

Preventing Needle Stick Injuries and the Role of Safety Devices

**Protection for Healthcare Professionals from
Needlestick Injuries and the Role of Safety Medical Devices**

Sharps and Needlestick Injuries

Prevention is Better Than Cure

Safety and Control at the Heart of Good Practice

Getting the Right Device



Problem

Passive safety pen needles protect you from needlestick injuries, but come with challenges of their own:



Lack of needle visibility¹



Premature activation of the safety mechanism¹



Limited control during the injection process¹

71% agreed that the safety pen needle activates before they have finished administering the injection¹

69% agreed that premature activation of the safety pen needle makes them unsure that the full medication dose had been delivered to the patient*¹

* Of the 71% of healthcare professionals who had experienced safety pen needles activating before they had finished administering the injection.

1. Project Saturn A (2017) Online study commissioned with an independent market research agency. Data on file.

Solved



*If you were given more control,
you'd take it*

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Published by Global Business Media

Published by Global Business Media

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United Kingdom

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Foreword

In the current year, we are waiting for a vaccine against Covid-19. That will require billions of injections around the world in addition to the vaccination injections that we already have against influenza, pneumonia and a host of other conditions, and not to forget that people with diabetes inject themselves multiple times a day. The hypodermic needle is a key component in modern health care and condition management, but one of its risks is needlestick injuries. Given these numbers of uses, it is important that the process of injection should be as well organised as possible with clearly understood procedures that comply with the requirements of regulations. It is also important that the devices themselves are as safe as possible. That safety is usually achieved through the use of a shield and the control afforded by an injector pen system.

In this paper, we have divided the topic up into five key sections. The first article comes from Owen Mumford, who have been at the forefront of medical

device innovation for over 60 years. The article looks across the whole landscape of protecting healthcare professionals from needlestick injuries (NSIs) based around the EU Council Directive 2010/32/EU. That is followed by an article about sharps and needlestick injuries, what they are, who is at risk of sustaining such an injury and the risk of that happening. We also consider what damage a needlestick injury could do. Then, Camilla Slade considers what solution might be needed for NSIs and, more importantly, how they can be avoided in the first place. Peter Dunwell then covers the key and inter-reliant matters of safety and control - processes and procedures to manage injections. Finally, we look at the devices used for injections and in, particular, how designed-in safety and control will ensure a better environment and experience for all users. Overall, a very important subject.

John Hancock
Editor

John Hancock, an Editor of Hospital Reports Europe, has worked in healthcare reporting and review for many years. A journalist for more than 30 years, he has written and edited articles, papers and books on a range of medical and management topics. Subjects have included management of long-term conditions, elective and non-elective surgery, wound management, complex health issues, Schizophrenia, health risks of travel, local health management and NHS management.

Protection for Healthcare Professionals from Needlestick Injuries and the Role of Safety Medical Devices

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Abstract

Council Directive 2010/32/EU - *Implementing the Framework Agreement on Prevention from Sharps Injuries in the Hospital and Healthcare Sector* was adopted by all member states of the European Union (EU) on May 11th 2013. This article examines key issues surrounding healthcare worker associated sharps/needlestick injuries.

Introduction

In 2010 the European Council identified the need to provide greater protection to all healthcare workers (HCW) in the hospital and healthcare setting who are at risk from sharps injuries¹. Council Directive 2010/32/EU provides a legal framework for the management of sharps and needlestick injuries (NSI) within the EU member states. The regulations assist healthcare organisations with their transition into a safer working environment for those at risk of sharps/NSI. The clinical, humanistic and economic burden associated with HCW who receive a sharps/NSI remains substantial².

Compliance with Council Directive 2010/32/EU

Mindmetre (2014), identified that one sixth of acute NHS hospitals in England that had not revised their sharps policies and one third of had not encouraged their staff to use safety devices 'wherever possible'³. In 2015-16 the independent regulator for Great Britain, The Health and Safety Executive (HSE) reported findings from their targeted inspection initiative to look at compliance with the *Health and Safety (Sharps Instruments in Healthcare) Regulations 2013*.⁴ Health and safety breaches were identified at 90% of organisations

visited: 83% failed to comply with sharps initiatives and 45% were issued with improvement notices. Examples included: failure to use safer sharps, lack of a sharps prevention strategy, lack of risk assessments, staff not provided with adequate information on what to do when presented with patients own insulin and standard needles, failure to undertake reviews and report RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) correctly.^{4,5,6}

The concerns associated with poor compliance with the Directive in Great Britain are also supported by the European Hospital and Healthcare Employers Association (HOSPEEM) and European Federation of Public Service Unions (EPSU) who monitored the implementation of the Directive in Europe. They reported that 19 of the 27 European social partners who responded to their survey identified problems associated with the practical transposition of the Directive. Issues noted included; failure to eliminate, prevent and protect from risks of medical sharps, and failure to have systems to report sharps/NSI.⁷

Risks Associated with a Sharps/NSI Injury

Rates of reported sharps/NSI vary from country to country. In the United Kingdom (UK), the National Audit Office⁸ identified that 17% of accidents reported were associated with needlesticks or sharps. In Italy Stefanati *et al.*, reported that 53% of nurses and nursing students had experienced at least one injury.⁹ In France, 6.3 bloody and body fluid exposures per 100 beds were noted with the most frequently reported being NSI.¹⁰

In 2010 the European Council identified the need to provide greater protection to all healthcare workers (HCW) in the hospital and healthcare setting who are at risk from sharps injuries

In addition to the psychological issues, sharps injuries can result in possible infection from over 20 potentially dangerous blood-borne pathogens

Effects of a sharps/NSI injury can be divided broadly into four key groups: psychological, physical, financial and reputational.

