



PREFILLED SYRINGE DEVICE TRAINING: NOVEL APPROACHES & TECHNOLOGIES TO INCREASE PATIENT CONFIDENCE & DECREASE ANXIETY

In this article, Joe Reynolds, Research Manager, Noble, outlines some of the fundamental principles and benefits of training devices in the context of prefilled syringes, and highlights some specific training device technologies including novel needle simulators and angle aids.

As one of the oldest forms of drug delivery, the first medical application of syringes can be traced back to the 9th century where early embodiments were used as surgical instruments by Egyptian surgeons. For hundreds of years following their advent, syringes were largely viewed as surgical instruments until the nineteenth century and the discovery of early injectable compounds, including morphine and other analgesics. During the 20th century the commercial use and application of syringes as drug delivery devices grew exponentially.

Today, more than 50 biologic medications and vaccines are marketed and supplied in prefilled syringes.¹ Globally, more than 3.5 billion prefilled syringes are produced annually and used by patients and healthcare providers to treat a broad spectrum of conditions. In addition to currently marketed products, PhRMA estimates that more than 907 biologic medications and vaccines are currently in clinical development (Phase I-III) across more than 100 disease states, many of which will leverage prefilled syringes as the preferred delivery systems and primary containers.² As these products continue to augment and launch into new therapeutic sectors, training and education will remain a critical success factor that will determine a patient's ability to safely and effectively use prefilled syringes and adhere to therapy.

According to the World Health Organization (WHO), 50% of patients

diagnosed with chronic conditions do not take their medications as prescribed.³ While a number of factors contribute to patient adherence and therapy acceptance, confidence and anxiety are key external variables that influence patients' perceptions and attitudes toward medications and drug delivery devices.

These attitudes are largely established as patients onboard to therapy (i.e. their first 30, 60 or 90 days of treatments) and are key indicators of future behaviours and outcomes. During onboarding, research suggests that 45% of patients skip or avoid injections due to anxiety or fear.⁴ Due to these avoidance behaviours, many patients fail to realise the full therapeutic benefits of medications and ultimately discontinue treatment.

Over the past decade, advancements in science and technology have greatly improved our understanding of patient adherence and the value of training and education in relation to health outcomes. Historically, training and educational initiatives were largely supported by Instructions for Use (IFU), package inserts and other content-based collateral. While these materials are effective for select populations, it is estimated that only 12% of patients have proficient health literacy and the ability to manage their health and wellness with these materials, resulting in significant training gaps and treatment barriers for prefilled syringe users.⁵



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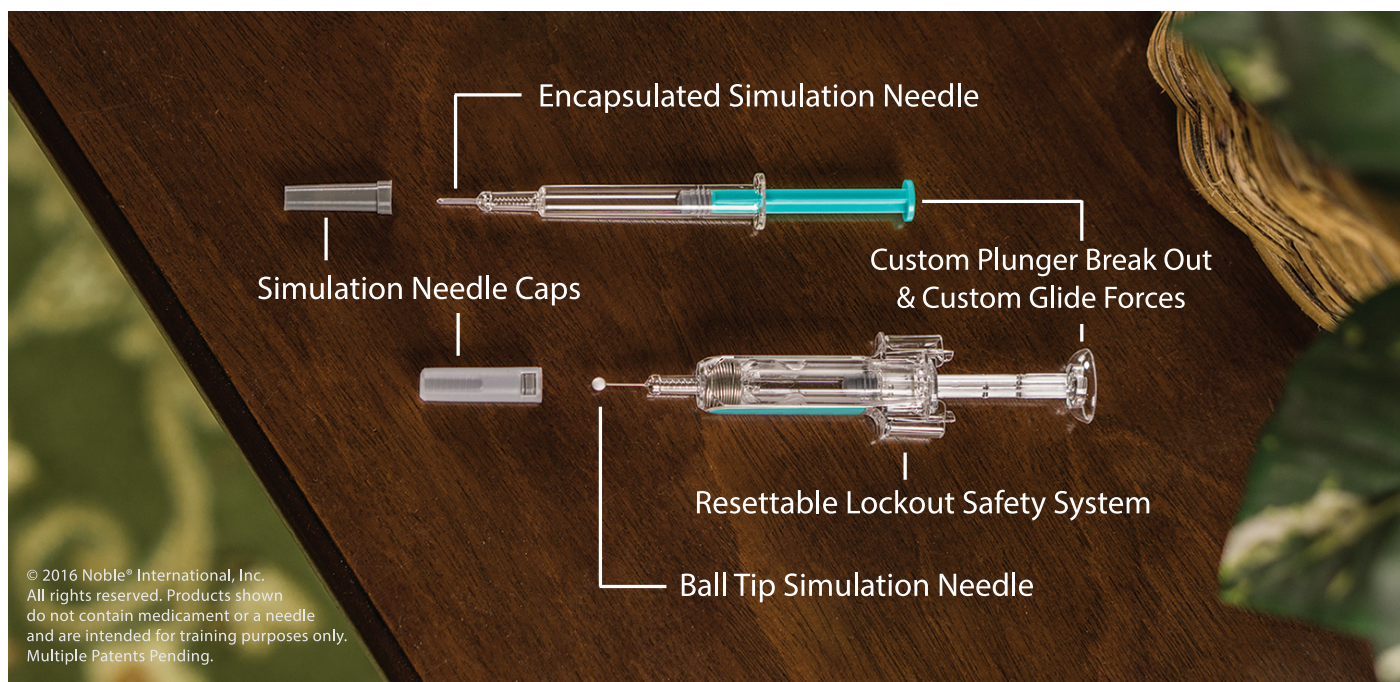


