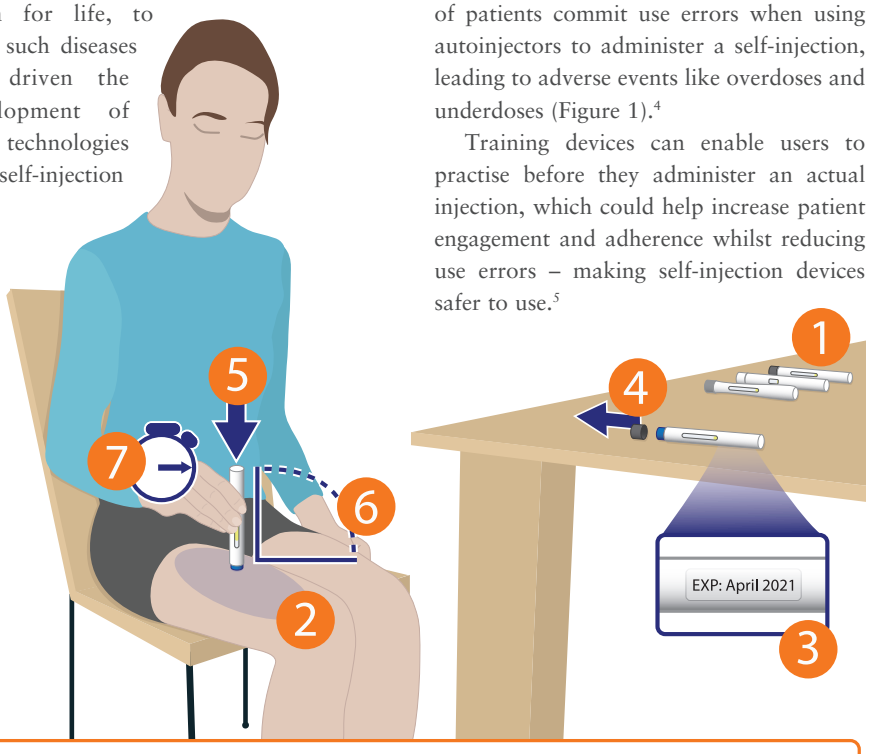
DESIGN CONSIDERATIONS FOR IMPROVING TRAINING DEVICE SAFETY AND EFFECTIVENESS

In this article, Yvonne Limpens, Managing Human Factors Specialist, and Brenda van Geel, Senior Human Factors Specialist, both of Emergo by UL, explore the design considerations that need to be taken into account when developing training devices that are safe and effective – and support patients in learning how to administer an injection correctly.

Globally, an increasing number of people are depending on injectable medications. The expectation is that the value of the injectable medication delivery market will surpass the oral medication delivery market by 2026. This is due to the high prevalence of chronic diseases such as diabetes and multiple sclerosis and the fact that the novel therapeutics to treat them are biologics, which are not readily suited for oral delivery and are therefore injected. The need for repeated dosing over prolonged periods, often for life, to treat such diseases has driven the development of new technologies and self-injection devices, leading to the emergence and rapid growth of products for self-injection.[1,2]

You might think self-injection devices are relatively simple and safe to use. However, they are typically used by patients who don't have any specific clinical knowledge and, therefore, the US FDA considers self-injection devices, like autoinjectors, to be among the medical devices on the market with the clearest potential for serious harm resulting from use error.[3] Furthermore, research has shown that 84% of patients commit use errors when using autoinjectors to administer a self-injection, leading to adverse events like overdoses and underdoses (Figure 1).[4]

Training devices can enable users to practise before they administer an actual injection, which could help increase patient engagement and adherence whilst reducing use errors – making self-injection devices safer to use.[5]



1. Selecting an incorrect injection device (i.e. differentiate between injection devices)
2. Selecting an incorrect injection site
3. Not performing the safety checks (i.e., expiration date, damage, drug colour)
4. Not removing the device's cap prior to an injection
5. Not activating the injection device
6. Administering the injection at an incorrect injection angle
7. Holding the injection device against the skin too short (not delivering the full dose)

Figure 1: Common use errors observed during Emergo by UL-led usability testing of self-injection devices.