Psychological Effects

The psychological effect that a sharps/NSI can have on a HCW can be significant. Costigliola et al.,¹¹ identified the several key emotional responses following such an injury. These included: episodes of depression, relationship issues, panic attacks, crying spells, post-traumatic stress disorder (PTSD), excessive anxiety, and the inability to work. Karen Daley¹² and Cassidi Linnenkugel¹³ are two nurses who have eloquently described both the physical and psychological issues Costigliola et al., identified when they experienced a sharps injury obtained at work.

Physical Effects

In addition to the psychological issues, sharps injuries can result in possible infection from over 20 potentially dangerous blood-borne pathogens (Collins and Kennedy, 1987¹⁴), the most common are; hepatitis B, hepatitis C and human immunodeficiency virus (HIV).

Between 1997 and 2018, there has been one HCW sero-converting to HIV and 23 seroconverting to hepatitis C in England, Wales and Northern Ireland, following percutaneous exposure to a virus-infected patient¹⁵.

Financial and Reputational Impact

The financial burden and reputational damage to an organisation may also be significant. Between 2012 and 2017, 1833 claims for NSI were made to NHS Resolution¹⁶; 1213 claims were successful at a cost of £4,077,441 with 326 claims still open, so costs may have been higher.

Sharps and Needlestick Injuries

Risk of Transmission of Infection

The risk of transmission of infection following sharps/NSI may be affected by several key factors¹⁷:

- Depth of injury.
- Type of sharp used – hollow bore needles are associated with increased risk, although needles used for subcutaneous injection also present a risk.
- The amount of blood or body fluid inoculated.
- Whether the device was previously in the patient's vein or artery.
- How infectious the patient is at the time of the injury.

Devices and Procedures commonly associated with sharps/NSI injury

Studies have shown that the device commonly identified with occupational acquired NSI is the

hollow bore needle. Hollow bore needles are primarily used in association with a syringe, butterfly cannulae and peripheral vascular access catheters and they have been responsible for up to 71% of all reported NSI¹⁸.

Cone¹⁹ reported that the most common procedures associated with NSI were: injection 28%, venepuncture 25%, suturing 14%, manipulating IV injection ports 11%, inserting peripheral IV catheters 11%, and other medical procedures 11%.

Reducing the Risk of Sharps/Needlestick Injuries

Sharps injuries occur for a number of reasons, including; types of devices used, procedures undertaken, lack of training on safe use and disposal of needles and sharps, and lack of knowledge of the consequences of such injuries. The World Health Organization²⁰ identified a hierarchy of controls to reduce the risk sharps/NSI (Table 1).

Safety Engineered Devices

Features of Safety Engineered Device

There are two main types of features used in the design of safety engineered devices (SED). These include passive safety devices, where no additional actions are required by the user to activate the safety feature, and active safety devices where the user is required to activate the safety feature²¹. It is essential that these devices are appropriately evaluated before introduction to ensure that they meet user requirements, do not interfere with their original use and function and reduce risk of NSIs²².

Evaluation and Effect of Safety Engineered Devices on Needlestick Injuries

Safety engineered devices are now widely available. Studies have demonstrated an associated reduction in risk of NSI following their implementation. It is, however, essential that the devices are appropriately evaluated before introduction to ensure that they meet user requirements, do not interfere with function and that they reduce NSIs²².

Several published studies have demonstrated the effect of introducing safety needles/syringes into clinical areas. In 2006, Adams and Elliott²³ undertook a four-year prospective study to evaluate the effect of the introduction of a range of hypodermic SED (including an insulin syringe and needle combo) on the number of reported NSI in a large acute teaching hospital. Following an enhanced sharps awareness strategy in 2002, the number of NSI reduced by 18% (P = 0.813). In 2003, when only standard training was provided, the number of NSI increased to 20/100 000 devices. However, the subsequent introduction

Table 1: Hierarchy of Controls to Reduce the risk of sharps and NSI.

