Safety pen needles – take control

Addressing challenges in the practical setting with a new generation of safety pen needles

Highlights

The legislative background: increasing prevalence of sharps regulations stresses the importance of workplace safety for healthcare professionals

Safety pen needle use: understanding the challenges for users, including uncertainty about delivering the full medication dose

Research insights on user experience: healthcare professionals are looking for a balance of safety and control of the drug delivery during the injection process

The latest development: an introduction to the next generation of safety pen needles as a new approach for healthcare professional needs

An innovative design: a new safety mechanism developed to balance protection against needlestick injuries and control during the delivery of the full medication dose

Owen Mumford

Current trends explained: the hazards, the legislation, and the impact on injection practice

Needlestick injuries – the numbers and the consequences

Healthcare professionals (HCPs) are at high risk of needlestick injuries (NSIs)[1]. Although NSIs can be prevented, they are a major occupational hazard, especially for nurses[1].

UP TO

69.4%

Depending on the country and setting, 14.9–69.4% of HCPs experienced NSIs[2]

In the USA, injections accounted for **23.6%** of NSIs[1]

In a survey of 24 hospitals in France, **92.9%** of NSIs from injection pens occurred after completion of the injection[3]

In the UK alone, 3,396 significant occupational exposures involved percutaneous NSIs between 2004 and 2013[4]. When blood contact is involved, NSIs pose the additional hazard of disease transmission via bloodborne pathogens like HIV or hepatitis B and C viruses[4]. Worldwide, exposure to contaminated sharps cause 37–39% of hepatitis B and C infections in HCPs[2].

Even if HCPs test negative for a bloodborne disease after an NSI, the psychological and physical damage to the individual can be substantial[2]. The economic cost for the healthcare industry related to injury claims and treatment further adds to the importance of HCP safety in the workplace[1,2].

Safety regulations to reduce sharps injuries

As a priority for employers and HCPs, NSI prevention is reinforced by an increasing prevalence of legislation globally. In 2001, the US Occupational Safety and Health Administration (OSHA) revised their Bloodborne Pathogens standard in response to Congress publishing the Needlestick Safety and Prevention Act. The OSHA standard states that safety "engineering and work practice controls shall be used to eliminate or minimize employee exposure", such as the use of sharps with a safety-engineered injury protection mechanism[2,5].

In Europe, the EU Council published "Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector"[6]. Since then, governments have introduced related laws and regulations to help protect HCPs, but regulations alone cannot guarantee HCP safety.

The real difference is made in the practical setting, and with the regulations in place, decision-makers in hospitals will find it necessary to review internal health and safety policies regarding safe use of sharps to eliminate and prevent the risk of NSIs, with safety engineered devices being key to reducing the likelihood of NSIs[1].

The trend towards injection pen use and continuity of care

Since their introduction in the 1980s, injection pens have been used in a wide range of therapy areas such as infertility conditions, osteoporosis, growth hormone deficiency, and mostly type 1 and type 2 diabetes.

To manage their diseases at home, patients have adopted injection pens for delivering medication. However, despite injection pens being increasingly favoured by both patients and HCPs[7], hospitals predominantly use syringes and vials[7]. This disparity in injection method can confuse patients when faced with having their treatment administered during hospital visits[7].

In hospitals that have adopted injection pens, the trend towards using these devices aligns with HCP preference. Compared with syringes and vials, HCPs experience greater satisfaction with injection pens for several reasons:

- HCPs believe it takes less time to teach patients how to self-inject, and feel more confident that patients deliver the required dose[8]
- Injection pens add value to the continuity of care because patients can replicate the hospital experience and self-inject with greater confidence and treatment adherence[7]
- People with diabetes who use injection pens suffer fewer hypo- and hyperglycaemic events, which, in the hospital setting, is a challenge for clinicians and correlates with poor patient outcomes[7]
- Nurses in the USA spend less time preparing and administering a dose with injection pens, improving their workload[8]

However, a study in France also identified that injection pen use correlates with a higher rate of NSIs amongst HCPs who give injections[3].

In response, manufacturers have developed safety pen needles which, when used with injection pens, help protect HCPs against NSIs.

While supporting the implementation of sharps regulations, safety pen needles come with challenges of their own.

Injection pen users: concerns about dose accuracy and research insights on challenges

Managing dose delivery with safety pen needles

Safety pen needles are used to protect against NSIs. Until recently, passive safety pen needles have been the only safety-engineered alternative to conventional pen needles, ensuring that the needle is covered before and after injection. Due to the design of passive safety mechanisms, some users find it hard to see the needle, and also need to adopt a different injection technique to conventional pen needles.