Yvonne Limpens
Managing Human Factors Specialist
T: +31 307 998 566
E: yvonne.limpens@ul.com

Brenda van Geel
Senior Human Factors Specialist
T: +31 307 998 566
E: brenda.vangeel@ul.com

Emergo by UL
Arthur van Schendelstraat 600-G
3511 MJ Utrecht
The Netherlands

www.emergobyul.com

"Focusing on user needs and potential risks early in the design process helps lead to successful development of devices that are safer by design."

To understand the training device's design requirements, it's best practice to adopt a user-centred design approach. Focusing on user needs and potential risks early in the design process helps lead to successful development of devices that are safer by design. This can be done by involving users at an early stage within both the injection device and training device development processes to provide a comprehensive understanding of the intended use, users and use environment.

UNDERSTAND THE USE, USERS AND TRAINING ENVIRONMENT

While it might be obvious that training devices reduce use errors, there's not one training device that "fits all". Imagine you're diagnosed with diabetes and require daily injections of insulin. A healthcare provider (HCP) demonstrates how to use the injection device. The following morning you start using the device to self-inject insulin.

Now, imagine you're diagnosed with a severe allergy and are prescribed an injection device to use in an emergency. Your HCP demonstrates how to administer the injection but you might not need to use the device for the next few weeks, months or even years.

"How do you develop a training device that's sufficiently representative but remains differentiable from the actual device?"

These two scenarios clearly illustrate that training needs can significantly differ. Specifically, the insulin training device will likely only be used when the HCP trains the patient how to use the device while providing verbal guidance. The emergency training device might be used in a home setting and the allergy sufferer might use the training device periodically for an extended period without any additional guidance from an HCP. As such, it's important to understand the training device's intended use, users and environment (Table 1).

THE NEED FOR REALISM AND DIFFERENTIATION

Everyone will understand that a training device should be very similar to the actual device in its look and feel (i.e. same size, shape, material) and act the same as the actual device (e.g. user activation method, accurate force application) – but should not contain a needle or medication. However, a training device that is very similar to the actual device could also introduce new use errors. A key example would be the need for users to distinguish between the training device and the actual device, especially in an emergency-use scenario.

As such, the question is: How do you develop a training device that's sufficiently representative but remains differentiable from the actual device? The answer depends on the user interface and risk assessment for the device in question. Specifically, one must consider essential device features on which the user must be trained and features whereby the training device provides risk control, as well as features that help distinguish between the training device and the actual device.

Intended use	What the use of the device will be How frequently the device will be used What the training program and process will look like
Intended users	Who the training device's users are
Intended training environment	Where the training device will be used

Table 1: Questions to understand the training device's intended use, users and training environment.

Training devices aren't only a way to reduce use errors through practice – they can also be developed to support users in self-correcting use errors. For example, if users need to hold the injection device for five seconds to administer an injection, a training device could teach users to hold the injection device for exactly five seconds. However, the speed with which we count isn't always very accurate. Developing a training device that teaches users to hold the injection device for a little longer by means of audible feedback, for instance, might ensure that users hold the device for a sufficient amount of time to complete the injection. The training device doesn't simply need to mimic the actual device but could truly support users in learning how to administer an injection correctly.

TRAINING DEVICE DESIGN CONSIDERATIONS

Below, we discuss some general and device-specific design considerations that could support manufacturers in developing a training device that's safe, effective and representative of actual use but also sufficiently different from the actual device.

Colour & Labelling for Easy Differentiation

It's important to differentiate the training device from the actual device to ensure users don't accidentally use the training device when they need to administer a real injection. An easy way to differentiate training devices from actual devices is to use colour. A different colour could be used for the device's hardware elements (e.g. cap and/or body) or for the device's (on-product) labelling.

However, medication is frequently available in different strengths and/or variations (e.g. dosage form, administration route) which is also often reflected by use of different colours and/or graphical elements. Therefore, additional means might be warranted for users to be able to successfully differentiate between the training device and actual devices of various strengths – like a "TRAINER" label and/or a written explanation of its use.

Tip: Some visual impairments (e.g. colour blindness) impact users' ability to differentiate between devices based on labelling and colour. As such, take these into account when developing a training device with colour differentiation (Figure 2).

Figure 2: Colour and labelling variations impact users' ability to differentiate between training and actual devices, including visual deficiencies such as red-green colour blindness.