<p>Elimination of hazard</p>	<ul style="list-style-type: none"> • Identify if there is a risk of injury, exposure to a blood or other potentially infectious material from sharps or needles both within the department, or when undertaking clinical visits. • Where possible substitute injections by administering medications through another route. Remove sharps and needles and eliminate all unnecessary injections. • Can the risk of exposure be reduced by using alternative devices?
<p>Engineering controls-used to isolate or remove the hazard</p>	<ul style="list-style-type: none"> • Employing a safety engineered device (SED). It is important that healthcare providers develop a robust conversion strategy when changing from one device type to another which includes; potential users of the device should be part of the SED evaluation process (Adams and Elliott, 2003), development of systems, processes and protocols, a robust education and training process and on-going support/resources identified. • Following the introduction of any SED it is essential to ensure that continuing product reviews are undertaken, to determine if there are any risks associated with use of the device such as splashing on activation^{22,33}. • The Health and Safety Executive³⁴ undertook a systematic review of the efficacy of SED and their impact on sharps/ NSI. The findings identified that when educational programmes were implemented alongside a safer sharps device, lower rates of sharps injuries were sustained for longer. • Strauss and WISE³⁵ have identified the main requirements of a SED (Table 3).
<p>Administrative controls</p>	<ul style="list-style-type: none"> • Wittmann³² developed a standardized risk assessment matrix for medical sharps which identifies the potential risks of blood borne virus transmission associated with devices/procedures and the appropriate level of sharps safety required (Figure 1). • Ensure the organization has developed an overall occupational exposure policy which includes the safe handling and disposal of sharps and that staff are aware of both it, and the actions they are expected to perform should such an incident occur. • Introduce an inoculation injury prevention committee; occupational health and safety, infection prevention and control, clinical users, pharmacists, risk management <i>et al</i>. • Remove any devices deemed as unsafe. • Improve occupational exposure awareness such as risks associated with exposure to blood, body fluids, cytotoxic chemotherapies and radiopharmaceuticals. • Health monitoring and vaccination should be provided where available. Pre-exposure vaccination to hepatitis B should be considered for all HCW who are at risk of exposure to the virus from contact with blood, blood stained body fluids or tissue³⁶. • Encourage occupational exposure reporting. • Inoculation injuries should be reported promptly and appropriately, and risks identified following a root cause analysis into each case. • Employers are responsible for ensuring all staff are aware of the risks associated with occupational exposure from inoculation injuries.
<p>Work practice controls</p>	<ul style="list-style-type: none"> • Review staffing levels to ensure they are appropriate for the work level. • All staff should have access to training on the safe handling and disposal to sharps. • Establish means for safe handling and disposal of sharps prior to beginning a procedure. • No needle recapping.
<p>Personal protective equipment</p>	<ul style="list-style-type: none"> • Place barriers and filters between the healthcare professional and the hazard, for example eye goggles, face shields, gloves, masks and gowns.

Safety engineered devices are now widely available. Studies have demonstrated an associated reduction in risk of NSI following their implementation

One of the most commonly used needles is that used for the delivery of insulin. When combined with lancet use the use of medical sharps by those with diabetes is far greater than any other patient population

Table 3: Requirements of a Safety Engineered Device³⁵

<p>During use:</p> <ul style="list-style-type: none"> • The safety feature can be activated using a one-handed technique • The safety feature does not obstruct vision of the tip of the sharp • Use of the product requires you to use the safety feature (bi-passing any safety actions is not possible) • The product does not require more time to use than a non-safety device • The safety feature works well with a wide variety of hand sizes • The device is easy to handle while wearing gloves • This device does not interfere with uses that do not require a needle • This device offers a good view of any aspirated fluid • This device will work with all required syringe and needle sizes • This device provides a better alternative to traditional recapping <p>After use:</p> <ul style="list-style-type: none"> • There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated • The safety feature operates reliably • The exposed sharp is permanently blunted or covered after use and prior to disposal • This device is no more difficult to process after use than non-safety devices <p>Training:</p> <ul style="list-style-type: none"> • The user does not need extensive training for correct operation of the device i.e. it is intuitive to use • The design of the device suggests proper use • It is not easy to skip a crucial step in proper use of the device <p>*These criteria represent optimal target features which may not be achievable in every device; they do not represent an exhaustive list and may evolve over time.</p>
--

Figure 1: Risk Assessment Matrix and Analysis (Wittmann, 2011)

RISK by amount of blood exposure per device	Critical		IV catheter	Blood collection	
	Serious		IM Injection	Lancet	
	Medium	Acupuncture	(Blood splashes)		Surgical devices*
	Low	No patient contact		Heparin Injection	Insulin injection
			Seldom	Sometimes	Often

FREQUENCY of NSA in health care settings

Required preventative actions:

Use of Safety Devices essential, vaccination against Hepatitis B and proper information and training for staff obligatory
Use of Safety Devices required, vaccination against Hepatitis B and proper information and training for staff obligatory
Training for staff obligatory to achieve the highest possible safety level. Eliminate use of sharp if alternative available.

