



## NOVEL APPROACHES & TECHNOLOGIES TO INCREASE PATIENT CONFIDENCE & DECREASE ANXIETY

Building on his previous articles in *ONdrugDelivery* on training devices and drug delivery device education, here, Joe Reynolds, Research Manager at Noble, introduces some of the latest approaches Noble is pioneering, and technologies it is developing – such as needle simulators – to equip patients for confident, anxiety-free self administration of parenteral drugs, with positive knock-on effects on adherence and treatment outcomes.

As one of the oldest forms of drug delivery, the first medical application of syringes can be traced back to the ninth 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 19th 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.

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Today, more than 50 biologic medications and vaccines are marketed and supplied in prefilled syringes.<sup>1</sup> 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 (Phases I-III) across more than 100 disease states, many of which will leverage prefilled syringes as the preferred delivery systems and primary containers.<sup>2</sup> As these products continue to augment and launch into new therapeutic sectors, training and education will remain a critical success factor that determines a patient’s ability to safely and effectively use prefilled syringes and adhere to therapy.

According to the WHO, 50% of patients diagnosed with chronic conditions do not take their medications as prescribed.<sup>3</sup> 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, 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.<sup>4</sup> As a consequence of these avoidance behaviours, many patients fail to realise the full therapeutic benefits of medications and ultimately discontinue treatment.



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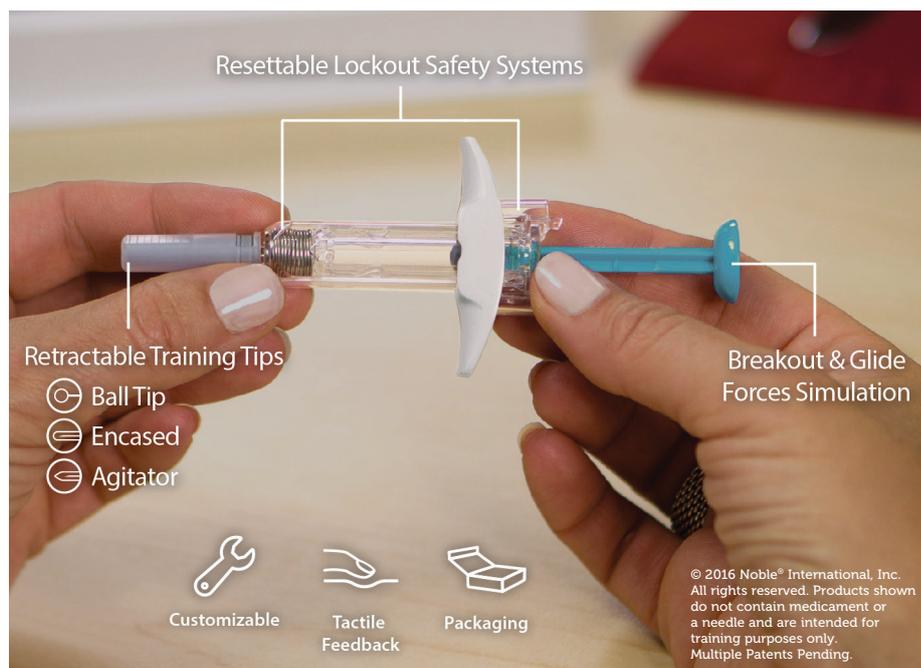
Over the past decade, advancements in science and technology have greatly improved our understanding of patient adherence and the value of training and education in relation to health outcomes. Historically, training and educational initiatives were largely supported by Instructions for Use (IFU), package inserts and other content-based collateral. While they 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.<sup>5</sup>

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 cornerstones to effective onboarding strategies by allowing patients and healthcare providers to learn how to use prefilled syringes and other forms of drug delivery devices safely. Based on the findings of a recent user study, training devices can increase patient confidence by 86% and decrease anxiety by 15%; two variables that research suggests are closely related to adherence and outcomes.<sup>6</sup>

## BUILDING MUSCLE MEMORY

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°) and depth into a pinched or stretched injection site, as required
5. Fully depressing the plunger to deliver the prescribed dose



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

6. Removing and properly disposing of the used syringe.

To maximise the value and consistency of training, training syringes (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 REDUCING 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 perception 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 mimic fully the deformation, puncture and insertion force characteristics of various needle gauges, bevel geometries and other key attributes (Figure 2). When applied to prefilled syringe training, these proprietary technologies allow patients to learn in safety the force and technique required to insert needles into the skin.

Key insertion behaviours captured in needle simulators include the following:

- Deformation. Induced when needle tip is in contact with 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. The insertion force continues to increase in relation to the insertion depth and injection site characteristics.

## ANGLE AID TRAINING SOLUTIONS IMPROVE DEPOSITION & TECHNIQUE

Subcutaneous (SC) 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 SC 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 tech 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”, and adds that “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 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 errors, while improving satisfaction and outcomes.

#### ABOUT THE COMPANY

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.

