points in time: before, during and after the mock injection.

The study produced several notable findings. Most significantly, coupling traditional training methods with PFS

training devices utilising needle simulation technology was found to reduce anxiety over traditional training in isolation or no training at all. Feedback from the study reported that:

- 73% of users reported that only having IFU and no other training materials would increase their anxiety.
- 64% of users reported having a training device to practice with at home would help decrease anxiety.
- 89% of users reported it is very important to have the most realistic training possible.
- 87% of users reported it is important to have a needle tip that closely simulates a real needle.
- 89% of users reported a better understanding of a real injection when having a simulated syringe during training.

Advances in PFS training technology are clearly important with regard to how they simultaneously enhance the patient experience and reduce patient anxiety. In a Noble user study, designed to evaluate the effectiveness of training, participants completed a multi-step injection process, during which errors were observed and tabulated.<sup>9</sup> A post-injection interview and survey were conducted to evaluate the effects of training methods on confidence, anxiety and injection outcomes. Across all groups tested, independent of education, age, gender and salary, confidence increased and anxiety decreased in tandem with the extent of training use, while errors decreased with the use of error-correcting devices such as those provided by Noble's proprietary technology.

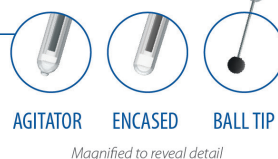
### SOLVING SELF-ADMINISTRATION CHALLENGES WITH EFFECTIVE TECHNOLOGY AND TRAINING

But how, specifically, can technology be integrated most effectively? Noble continues to push the boundaries of the answer, developing novel PFS trainers and

**PLUNGER FORCE SIMULATION\***  
Replicate viscosity and plunger forces

**RESETTABLE SAFETY MECHANISMS\***  
Designed for repeated use

**NEEDLE TIP SIMULATION OPTIONS\***  
Realistic injection simulation



**DEVICE REPLICATION**  
True to form and function

**NEEDLE SHIELD OPTIONS**  
- Rigid  
- Soft

**Figure 2: Noble offers a variety of innovative features designed to simulate BD UltraSafe™ with the goal of familiarising and preparing patients to self-inject**

onboarding platforms, in collaboration with device design companies, to help patients with both initial device training and the overall onboarding process (Figure 2). The goal of these initiatives is to counteract self-injection training decay to improve adherence and, ultimately, the therapeutic outcomes.

Some of the proprietary PFS training device enhancements at Noble include tailored plunger resistance and breakout forces, accurately simulating actual PFS resistances and drug viscosity, and needle insertion technologies, simulating needle sensation and force. These features habituate patients early on to the feel of the injection, enhancing its familiarity. Noble is collaborating with pharmaceutical teams to improve these outcomes through “true to form and function” platforms, including safety and standard PFS trainers as well as “Smart Injection Pads” (wirelessly connected error-correcting injection training pads used for instructing, tracking, monitoring and collecting data to assist in improving adherence).<sup>10</sup>

These error-correcting features are complemented by plunger force/viscosity

simulation, needle force and feel simulation, aimed to provide users with realistic simulation. Multisensory features, designed to provide patients with the most realistic simulation possible, include:

- Agitator needle simulation tips, designed to replicate the feel and forces involved for manual insertion.
- Resettable safety systems, allowing users to train multiple times prior to an actual injection.
- Device replication, designed to simulate all aspects of the patient experience, including:
  - design form
  - colour adjustments
  - window size
  - tactile feedback
  - cap removal force
  - actuation force.

The sophistication, attention to detail and level of functionality of these trainers offers several advantages over traditional saline solution injection demonstration procedures. Due to there being no actual injection involved, there is no risk for misuse during the training regimen. Also, it is more cost-effective to utilise a reusable device such as a trainer, rather than expend an actual syringe that must be discarded following the demonstration.

Research has also determined a link between device training and patient compliance. Based on a literature review and other activities, a study conducted by Noble sought to further explore the

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relationship between device training and patient compliance.<sup>11</sup> The objective was to investigate if compliance differs between patients who trained with a needleless training device versus those who did not.

The research consisted of a 31 question online survey to patients who regularly self-administer a prescription injection medication. Patients were asked detailed questions related to the training and onboarding of their injectable prescription drug. Amongst the findings it was discovered that:

- 61% of patients do not completely read the IFU.
- 56% of patients have never used a trainer.
- 90% of patients rated the value of a trainer “7” or higher on a scale of 1 to 10.
- 74% of patients reported that, in hindsight, they should have used a training device.
- As respondent age increased, the perceived value of device training increased.
- Patients who are recommended to use a trainer by their healthcare provider and use it as recommended are more compliant.
- Patients who use a trainer were found to be more compliant overall and less likely to discontinue treatment.

In light of all of these insights, and the continued growth of the PFS market, ensuring compliance will continue to be a priority. The future is likely to bring additional benefits to pharmaceutical companies and healthcare providers utilising innovative, realistic onboarding training methods and smart devices with PFS to help ensure optimal patient care.

## ABOUT THE COMPANY

Noble® works closely with the world’s leading pharmaceutical and biotechnology companies to develop autoinjector, prefilled syringe and respiratory device 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 production, in both regulated and non-regulated environments.

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## ABOUT THE AUTHOR

Paul Sullivan is Associate Director of Business Development at Noble, a product development company with a focus in designing and manufacturing drug delivery training and patient onboarding solutions. Prior to Noble, Mr Sullivan worked at Informed Medical Communications, as Director of Business Development and Client Service and before that, as a pharmaceutical sales representative with Procter & Gamble. He holds a Kinesiology degree with Honours from the University of Western Ontario, Canada.



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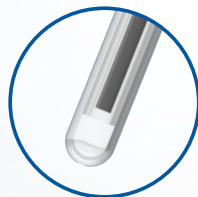
User Guide



Travel Kit



AGITATOR



ENCASED



BALL TIP



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