* Where safety devices do not exist we recommend the use of double gloving, vaccination against Hepatitis B and proper information and training for staff

Table 2: Examples of Insulin delivery Safety Engineered Devices

Owen Mumford: Ateria® SafeControl® Safety Pen Needle (active device)	BD: AutoShield™ Duo Safety Pen Needle (passive device)	Owen Mumford: Unistik 3® Safety Lancet (passive)	Monoject™: Insulin Safety Syringe (active device)	Terumo: SurGuard™ (active device)
				

of three SED with concomitant training resulted in a significant reduction in the number of reported NSI by 70% in 2004 (P = 0.045).

One of the most commonly used needles is that used for the delivery of insulin. When combined with lancet use the use of medical sharps by those with diabetes is far greater than any other patient population²⁴.

Several studies have looked at the risk of NSI from insulin pens. Pellisier *et al*²⁵; identified that standard injection pens were associated with NSI six times more often than standard syringes. Kiss *et al*²⁶ reviewed NSI in a care home; insulin pens were involved in over 40% of the reported NSI, due to re-capping and needle removal. Onuorah *et al*²⁷ reported a nine-year review on the impact of insulin delivery devices on the incidence of NSI. The use of insulin pens reduced the risk of NSI compared to insulin vial and syringe SED. Therefore, insulin pens are associated with the risk of NSI and the use of SED technology would be supported. However, SED may not be the whole answer and awareness of unintended consequences with any devices must be monitored. Yu²⁸ reported a case where a patient with type 2 diabetes was repeatedly admitted with diabetic ketoacidosis. The cause identified was that the patient using an active type of SED insulin pen which had an automatic shield. The shield was designed to retract on application of pressure to the skin. However, in cases where there is soft redundant skin the insulin may be deployed outside of the body. Therefore, risk assessment and patient education is paramount.

In 2016, NHS Improvement issued a patient safety alert²⁹. They noted that there was evidence of issues with the both availability of appropriate safety needles, and a lack of adequate training for staff and patients in using insulin pens and safety needles. Thus highlighting the continued

need for training, education and the availability and appropriate use of SED. Some examples of ED associated with insulin delivery can be seen in Table 2.

Financial Implications

The cost of SED is often highlighted as a block to their introduction. However, Larmuseau³⁰, a health economist demonstrated that a conversion to SED saved nearly half a million euros per year. This was supported by Mannocci, de Carli, di Bari *et al*³¹, who concluded that whilst the costs for prevention of NSI may seem high initially, ultimately they prove to be the opposite as NSI generate significant direct, indirect, potential and intangible costs.

Conclusion

The Council Directive 2010/32/EU provided a framework for European countries to focus their sharps and NSI reduction programme¹. Across Europe there has been differing levels of uptake of the framework⁷. Regardless, there still remains work to be done and we must not get complacent nor distracted. At present healthcare workers remain at risk from avoidable sharps/NSI, if appropriate precautions and practices are not complied with.

It is therefore essential that:

- Healthcare providers consider developing robust, appropriate and effective strategies to reduce the risk associated with sharps/NSI.
- Continuing implementation of safe working practices is paramount, as is; risk assessment, risk elimination, evaluation and introduction of SED following clinical evaluation and training, and awareness of consequences of sharps/NSI.
- Device manufactures should continue to work with end users to develop affordable SED to protect HCW from injury.

The cost of SED is often highlighted as a block to their introduction. However, Larmuseau, a health economist demonstrated that a conversion to SED saved nearly half a million euros per year

Sharps and Needlestick Injuries

John Hancock, Editor

The risk might not be high but the outcome has huge potential for damage

Needlestick injuries occur when needles accidentally puncture the skin. They usually affect people who work with hypodermic syringes and other needle equipment and can occur at any time when people use, disassemble, or dispose of needles

The media often bring us stories of drug users who share needles and dispose of used needles in litter bins or in open spaces where children can find them. While that is hazardous enough for those concerned, there are groups who, through their work or because of their health conditions, are compelled to use needles every day and so are routinely exposed to the hazards of needlestick injuries. Medical Life Sciences News³⁷ reported in 2019 that; “One hundred thousand needlestick injuries occur across the NHS each year, with many more going unreported. It has been estimated that needlestick injuries cost each NHS Trust £500,000 every year - an estimated £127m across England.” That is a significant cost but, more importantly, a significant number of incidents of potential harm for, mainly, NHS and care workers.

What Are Sharp or Needlestick Injuries?

Needlestick injuries occur when needles accidentally puncture the skin. They usually affect people who work with hypodermic syringes and other needle equipment and can occur at any time when people use, disassemble, or dispose of needles. When incorrectly stored or not disposed of properly, needles might end up in laundry or in the rubbish where they could injure workers who encounter them unexpectedly. Injuries can also occur when dealing with uncooperative people who might lash out unexpectedly or even bite. All needlestick injuries put the recipient at risk of blood borne viruses (BBVs).

The Royal College of Nursing (RCN) guidance ‘Sharps Safety’³⁸ explains; “The sharp instruments in health care regulations refer to medical sharps as being an object or instrument necessary for the exercise of specific health care activities which is able to cut, prick or cause injury. These include equipment such as needles and scalpels.” The UK Health and Safety Executive (HSE)³⁹ tells us that; “Healthcare workers can be at risk of exposure to blood borne viruses (BBVs) due to the nature of their work. Although rare, injuries from sharps contaminated with

an infected patient’s blood can transmit more than 20 diseases, including Hepatitis B, C and human immunodeficiency virus (HIV).” So, it is understandable that organisations such as NHS Employers take Needlestick injury very seriously.