#### REFERENCES

1. Makwana S, et al, “Prefilled syringes: An innovation in parenteral packaging”. *Int J Pharm Investig*, 2011, Vol 1(4), pp 200–206. (DOI: 10.4103/2230-973X.93004)
2. “2013 Report: Medicines in Development – Biologics”. *PhRMA*, 2013. (Retrieved from <http://phrma.org/sites/default/files/pdf/biologicsoverview2013.pdf>)
3. Brown MT, Bussell JK, “Medication adherence: WHO cares?”. *Mayo Clin Proc*, 2011, Vol 86(4), pp 304–314 (DOI: 10.4065/mcp.2010.0575)
4. Zambanini A et al, “Injection-related anxiety in insulin-treated diabetes”. *Diabetes Res Clin Pract*, 1999, Vol 46(3), pp 239–246.
5. “Health Literacy Basics”. *USDHHS Fact Sheet*. (Retrieved from <http://health.gov/communication/literacy/quickguide/factsbasic.htm>)
6. Baker C, “Advanced Delivery Devices – Self-Administration Device Training: Incorporating New Technologies to Reduce Device Errors”. *Drug Development & Delivery Magazine*, April 2015.

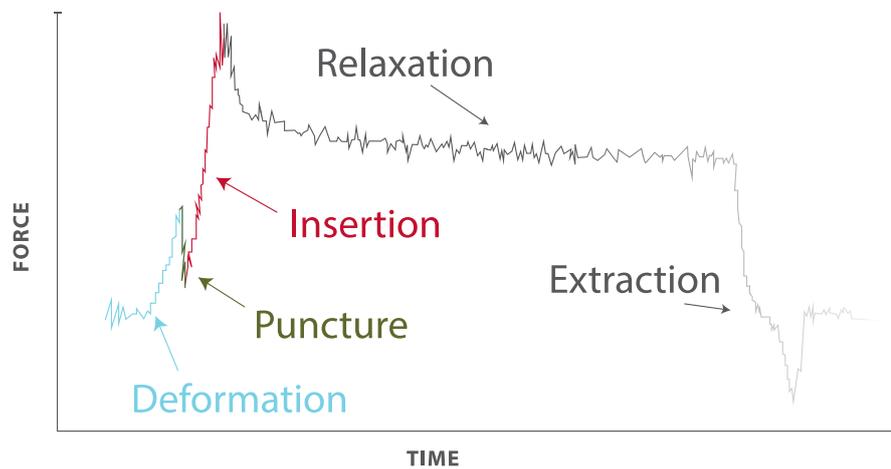


Figure 2: Needle insertion force from injection beginning to completion.

