SHORT REPORT

Implications of the EU Directive on prevention from sharp injuries in the hospital and healthcare sector on procurement decisions

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A STUDY OF PRESENTATIONS OF LOW MOLECULAR WEIGHT HEPARINS

A sharps injury is defined as an incident that causes a needle or sharp object to penetrate the skin.[1] Needlestick injuries are the most common cause of sharps injuries and pose a serious risk to healthcare workers. Current UK numbers of needlestick injuries are grossly underestimated due to underreporting and no coordinated national surveillance programmes. It has been estimated that 100 000 needlestick injuries are reported in the UK each year but these numbers are likely to be an underestimate.[2–4] The Royal College of Nursing reported that 48% of nurses polled (n=4407) had experienced a needlestick injury during their career[5] and more than 1 million needlestick injuries are estimated to occur in the European Union each year.[6]

Injuries from contaminated needles carry a risk of infection from more than 20 blood-borne pathogens, including hepatitis B, C and HIV. The risk of transmission of infection from an individual needlestick injury is small but because instances are so common the potential for infections is large.

EU DIRECTIVE 2010/32/EU[7]

The introduction of EU Directive 2010/32/EU in 2010 aimed to prevent injuries and reduce blood-borne infections to healthcare workers from sharp instruments including needles. The EU Directive was published in June 2010, and is required to be implemented as national law in all EU countries by May 2013.

Following the publication of the Directive there are many implications for hospital pharmacists and support staff as well as other healthcare professionals. The issues will be difficult to address in pharmacy technical services units and radiopharmacies as well as for reconstitution and drawing up of drug solutions on wards. In the more clinical setting and with potential risk of needlestick injuries causing blood-borne infections, including HIV and hepatitis, then the issues are clearer cut, any measures taken to reduce these risks need to be encouraged.

- The main principles of the Directive include:
- a well trained and adequately resourced workforce;
- the need for effective working procedures and safe disposal processes, minimising risk;
- using the hierarchy of controls to eliminate sharps injuries;
- use of devices with safety engineered features;
- promotion of a no blame culture, focusing on systemic factors rather than individual errors together with suitable reporting mechanisms;
- a ban on recapping when there is risk of infection or injury.

Even before the Directive became law there was a raft of UK legislation addressing the issues of protecting healthcare workers, including The Health and Safety at Work Act (1974); Control of Substances Hazardous to Health (2002); The Management of Health and Safety at Work Regulations (1999). The Health and Safety Executive (HSE) already recommends that, if reasonable, practical conventional products should be replaced with those that are safer devices.

LOW MOLECULAR WEIGHT HEPARINS

Low molecular weight heparins (LMWHs) are one of the most commonly administered injections in secondary care, they are also used extensively in the community setting. Although these products are administered by subcutaneous injection and hence subject to a lower risk than injections given by other routes, their frequency of use means that the risk is still significant.[8] Furthermore, because of the subcutaneous route, it is likely that they will always need to be administered using a needle or possibly micro-needle technology.

With this in mind I undertook a review of the currently available LMWHs to assess their likely compliance with the Directive and with safer injections advice, much of which has come from the trade unions within the EU and from the USA. I also chaired a consensus group of fellow healthcare professionals to discuss the Directive and its implications for hospital pharmacy in the aseptic services department and for procurement.

AVAILABLE PREPARATIONS

The current *British National Formulary* (September 2011) lists four different LMWHs which come in a variety of presentations, mainly prefilled syringes of various doses and volumes. Initial research showed that one of these bemiparin sodium (Zibor; Archimedes, Reading, UK) is not currently readily available in the UK supply chain. Hence my focus was on the remaining three preparations: dalteparin sodium (Fragmin; Pharmacia, New York, USA), enoxaparin sodium (Clexane; Sanofi Aventis, Paris, France) and tinzaparin sodium (Innohep; Leo, Princes Risborough, UK). Although these products

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were sourced from the UK market they are available in similar presentations across the EU.

FOOD AND DRUG ADMINISTRATION GUIDELINES

The US Food and Drug Administration suggests that the characteristics of a needle with a safety feature to protect healthcare workers should:

- provide a barrier between the hands and the needle after use;
- allow the workers' hands to stay behind the needle at all times;
- be an integral part of the device;
- be in effect before disassembly and remain in effect after disposal to protect downstream workers;
- be simple to operate requiring little or no training to be used effectively.

Safety features can be categorised according to their passive or active nature. Passive safety features are preferable as they do not require intervention by the operator. The safety features remain in effect before, during and after use, meaning healthcare workers do not have to activate them. Examples include retractable needles and protective sleeves which automatically cover the needle after use.