The Risk of Sustaining an Injury

All healthcare workers are at risk, yes, but, as the RCN guidance (above) clarifies, “perhaps unsurprisingly, the majority of sharps injuries occur to nurses because they are most likely to be carrying out procedures using sharps, such as giving injections, cannulating or taking blood.” Because they can hold more fluid, i.e. blood, within the needle, hollow bore needles are considered a greater risk when associated with an injury. Also, the RCN guidance reports that injuries usually occur during use, after use but before disposal, between steps in procedures, during disposal, while re-sheathing or recapping a needle. It also seems that some procedures, such as inserting IV cannulas can be associated with higher risk.

The Damage Done by a Needlestick Injury

As we’ve already stated, needlestick injuries are rare and the chance of any health problem resulting from them are even more rare. From the late 1990s to 2012, there were some 20 cases of UK health workers contracting hepatitis C and 5 documented cases of HIV transmission. The very helpful RCN guidance includes some of the main factors that might affect the risk of infection. These include the depth of the injury, the type of sharp used, whether the device has been in a patient’s vein or artery and, of course, the extent of the patient’s illness or injury and how infectious they are. In all circumstances the risks of infection can range from one in three (hepatitis B), one in thirty (hepatitis C) and one in 300 for HIV.

Damage to the victim of needlestick injury

These are, of course, the physical injuries, but just as damaging are the psychological and mental



Owen Mumford: Ateria® SafeControl® Safety Pen Needle - 0.30mm x 8mm (active device)

stress caused to a worker while waiting for test results to be returned and confirm whether they have contracted any infectious diseases or bbvs and, if so, what. Looking at the list of what might result from a needlestick injury, it is unsurprising that anyone would be very worried about the risk. High Speed Training⁴⁰ explains; "The period of testing after exposure to bodily fluids from a sharps injury can be very stressful. This stress can last for several months and can seriously impact the lives of the injured individual and their family." And even after the test results are in, the long-term psychological damage can be life changing. Solicitors, Carter & Carter⁴¹ record one of their clients, a nurse, who suffered a needlestick injury with the consequent psychological damage but then, "developed Obsessive Compulsive Disorder (OCD) [underlining] how utterly devastating the psychological effects of a Needle Stick Injury can be."

Damage to the employer's organisation

Any quote from a solicitor would suggest that an injurious (physical, medical or psychological) outcome can translate into a financial cost for

the organisation employing the victim. NHS Resolution⁴², which handles claims against the NHS, explains; "1,833 incident claims for needlestick injuries were received by NHS Resolution between 2012 - 2017 (fiscal years). Of these, the 1,213 successful claims cost the NHS £4,077,441¹⁶." The report continues with the point that most such injuries are preventable, as we'll see in the next article, but concludes with the sobering thought that, "If the NHS had not spent this, it could have funded 125 band 5 nurses for one year." And that leads on to the reputational damage to the institution, largely as an employer and from the fact that the injury occurred at all, but also from the risk of what won't get done if funds intended to care for patients have to be paid out in compensation claims.

Summary

In risk assessment terms, needlestick injuries are at very low risk of occurring and even lower risk of causing injury. However, should such an injury occur, the damage, even in the event of no injury or infection, can be considerable and of long duration, as well as financially and reputationally costly. All in all, well worth avoiding.

Injuries usually occur during use, after use but before disposal, between steps in procedures, during disposal, while re-sheathing or recapping a needle

Prevention is Better Than Cure

Camilla Slade, Staff Writer

To prevent harm, the use of sharps and needles operates in a well regulated environment

Ensuing treatment will vary from nothing at all in the event that the person who has been injured is judged at low or no risk of infection, to antibiotics, vaccination against hepatitis B and, where the risk of HIV contamination is high, treatment (such as post-exposure prophylaxis (PEP)) to try and prevent infection

In the previous article, John Hancock explained what needlestick injuries are and what can happen as a result of receiving one. But most people who receive such an injury will be most interested in what to do about it.

Dealing with a Needlestick Injury

The UK Health and Safety Executive (HSE)⁴³ has a useful guide...

If you suffer an injury from a sharp which may be contaminated:

- Encourage the wound to gently bleed, ideally holding it under running water
- Wash the wound using running water and plenty of soap
- Don't scrub the wound whilst you are washing it
- Don't suck the wound
- Dry the wound and cover it with a waterproof plaster or dressing
- Seek urgent medical advice (for example from your Occupational Health Service) as effective prophylaxis (medicines to help fight infection) are available
- Report the injury to your employer.