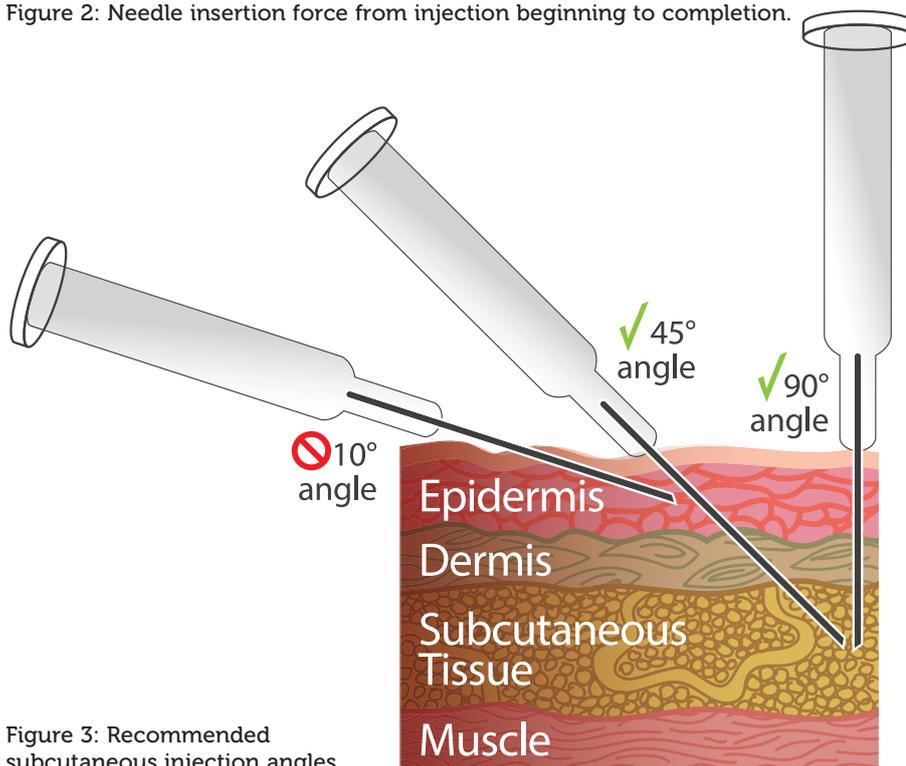
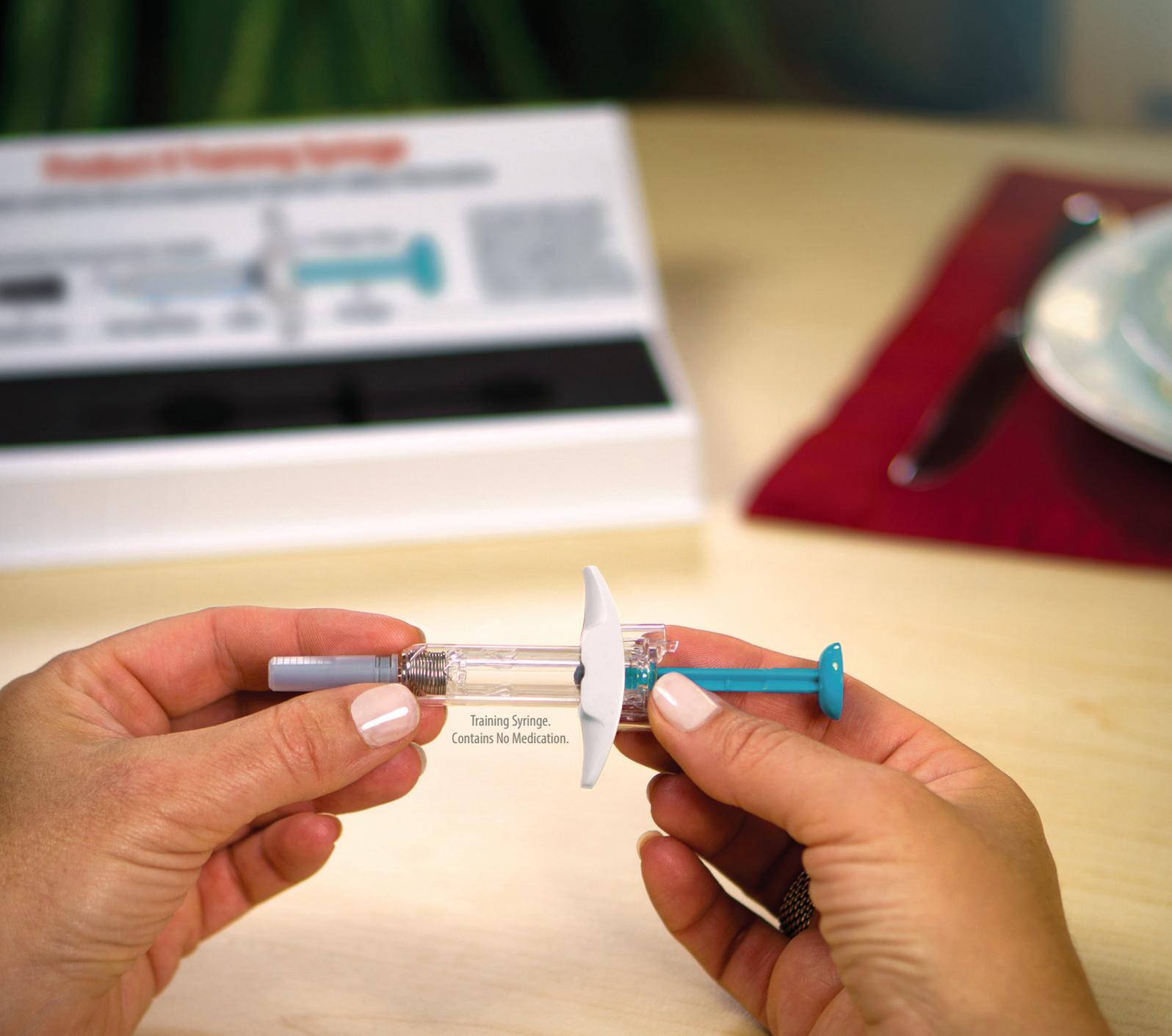


Figure 3: Recommended subcutaneous injection angles.

#### 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, pharma and biopharma brands. Mr Reynolds holds a BS in Business Administration from the University of Central Florida, an MS in Marketing from the University of South Florida and an MS in Pharmacy and Master Certificate in Drug Regulatory Affairs from the University of Florida.



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There's life beyond injections. Anxiety, confidence and understanding correct administration technique can all affect compliance. Findings reveal 45% of patients skipping or avoiding injections due to anxiety.<sup>1</sup> Another study suggests developing familiarity with self-injection through repeated exposure can reduce phobic symptoms.<sup>2</sup>

*Will your patients correctly administer their drug delivery device?*

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## Onboarding and Device Training

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References: 1. Zambanini, A., Newson, R. B., Maisey, M., & Feher, M. D. (1999). Injection related anxiety in insulin-treated diabetes. *Diabetes Research and Clinical Practice*, 46(3), 239-246. doi:10.1016/s0168-8227(99)00099-6. 2. Mohr, D. C. (2010). *The stress and mood management program for individuals with multiple sclerosis: Therapist guide*. Oxford: Oxford University Press.