Moreover, the passive safety mechanism can activate before the full medication dose is delivered, and without the HCP's knowledge. This can happen before or during injection if the safety pen needle is lifted off the skin by accident, for example:

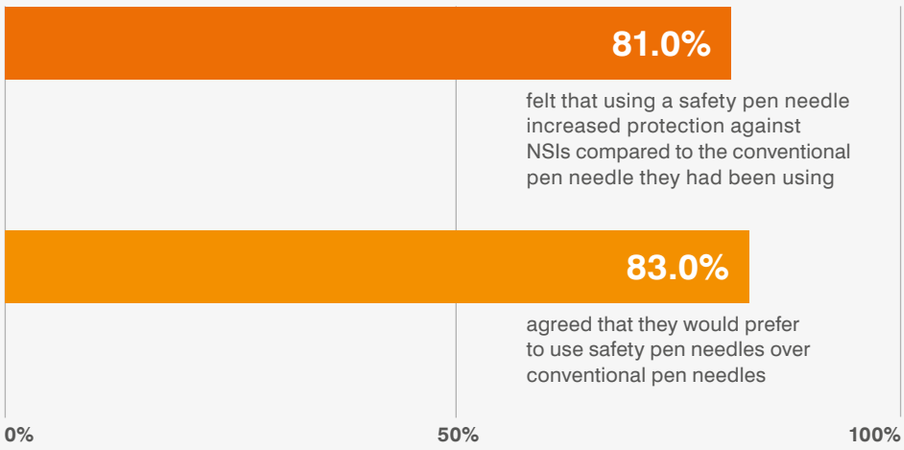
- when the injection site and angle are difficult to see because of how the skin folds
- when the patient withdraws or pulls away from the needle
- when the HCP lets go of the pinched skin prematurely

Events like these may affect the delivery of the full drug dose and, if unnoticed, may also interfere with the standard of patient care; both cause concern for HCPs. A thorough understanding of potential challenges is therefore relevant for enabling good injection practice and confidence in medication delivery.

To gain a comprehensive understanding of the challenges for HCPs using passive safety pen needles, detailed insight was gathered by an independent research company specialised in medical devices.

Pen needle preferences of healthcare professionals – research insights[9]

An online survey answered by 204 HCPs (from the USA, UK, and France) who were using passive safety pen needles confirmed that they were concerned about NSIs and preferred to use this needle type:



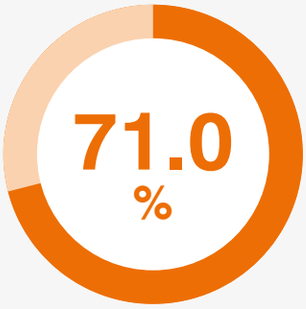
Despite this preference, HCPs faced challenges with these safety pen needles[9].

A closer look at passive safety pen needle use[9]

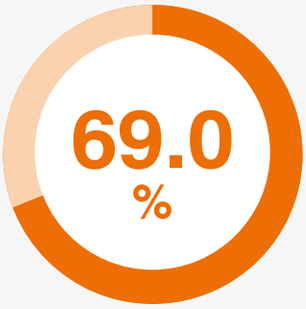
Initially, the majority of HCPs were satisfied with their current safety pen needle. However, a closer look at their responses revealed issues with needle visibility, control over the injection process, and standard of patient care.

When asking HCPs about passive safety pen needles:

- **39.7%** agreed that they can't see the needle as well as they would like
- **40.7%** agreed that they did not feel as much in control of the injection process as they had with the conventional pen needle



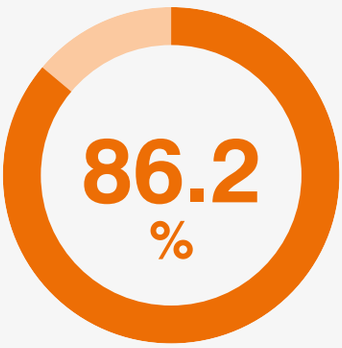
agreed that the safety pen needle activates before they have finished administering the injection



agreed that premature activation of the safety pen needle makes them unsure that the full medication dose has been delivered to their patient (of the 71.0%)

Also, **48.0%** agreed that premature activation of the safety pen needle makes delivering a consistent standard of care to their patients difficult (of the 71.0%).

Currently, all safety pen needles on the market rely on passive activation of the safety mechanism – except for one.



agreed that it is equally important for their pen needle to provide them with a combination of safety and control of the drug delivery during the injection process

Both safety and control are key elements of clinical best practice, yet HCPs could only choose between compromising safety for control (with conventional pen needles) or control for safety (with passive safety mechanisms) – until now.