That would be first aid, but anyone who has received a needlestick or a sharps injury will want to get trained medical treatment as quickly as possible. The NHS⁴⁴ explains what will happen next as the injury is assessed. "The healthcare professional treating you will assess the risks to your health and ask about your injury – for example, how and when it happened, or who had used the needle. Samples of your blood may need to be tested for hepatitis B and C or HIV. Although rare, there's also a small risk of other infections being transmitted through contaminated blood, such as cytomegalovirus (CMV) and Epstein-Barr virus. Your healthcare professional may also arrange to test samples of the other person's blood if they give their consent."

Ensuing treatment will vary from nothing at all in the event that the person who has been injured is judged at low or no risk of infection, to antibiotics, vaccination against hepatitis B and, where the risk of HIV contamination is high, treatment (such as post-exposure prophylaxis (PEP)) to try and prevent infection, although it doesn't always work.

A Regulated Device and Process

As in any health-related issue, prevention is better than cure and so there are regulations that govern the use and handling of sharps and needles to try to avoid injuries occurring. The regulations acknowledge that sharps such as needles and scalpels will remain essential tools for effective medical care but aim to ensure they are only used where their use cannot be avoided. Those regulations and associated resources are too many and lengthy to detail here but readers will find a useful HSE central resource with numerous links at 'Sharps injuries – Further information'⁴⁵. But prevention goes further than simply only using sharps and needles where their use cannot be avoided. Often their use cannot be avoided, in which case, the UK Care Quality Commission (CQC)⁴⁶ explains that; "Health and Safety Executive guidance says an employer will need to act to manage the risks if workers:

- Use sharps to provide care or other services to people;
- Provide care or other services to people who are likely to use sharps;
- Are involved in handling such equipment after use - for example in sterile services and waste disposal;
- Are likely to inadvertently come across used sharps - for example during laundering.

Employers are legally required to assess risks from sharps injuries and put appropriate control measures in place."

Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 apply to all organisations providing healthcare. This includes



nursing homes and providers delivering healthcare in residential homes or people's own homes.

As well as risk assessments, employers are also encouraged to use safe sharps and needles. There will be more on this in following articles but the CQC guidance does also explain that; "Syringes and needles are available with a shield or cover. This slides or pivots to cover the needle after use to prevent or minimise the risk of accidental injury. ASC providers should work with prescribers and healthcare providers to make sure safer sharps are used where possible." [author's emphasis].

Perhaps the most significant piece of regulation in this area is the 'European Agency for Safety and Health at Work' Directive 2010/32/EU – prevention from sharp injuries in the hospital and healthcare sector⁴⁷. The Directive provides a legal framework for the management of sharps and needlestick injuries (NSI) within the EU member states with the aim to; "... protect workers' health and safety, and create a safe working environment following the hierarchy of general principles of prevention via information and consultation." Although the UK has now left the EU, the Directive still provides an excellent structure within which to work.

Compliance with Regulations

Regulations are all well and good but, perhaps stating the obvious, they only work when people comply with them. In 2014, Building Better

Healthcare⁴⁸ reported, "Worrying research has revealed that a third of NHS trusts have not properly implemented safer sharps initiatives to protect healthcare workers and patients from the dangers of needlestick injuries. Data from MindMetre reveals 33% of trusts do not instruct staff to use safety devices 'wherever possible' in their sharps policies, despite this being an explicit requirement of... legislation aimed at reducing needlestick incidents within the sector." Later, in 2016, Nursing Times⁴⁹ returned to the topic to find; "NHS still failing to comply with sharps safety laws... A sample of NHS organisations has found more than 80% to be breaching sharps regulations..." One point raised was that, "The most common type of breach was a failure to use safer needles or their unsafe disposal." We'll address the issue of safer needles and of unsafe disposal in the following articles.

Summary

As we have already said, prevention is better than cure. Not only, and most importantly, does it avoid unnecessary discomfort and threat for patients, but also it reduces pressure on resources and consequent costs by significant margins. Because it is an area where, while the risk of injury is small, the consequences can be devastating, the use of sharps and needles is a well-regulated area. Of course, if all else fails, treatment is also important.

The most common type of breach was a failure to use safer needles or their unsafe disposal

Safety and Control at the Heart of Good Practice

Peter Dunwell, Medical Correspondent

A well-controlled process will also be a safer process and that should be the objective of all parties in healthcare

There are around 100,000 needlestick injuries reported every year in the UK and many more that go unreported³⁷

In her article, Camilla Slade set the scene for the regulations that govern handling and using sharps and needles. Employers are always under an obligation to ensure the safety of staff, the more so when those staff work in potentially hazardous environments with potentially hazardous devices. There are around 100,000 needlestick injuries reported every year in the UK and many more that go unreported³⁷. Safety demands processes that have been designed with safety in mind and procedures designed to avoid risk. So, what can be done to avoid sharps and needlestick injuries for healthcare workers?