Internal Reactivation Mechanism for Repeat Use

Users may practise injecting repeatedly. That's why it's important to consider how the training device can be reactivated. Considering the users' manual capabilities and how frequently they will use the training device will help to determine which reactivation feature(s) would be optimal. For example, if the training device will mainly be used by HCPs to train multiple patients a day, a very durable, robust, ergonomic and efficient reactivation feature will help the HCP to use the training device effectively when used frequently. This might be of less importance when the training device will only be used sporadically by a patient at home.

Tip: Dexterity impairments might impact users' ability to interact with and reactivate the device (e.g. the reactivation feature requiring a certain force). Therefore, it's important to consider potential dexterity impairments when developing a training device.

Representative Sensory Feedback

Several self-injection devices provide sensory feedback (e.g. visual, audible and/or tactile feedback). Some devices produce an audible "click" to indicate that medication delivery has started, and another "click" when it has finished. It's essential to replicate sensory feedback in the training device and ensure that changes made to device features that facilitate training purposes – such as reactivation features – don't elicit additional or different feedback. Any different sensory feedback might confuse users when using the actual device to administer an injection.

Tip: Hearing impairments might impact users' ability to hear audio feedback provided by the training device. As such, consider various hearing impairments that might be prevalent in your intended user group(s) when developing a training device.

Guidance on Use Sequence & Injection Performance

Patients who interact with the training device under the supervision of an HCP should receive guidance and feedback on their performance from the HCP. Therefore, HCPs have the opportunity to correct any mistakes patients make. Alternatively, patients who use the training device independently might not have received such training from an HCP or might forget their instructions and continue training independently at home. For such expected use cases, it's important that the training device guides users in learning how to administer a correct injection in lieu of an instructor. This is particularly important when developing a training device for emergency use where there is rarely an instructor in real use and it concerns a life-and-death situation.

The most straightforward guidance on use sequence and injection performance would be through labelling – such as clear, written instructions supplemented by illustrations. These documents are useful but have limitations because users need to locate and comprehend the necessary information. More advanced yet promising guidance employs sensor-based error correction technologies that use visual and audio feedback to guide users through the injection process, while communicating their performance (e.g. committed use errors).

"More advanced yet promising guidance is sensor-based error correction technologies that use visual and audio feedback to successfully guide users through the injection process, while communicating users' performance."

Such technology could be implemented in the training device itself or developed as part of multisensory smart packaging or smart device applications.

Visual Inspection of Medication & Delivery Confirmation

In some cases, visually inspecting the medication for discolouration prior to injection is considered a critical use-step. Users might also need to visually inspect the plunger after administering the injection – to determine if the medication was delivered. In pen injectors and autoinjectors, visual inspection can be done through a so-called viewing window. There are currently training devices on the market that, unlike the actual device, don't contain a viewing window. In addition to colour and labelling differentiation, the absence of a viewing window might be a strong design feature that supports users in differentiating between the training device and actual device.

The decision as to whether to outfit the training device with a viewing window depends on whether visual inspection is considered a critical task that's mitigated by this design feature. If checking the viewing window to ensure the medication was delivered is a critical task, then developing a training device with a viewing window might be essential.

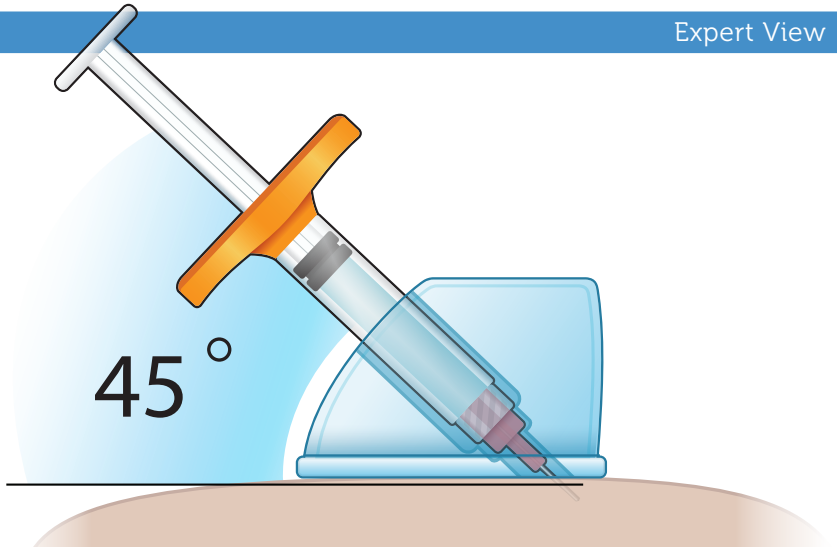


Figure 3: Component teaching users to inject at the prescribed injection angle.

