

Nemera

INJECTION DEVICES & PAIN PERCEPTION

In this article, Severine Duband, Category Manager, Nemera, discusses the issue of patient comfort and pain perception in relation to injectable drug delivery and how the features of Nemera's two-step autoinjector, Safelia®, help take on this challenge.

Based on a presentation given by Séverine Duband at SMI's Prefilled Syringes West Coast Conference, San Diego, CA, US, June 4-5, 2018.

INTRODUCTION

In today's healthcare world, there is an ever-increasing emphasis on patient-centricity. A key aspect of this is pain perception; in order to be truly patient-centric, we must seek to minimise the pain experienced by the patient. With the shift towards moving healthcare out of the clinical setting and into the home as much as possible, designing devices with minimal pain perception becomes important than ever before, as it has a direct impact on a patient's willingness to administer their prescribed treatment.

FACTORS INFLUENCING PAIN PERCEPTION

The factors that play into the pain a patient perceives when administering a drug can be broken up into three categories based on their origin:

- The drug
- The user
- The device.

Factors Originating from the Drug

The first factor defined by the drug is the required volume to be injected. When considering prefilled syringes and autoinjectors, which typically inject their full payload in ten seconds or less, pain is most frequently associated with filling volumes of greater than 2.5 mL. Such devices rarely go above these volumes, with modern biologics

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requiring higher fill volumes targeting the wearable injector space, which tackles this problem via injection speed instead.

Secondly the formulation needs to be considered. There is limited relevant data on this subject, however it can be said that certain characteristics of formulation do have an impact on pain perception. One of the most notable of these, especially given the biologics market, is viscosity. Another factor known to have a direct impact on pain perception is the pH of a formulation.

Finally of consideration here is the injection site defined by the drug. The hypodermis is a highly variable tissue, significantly differing across body sites and skin types. For example, injection in the thigh is associated with a lower pain perception than injection in the abdomen. A secondary factor to this is injection depth, which may also play a role in how painful the injection is.

Factors Originating from the User

Injection speed is primarily a user-defined factor but is intrinsically linked to injection volume and can be influenced by device design. Slower injections are considered to



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be less painful. For example, 2 mL injected over 10 seconds would be more painful than 2 mL over 15 seconds, but less painful than 2 mL injected over 5 seconds. The total time is not the only aspect to consider however, the speed profile, in particular the beginning and end of the injection, also plays a role.

The temperature of a drug is another factor. Many drugs require refrigeration for storage but should be injected at room temperature to minimise pain perception. Patients often fail to follow instructions for use (IFU) in this regard and end up increasing the pain they experience because of it.

The patient themselves, naturally, a factor in this category. Every patient is unique, and part of that is how sensitive they are to injection pain. There are myriad aspects that play into this, as it is often a subjective

problem. A patient may experience higher pain because they are tense due to unfamiliarity with a device or simply because they have a lower pain threshold. Training is a potential solution to the former scenario and a pre-treatment with anaesthetic is a possibility for the latter.

User skill is the last factor originating from the user to mention. This is another ill-defined factor, with little in the way of significant data to suggest how much of an impact it has. However, it is worth mentioning that for a device to be patient-centric, it should aim to minimise the skill level required for optimal use and ensure that painful mistakes, such as needlestick injury, are rare or impossible.

Figure 1: Nemera's Safelia® two-step autoinjector.



Factors Originating from the Device

When discussing injection devices, the most obvious device-derived factor influencing pain perception is the needle itself. Thinner needles with five bevels are associated with lower pain perception. The needle insertion speed is a difficult factor, as it varies from patient to patient whether faster or slower insertion is associated with less pain.

The device type may also be a factor, although no relevant clinical data is available. It is however worth considering that patients may display a preference for prefilled syringes, pen injectors or autoinjectors and subjectively associate their favourite with less pain. The device type also defines the designer's ability to build in systems to control other factors.

Device human factors studies also show that a device without proper feedback leads to patient anxiety and stress, thus often increasing pain perception. To minimise pain perception a patient should be able to be sure that the needle has been inserted correctly, when an injection starts and finishes and that the full payload of drug has been delivered, all of which should be done in a way that is not upsetting or disturbing for the patient.

NEMERA'S SOLUTION – SAFELIA®

To optimise patient comfort, Nemera has designed the award-winning Safelia® two-step autoinjector (Figure 1). Safelia® works by the patient simply removing the rigid needle shield and applying the autoinjector to the skin, with a single click