Keeping People Safe When Using Needles and Sharps

The BMJ, in its article 'Reducing the risk of needlestick injuries in hospital'⁵⁰ summarises the problem of disposal; "After performing procedures involving one or multiple sharp pieces of equipment or 'sharps' there is often no quick and accessible sharps bin for their safe disposal. Instead one must transport this equipment, potentially infected with hazardous blood products, away from the bedside to bins situated elsewhere (e.g. end of bays), risking injury and exposure to others en route."

NHS Resolution⁵¹, the organisation handling claims against the NHS, adds some specific red flags that can identify problems in processes and procedures using needles; "... non-compliance with standard infection control precautions; inadequate disposal of clinical waste; overfull sharps bins; not using safer sharps and not using Personal Protective equipment." Also, the regulations state that all employers are required, under existing health and safety law, to ensure that risk of sharps injuries from needles are adequately assessed, and that appropriate preventative and control measures are in place. That is a theme taken up in another quarter. A large number of healthcare workers are members of the UNISON Trade Union and so it's worth checking their booklet, 'Managing and preventing sharps

injuries'⁵². It says; "All employers must as far as is reasonably practical, ensure the health and safety of both their employees and the public... As part of this duty they must carry out a careful examination of the workplace to identify what hazards could cause harm, assess the likelihood of harm occurring, and then implement measures to eliminate so far as reasonably practicable, or otherwise minimise the risks associated with such hazards..."

Perhaps because of claims and their cost, the NHS has developed detailed rules around this area. The guidance that it offers, 'How should I dispose of used needles or sharps?'⁵³, sets out some clear guidelines as do a number of sources. A summary of how to stay safe might seem obvious, but sometimes the obvious bears repetition.

- Safer sharps should be used where available;
- Avoid leaving sharps lying around;
- Avoid re-sheathing any used needles;
- Do not bend/break needles before discarding them;
- Place contaminated sharps in disposal containers approved to BS 7320:1990, immediately after use.

There is a pattern emerging here: a pattern that might best be summed up in NHS Greater Glasgow and Clyde 'Safe Use of Sharps in Healthcare Policy & Guidance for Managers and Staff', that the employer's obligation is, "To protect employees and others from the hazards inherent in the use of clinical sharps and to ensure that all activities involving a clinical sharp are conducted in a manner that does not jeopardize employee or other persons health and safety."

A Safe and Controlled Injection Process

Notwithstanding the importance of regulations, disposal and treatment of injuries, at the heart of this issue is the process of injection and the importance of safety and control to ensure that



Owen Mumford: Ateria® SafeControl® Safety Pen Needle - 0.30mm x 5mm (active device)

the process is well managed using the most appropriate equipment. That principle is important enough for the World Health Organisation (WHO) International Council of Nurses to have published 'Giving safe injections'⁵⁴ in which the factors for safety are set out:

- Eliminate unnecessary injections;
- Use sterile injection equipment and sharps;
- Prepare and give injections without contamination; and
- Dispose of sharps to prevent re-use and harmful waste.

Control might be well illustrated by the Premier paper 'Safe Injection Practices'⁵⁵ which opens with: "Safe injection practices include measures taken to perform injections in a manner that is safe for patients and providers... Healthcare should not provide a pathway for transmission of bloodborne viruses to patients or providers." Having an agreed and understood injection process ensures the control on which safety depends. That controlled environment is also cited in the paper 'Needlestick' by Kevin C King and Ronald Stormy⁵⁶ which states that, "Although many advances have been made in the development of safer needles and sheathing devices, these devices are not fail-safe and only work in settings where the work environment is constantly monitored. Studies, however, do show that the routine use of these needleless systems leads to a marked decrease in needlestick injuries."

Control is recognised as a very important component in the management of safe injection processes with Medsafe '5 Steps to

Take Following a Needlestick and How to Prevent an Injury in the Workplace'⁵⁷ telling us that employers should, "Implement the use of engineering controls to reduce needlestick injuries." As the first of a comprehensive list of control steps.

Safety by Design

The other significant way in which safety can be built into the injection process is in the design of the devices - the hypodermic syringes and needles themselves. Springboard 'An introduction to needlestick protection and safety syringes'⁵⁸ explains, "... the hazard is most effectively handled by engineering solutions which separate those at risk from the sharps."

Clinical Services Journal 'Safer Hypodermic Syringes'⁵⁹ makes the point that, "Over 70% of nurses surveyed said they preferred syringes where hands and fingers stay behind the needle area when activating the safety mechanism, and where the syringe is permanently disabled after the safety mechanism is activated. Over 60% required the safety feature to be integral to the design of the syringe." That's the human side of safety but the article also addresses the wider issues, "Safety syringes help protect staff from the health risks of needlestick injuries, and the Trust from damages claims."

As in many procedures, safety when administering an injection is best assured through a combination of safe practices, a controlled process and equipment where safety is designed in.