Assistance with Injecting at Prescribed Angle

Depending on the injection device type and its intended use (e.g. formulation, injection site), injections are administered at different angles (i.e. 90°, 45°, 25° or 10-15°). One commonly observed use error is that users don't always achieve the prescribed injection angle. Supplying the training device with a component that guides users into positioning the training device at the prescribed injection angle will likely help users to understand the correct angle. Equipping the actual device with such a component might obstruct the user's view during injection and increases production costs (Figure 3).

[Continues...]

Instructional Information Highlighting the Differences

A training device will evidently differ from the actual device in one or multiple ways. Therefore, it's essential to communicate the extent to which the training device is similar to and differs from the actual device. Training devices that are expected to be used without any guidance from an HCP will require more comprehensive, yet still inclusive, written information highlighting these similarities and differences.

For training devices that are being used by or under the supervision of HCPs, condensed written information might be sufficient because HCPs can verbally communicate the differences to patients as needed. Furthermore, the information that will be provided should be tailored to its users. For example, use of clinical jargon is acceptable for HCPs, whereas it isn't for users without clinical knowledge or prior injection experience.

CONCLUSION

Developing a training device that's safe and effective – and supports users in learning how to administer an injection correctly – requires a comprehensive human factors engineering (HFE) approach. Involving users throughout the training device's development process – and thinking through the use and environment – is fundamental in developing an optimal training device that can truly support users in learning how to administer an injection correctly and that doesn't elicit additional use errors.

ABOUT THE COMPANY

Emergo by UL is a regulatory consultancy specialising in medical device, combination product and IVD compliance. Its human factors research & design global team specialises in early-stage user research, product design, usability testing and user interface design.

REFERENCES

1. *"With Prevalence of Chronic Diseases, Global Self-injection Device Market To Grow At Rapid Pace; Market To Research Valuation Worth US$11,380.9 MN By 2026". Press Release, Transparency Market Research, January 2019.*
2. *"Global Injectable Drug Delivery Market Size Will Reach USD 640.50 Million by 2021: By Device Type, End-user, Application and Region". Press Release, Zion Research, October 2016.*
3. *"Draft Guidance for Industry: List of Highest Priority Devices for Human Factors Review". US FDA, February 2016.*
4. *Potera C, "Misuse of Autoinjectors and Inhaler". American J Nurs, 2015, Vol 115(3), p 17.*
5. *Miller E, "Training Devices Increase Patient Engagement and Adherence – Creating Better Outcomes". ONdrugDelivery Magazine, Issue 97 (May 2019), pp 47-50.*

ABOUT THE AUTHORS

Yvonne Limpens is a Managing Human Factors Specialist with Emergo by UL's Human Factors Research & Design team. She has been with the team since 2013 and has experience delivering HFE services to the medical device, pharmaceutical and laboratory equipment industries. Yvonne leads research activities, and helps clients develop key HFE documents for their design history files, including use-related risk analyses. Furthermore, she advises and trains clients on how to apply HFE during product development to meet regulators' expectations. Yvonne holds a BSc in Industrial Design and an MSc in Human Technology Interaction from Eindhoven University of Technology (The Netherlands).

Brenda van Geel is a Senior Human Factors Specialist with Emergo by UL's Human Factors Research & Design team. She has been with the team since 2016 and has experience delivering HFE services to the medical device and pharmaceutical industries. Brenda is involved in a variety of research and design activities, including conducting usability tests, developing key HFE documents, designing safe and satisfying user interfaces and instructional materials, and identifying user needs and improving overall user experience through user research. Brenda holds a BSc in Architecture and an MSc in Design for Interaction from Delft University of Technology (The Netherlands).