Figure 1: Training syringes simulate attributes of real syringes including: plunger break-out, glide forces for varying viscosities, volumes, resettable safety systems and other product-specific features to build confidence and proper administration behaviours.

In recent years, novel training strategies have emerged and greatly improved the patient onboarding experience through the use of training devices, multisensory packaging, angle aids and other ancillary support tools. By many industry standards, training devices have become the cornerstones of effective onboarding strategies by allowing patients and healthcare providers to learn safely how to use prefilled syringes and other forms of drug delivery device. Based on the findings of a recent user study, training devices can increase patient confidence indicators by 86% and decrease anxiety by 15%; two variables research suggests are closely related to adherence and outcomes.⁶

ESTABLISH MUSCLE MEMORY & ADHERENT BEHAVIOURS TO BUILD CONFIDENCE

As drug delivery devices, prefilled syringes have specific handling and operational requirements to support their intended use by patients and healthcare providers. In order to train and onboard users to prefilled syringes successfully, training devices must fully mimic the handling and operational requirements of commercial syringe experiences, which commonly include the following tasks:

1. Visually inspecting the syringe for damage, clarity and expiration
2. Selecting and cleaning an approved injection site (typically the thigh, abdomen

and/or the back of the upper arm for caregivers)

3. Preparing the prefilled syringe by removing the needle shield and priming and/or re-constituting/suspending, as needed
4. Inserting the needle at the proper angle (typically 90 or 45 degrees) and depth into a pinched or stretched injection site, as required
5. Fully depressing the plunger to deliver the prescribed dose of medication
6. Removing and properly disposing of the used syringe.

To maximise the value and consistency of training, training syringes (see Figure 1) can be further supported by multisensory or ancillary support tools to improve the perception, retention and recall of key usage behaviours. Such capabilities allow patients

to establish the muscle memory and motor skills required to build confidence and effectively use prefilled syringes.

NOVEL NEEDLE SIMULATORS REDUCE NEEDLE ANXIETY

Needle anxiety is a significant adherence barrier for patients using prefilled syringes and other forms of injectable drug delivery. Many of these associations are related to patients' negative perceptions of needles and past experiences with injections. This anxiety is often magnified when needles are visible, lengthy, or are of larger gauge.

To help reduce this anxiety and overcome the emotional barriers of self-injecting, novel needle simulation technologies have been developed to fully mimic the deformation, puncture and insertion force characteristics of various needle gauges, bevel

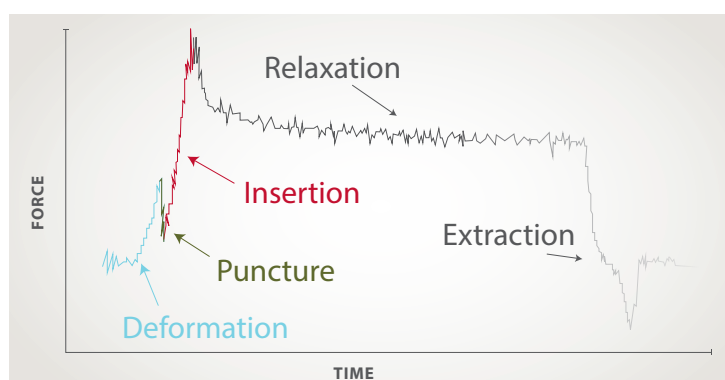


Figure 2: Needle insertion force graph depicting an injection from beginning to completion.

geometries and other key attributes (see Figure 2). When applied to prefilled syringe training, these proprietary technologies allow patients to safely learn the force and technique required to insert needles into the skin.