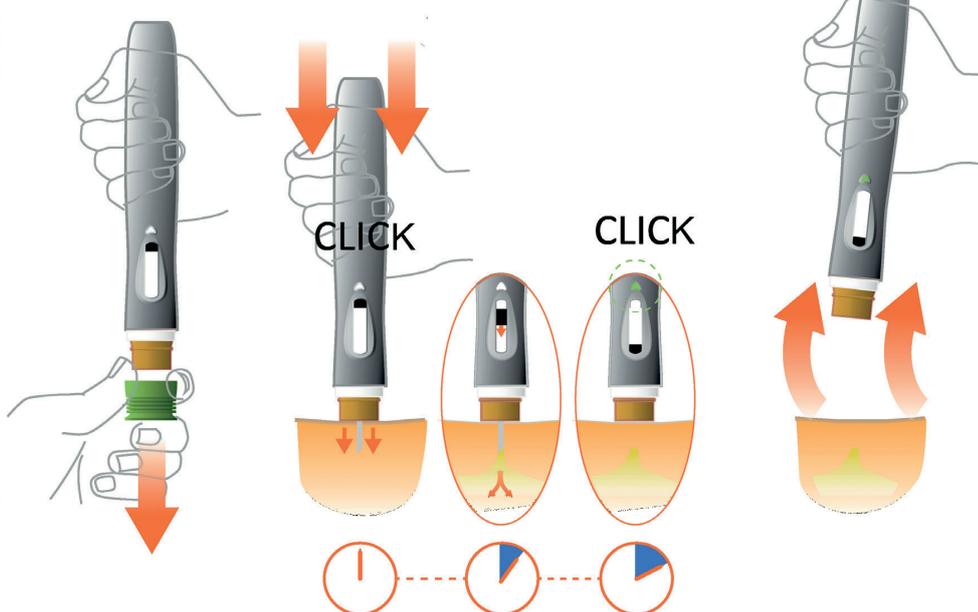


Figure 2: Operation of Safelia®.

“To optimise patient comfort, Nemera has designed the award-winning Safelia® two-step autoinjector.”

signalling proper needle insertion at the start of injection and a second click to signal complete delivery at the end of injection (Figure 2). Safelia® is compatible with 1 mL and 2.25 mL prefilled syringes, is able to deliver extremely viscous (>100 Cp) formulations and is highly customisable to formulation and patient requirements.

Safelia® has been designed to optimise patients' self-injection experience whilst allowing for tailoring of the injection to deliver even the most challenging drugs. What makes Safelia® different from other autoinjectors?

1. A powerful engine – To deliver viscous formulations through thinner needles in 15 seconds or less.
2. Limits the risk of glass breakage – Force transmitted on the syringe shoulder instead of the flange.
3. Delivery of the right dose at the right depth – Disconnection between the needle insertion and the injection.
4. Thinner needles for patient comfort – Reduced needle gauge and tailored needle insertion and injection speed.

5. Safety – The needle is never exposed throughout automatic needle insertion, delivery and needle retraction.
6. Ergonomic and easy to handle – for optimal patient comfort.

Safelia® uses a cam-based design in order to enable control of several injection process parameters (Figure 3). The cam allows tailoring of both needle insertion and injection speeds, as well as disconnecting needle insertion from the injection itself, which allows for fine control of the needle insertion depth. These factors are key in being able to design in lower pain perception for patients, along with more obvious factors like Safelia's ability to use thinner needles.

CONCLUSION

Whilst there is little in the way of concrete data concerning patient pain perception due to its highly subjective and variable nature, it is nonetheless a key factor to manage when designing a patient-centric device. Several factors affecting pain perception can be influenced by the device design, such as thinner needles, controlled needle insertion speed, precise injection depth and tailored injection profiles. There are further factors that require exploration, but Nemera has made a strong start with its Safelia® platform.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacture of drug delivery devices for the pharmaceutical, biotechnology and generics industries. Nemera's services and products cover

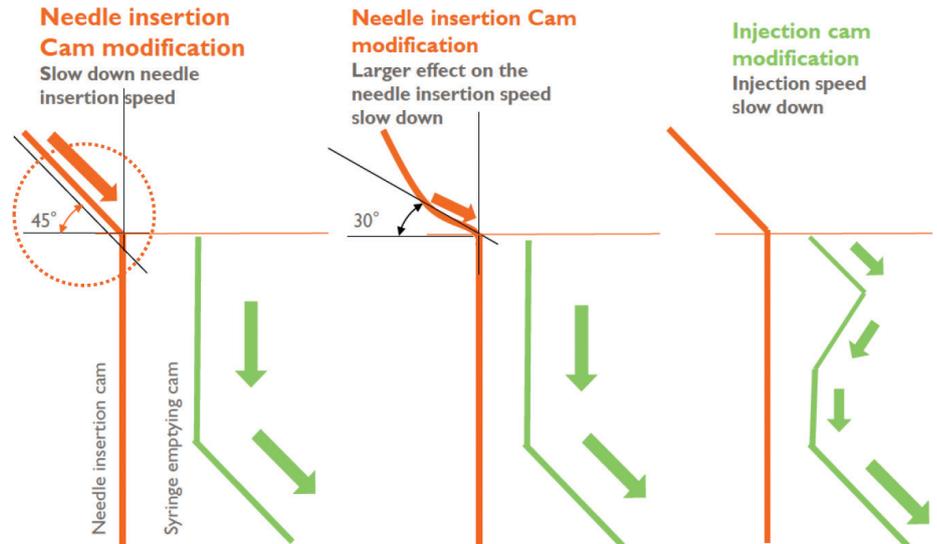


Figure 3: Safelia's cam-based design.

several key delivery routes:

- Parenteral (autoinjectors, pens, safety devices & implanters)
- Ophthalmic (multi-dose, preservative-free eyedroppers)
- Nasal, buccal, auricular (pumps, valves and actuators for sprays)
- Inhalation (pMDIs, DPIs)

- Dermal and transdermal (airless & atmospheric dispensers).

Nemera always puts patients first, providing the most comprehensive range of devices in the industry, including innovative off-the-shelf systems, customised design development, and contract manufacturing.

ABOUT THE AUTHOR

Séverine Duband is Category Manager at Nemera in charge of the parenteral range of proprietary products including Safe'n'Sound®, the passive safety device platform for prefilled syringes. Ms Duband joined Nemera in 2018. She has ten years' marketing experience in fast-moving consumer goods with key competencies including strategic planning, NPD launches, project management, brand communication and team leadership in an international environment. Ms Duband has a Masters in Science in Business Marketing from EMLYON Business School, Lyon, France.



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