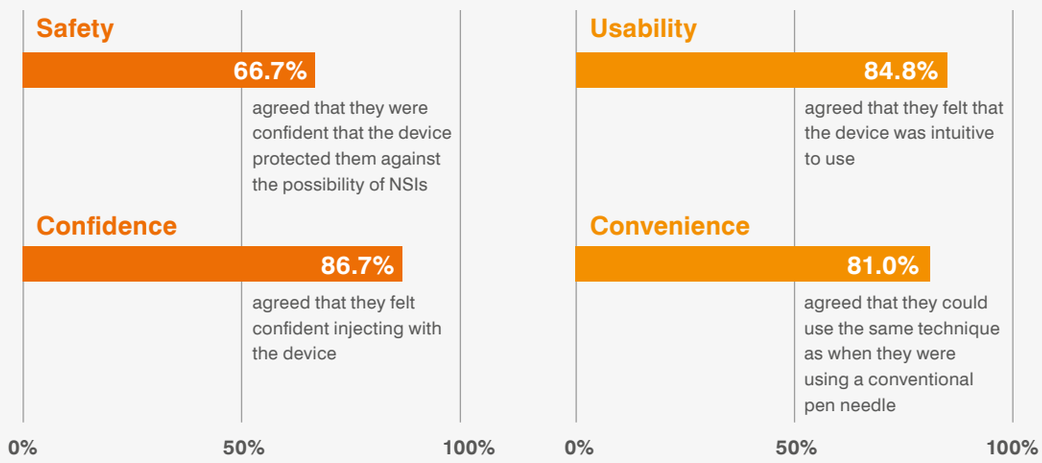
The next generation of safety pen needles: a novel safety mechanism to address the unmet needs of healthcare professionals

Designed to provide a balance of safety and control

As a solution that combines safety and control, R&D engineers at Owen Mumford designed a pen needle with a safety mechanism that is manually activated after the injection process, using just one hand. This safety mechanism prevents NSIs by covering both ends of the needle, while enabling the HCP to use the same injection technique as a standard pen needle (see image below). Fittingly, this safety pen needle was named Ateria® SafeControl®.

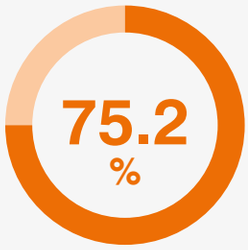
To assess whether these safety pen needles overcome challenges for users, face-to-face interviews were held with 106 HCPs (who had not participated in the online survey and were using either passive safety pen needles or conventional pen needles) before and after they tested this next generation of safety pen needles[10].

After healthcare professionals had tested Ateria® SafeControl®[10]:



Ateria® SafeControl® – a new approach for challenges with conventional and safety pen needles[10].

A balance of safety and control

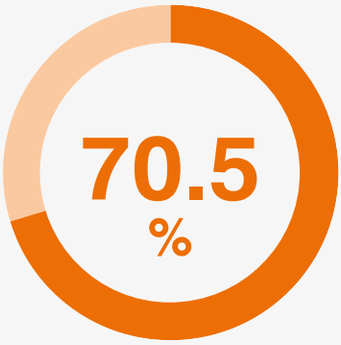


agreed that the device gives them the right combination of safety and control of the drug delivery during the injection process

Dose delivery

agreed that they were 100% sure that the medication dose was fully delivered

Preference



agreed that they would prefer to use Ateria® SafeControl®, if given the choice

Conclusion: a balance of safety and control for healthcare professionals

Safety pen needles protect against NSIs, but until recently, all models were based on passive activation of the safety mechanism. These safety mechanisms can activate prematurely (before or during injection, and without the HCP's knowledge), making HCPs uncertain if they have delivered the full medication dose to their patient.

Ateria® SafeControl® is a next-generation safety pen needle that is designed to provide a balance of safety and certainty that the full medication dose is delivered. The manually activated safety mechanism covers both ends of the needle to prevent NSIs, while enabling the HCP to use the same injection technique as a conventional pen needle.

After testing Ateria® SafeControl®, the majority of HCPs were certain that the full medication dose was delivered and that the safety mechanism protected them against the possibility of NSIs. They also found the device intuitive to use and that they could apply the same injection technique as used for conventional pen needles.

Overall, HCPs agreed that Ateria® SafeControl® provided the right combination of safety and control of the drug delivery during the injection process.

If given the choice, the majority of HCPs agreed that they would prefer to use Ateria® SafeControl®.

Research notes

All research was performed by an independent research company specialised in medical devices. For statistical analysis, a z test was used. For all relative figures on statements quoted here, $p < 0.05$ was applied.

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10. Project Saturn B (2017) Face-to-face interviews and product evaluations commissioned with an independent market research agency. Data on file.

About Owen Mumford

Owen Mumford is an international family company and global leader in designing and manufacturing pen needles. With over 60 years of experience in medical devices, Owen Mumford understand the importance of listening to the needs of both users and decision-makers.

This understanding of key needs translates directly into innovative device solutions that support self-management plans, hospitals, doctors' surgeries, pharmacies, care homes, and clinics around the world.

Owen Mumford are committed to constantly developing life-saving and life-changing devices.

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