Key insertion behaviours captured in needle simulators include the following:

- Deformation: induced when the needle tip is in contact with the injection site. The force continues until a deflection at which the deformation force is maximised.
- Puncture: force related to the needle tip puncturing and entering the skin.
- Insertion: insertion force continues to increase in relation to the insertion depth and injection site characteristics.

ANGLE AID TRAINING SOLUTIONS TO IMPROVING DEPOSITION & INJECTION TECHNIQUE

Subcutaneous tissue is the lowermost layer of the integumentary system, consisting of connective and vascular tissues that support the absorption and systemic uptake of injectable medications. Clinical guidelines recommend that prefilled syringes be administered at 45° or 90° to achieve the optimal deposition for subcutaneous injections (Figure 3). Failure to achieve the proper injection depth can result in injection site pain and adversely affect the bioavailability and other pharmacokinetic properties of medications that reduce their overall efficacy or tolerability. To mitigate these risks, angle aids were developed to demonstrate proper needle insertion angles and techniques required to administer medications successfully. The geometry, form, angle, skin-pinch and features of these products are customisable based on the unique needs of patients and prefilled syringe platforms. To enhance the training experience further, feedback loops, spoken instruction, sensors and wireless technologies can be incorporated into angle aids to provide active learning experiences and collect data related to prefilled syringe training.

As noted by Tim McLeroy, Senior Manager at AbbVie (North Chicago, IL, US): “The goal of training is to decrease patient anxiety and increase confidence through hands-on experience.” From his industry experience, Mr McLeroy has found that “the patient’s first experiences with drug delivery devices can largely determine their outcome to therapy”. He said, “Self-injection is a lot like dating, if you have a bad first date, it’s difficult to want to go on the second one.”

Novel training technologies like simulation needles, angle aid tools, auditory packaging and other multisensory solutions help promote positive onboarding experiences and empower patients to lead healthier

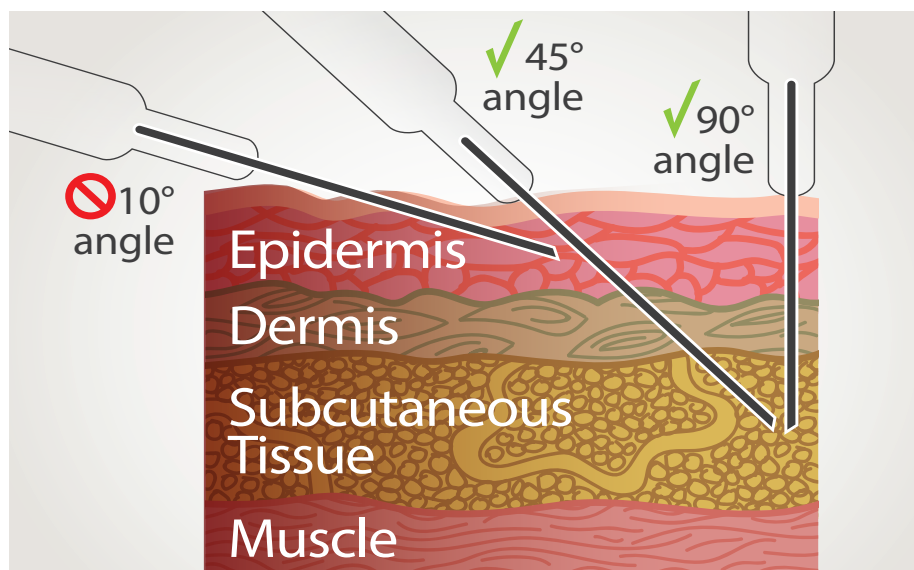


Figure 3: Recommended subcutaneous injection angles.

lives. In the modern era of patient-centric care, products that are able to provide superior onboarding and patient experiences will be well positioned and benefit by reducing patient errors, while improving patient satisfaction and outcomes.

ABOUT NOBLE®

Noble, the leader in onboarding and device training, is a patient-centred product development and manufacturing company. Noble works closely with the world’s leading pharmaceutical and biotechnology companies to develop educational and training solutions that improve the patient journey. Cross-disciplinary designers and engineers provide fully customised solutions from the first concept sketch through production in both regulated and non-regulated environments. Noble is headquartered in Orlando, FL, US.

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