Over 70% of nurses surveyed said they preferred syringes where hands and fingers stay behind the needle area when activating the safety mechanism, and where the syringe is permanently disabled after the safety mechanism is activated

Getting the Right Device

John Hancock, Editor

Device safety and control are essential elements in the administering of injections

There was no doubt that passive safety pen needles improve safety against needlestick injuries (NSIs) but in the same survey respondents felt that a combination of safety and control during the injection process were equally important

We've now considered needlestick injuries, how to treat and how to avoid them through regulation of the injection process and careful procedures. But, as Peter Dunwell suggested at the end of the previous article, the other significant way in which safety can be built into the injection process is in the design of the devices. So, let's have a look now at the devices and what is being done to make them safer and more effective.

Engineering Safety into the Device

When an injection device has safety engineered in to the device, that is often some sort of shielding either of a sort that can be removed by the user, usually a healthcare professional (HCP) who is administering the injection, or of a sort that retracts when the device is pressed against the patient's skin so that, before and after the injection, the actual needle is shielded. *Cision PR Newswire*⁶⁰ citing the survey 'Safety Pen Needles – Take Control' reported, "practical challenges with passive safety pen needles, including premature activation of the safety mechanism before the injection has been completed leads to uncertainty as to whether the full medication dose is delivered to the patient." There was no doubt that passive safety pen needles improve safety against needlestick injuries (NSIs) but in the same survey respondents felt that a combination of safety and control during the injection process were equally important.

This blend of safety and function becomes more important when patients are administering their own drugs such as diabetics administering insulin. *Pharmacy Times*⁶¹ relayed, "a recently hospitalized patient with type 1 diabetes did not know to remove the standard needle cover from the standard insulin pen needle prior to administration. She was unaware that she was using the pen incorrectly and, thus, had not been receiving any of her insulin doses. The patient developed diabetic ketoacidosis and later died." So, a good design is one that is able to meet both the need for patient and HCP safety as well as observably completing the injection process and giving the administrator full control over the process.

Healthcare Professionals' Concerns with Passive Safety Pen Needles

Going a little more granular, *Healthcare Purchasing News*⁶² notes, "Healthcare professionals who use passive safety pen needles have reported that design flaws often make it difficult to deliver a consistent standard of care to their patients. Hidden needles and premature activation are common concerns. Additionally, a study in the *Journal of Hospital Infection* revealed that injection pen use correlates with a higher rate of NSIs among healthcare professionals who give injections." Add to that that there are several brands of injection pens with which any safety needle needs to be compatible.

Some important safety and control factors that have been identified in a number of surveys and reviews are that the needle should be visible throughout the injection process to ensure control, that there should be a means for the user to know when the safety mechanism is active and correctly timing the activation and dosage dispensed.

Key Considerations When Choosing Passive Safety Pen Needles

Unsurprisingly, the key considerations are mainly in respect of the requirements already listed. So, it will be important to know that the needle conforms to standards for the jobs it will have to do and that its operation is reliable, that it is easy to use and safe.

Essentially, users, whether healthcare professionals or patients, should not have to compromise between safety and function, delivering the required dose. The wrong dose can be more than simply inconvenient. Some drugs are effective over a very narrow therapeutic range which is gauged for each case. For example, inappropriately low doses of insulin can cause excessive levels of glucose in the blood (hyperglycaemia). This can result in a condition called ketoacidosis, which can lead to coma, swelling of the brain and even prove fatal. Conversely, inappropriately high doses of insulin can lead to low blood glucose levels

(hypoglycaemia). Low blood glucose levels can cause numerous complications including nausea, falls and seizures. And part of that safety requirement is that, as the UK Health and Safety Executive (HSE)⁶³ explains, “the care-giver should be able to maintain appropriate control over the procedure.”

Caring for the Carers: Clinician Safety

The processes and regulations covered have been well-established in the healthcare sector but this year, 2020, and the Covid-19 pandemic has added a whole new aspect to healthcare, that of personal protective equipment (PPE). *Medical Life Sciences News*⁶⁴ reports that, “93% of UK surgeons think that high quality gloves reduce the chance of exposure to blood borne viruses... 92% agreed that clinician safety in the operating theatre was improved though the use of high-quality gloves.” Certainly, *Nursing Times*⁶⁵ confirms that, “Expert opinion agrees that the two main indications for the use of gloves in preventing HCAI (Pratt *et al*, 2001; Clark *et al*, 2002) are to protect hands from contamination with organic matter and microorganisms, and to reduce the risks of transmission of microorganisms.”

The Future Outlook

For a variety of reasons including the growing prevalence of diabetes and other chronic diseases, the use of pen needles is growing year on year with *Markets and Markets*⁶⁶ reporting



that, “The pen needles market is expected to reach USD 1.8 billion by 2024 from an estimated USD 1.1 billion in 2019, at a CAGR of 10.8% during the forecast period.” In these circumstances and given the high cost when things go wrong (see first article ‘Sharps and needle stick injuries’), the safer and more effective a device can be, the better.

A good design is one that is able to meet both the need for patient and HCP safety as well as observably completing the injection process and giving the administrator full control over the process

Users, whether healthcare professionals or patients, should not have to compromise between safety and function, delivering the required dose. The wrong dose can be more than simply inconvenient. Some drugs are effective over a very narrow therapeutic range

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