Active safety features require the healthcare worker to manually activate the safety feature, for example, a needle with a sheath and needle retraction. Needle shielding describes when a hinged needle shield is attached to the hypodermic syringe and following use the needle can be placed in the sheath and contained therein.

Passive safety features are deemed advantageous as they do not rely on the healthcare professional remembering to use them; they are automatically in place once the device has been used.

METHOD

I obtained each product in a variety of doses in prefilled syringes and assessed each using simulated injections into an orange. I had no previous experience of giving injections or using any of the assessed products. During the assessment I made use of the Safety Syringes—Safety Feature Evaluation Form produced by Unison[9] and originally developed by Training for Development of Innovative Control, Technology Park, San Francisco, USA. This assesses the device during and after use and also the need for training.

FRAGMIN

On initial examination the Fragmin products looked the simplest devices, being a syringe with a capped needle with no safety features. For use the needle cap is removed, the injection administered and then the syringe discarded with a naked needle. Hence this does nothing to protect downstream users and means that the burn bin needs to be carried to each patient's bedside to immediately dispose of the used syringe.

INNOHEP

The Innohep products are presented as similar syringes and needles to Fragmin, however they do have an attached active safety device. This device, intended to contain the needle after use, is taped to the barrel of the syringe near the tip (see figure 1). To administer the product, the healthcare professional needs to bend the safety device upwards and hold it in place away from the needle while removing the needle cap and administering the injection. Although this is easy to achieve, it does feel rather clumsy.

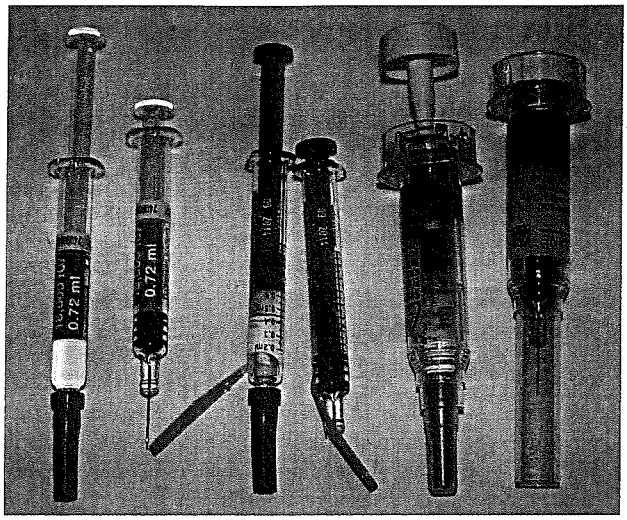

Figure 1 The low molecular weight heparin preparations before and after use (left to right): Fragmin, Innohep and Clexane.

Following administration, the safety device is bent back to its original position so that it is underneath the needle; this is then placed against a hard surface and pushed downwards so the needle clicks into the safety device. It should then be bent to an angle of 45° to the syringe prior to disposal. Of course there is nothing to stop direct disposal of the syringe without using the safety device.

If the device is used correctly then this does protect downstream workers from the needle. I tested the ability of the device to withstand bending over to a much higher degree and it did this without the needle or device being compromised. It is possible to engage the safety device with a one-handed operation, making use of a hard surface. The device is simple to use, requiring no training apart from reading the information supplied. The device worked reliably on all the samples tested.

There are some downsides to this device. First, the handling ahead of and during administration is slightly more difficult and there is an additional step after use. Second, surfaces could be contaminated during the process of making the needle safe, a situation confirmed by the work of Roff.[10] Third, the product can be used and discarded without using the safety feature.

CLEXANE

Clexane is presented in a capped syringe with an in-built automatic (passive) safety device which totally covers the needle following injection. The original syringe is presented as a capped needle, the cap is removed and the injection given. Once the plunger is fully pressed down, the safety device is activated automatically and a sleeve covers the needle totally as it is removed and with a safety margin to spare. This device worked well on all the samples supplied; the only way that I could stop it working was to not fully press the plunger down and hence not give the whole dose.

When this device is assessed against the Safety Feature Evaluation Form it scores top marks in all applicable fields. The device is simple to use with a one-handed technique. The safety device is totally automatic and cannot be bypassed and worked reliably throughout the trial with a range of sizes (see online supplementary video).

CONCLUSIONS

From this study it can be concluded that Clexane is currently the only device among LMWHs which scores well on the safety

feature evaluation process for a safer needle device, protecting the healthcare worker administering the product and downstream workers. Innohep has a safety device but this requires extra steps in the process, is rather clumsy and can be bypassed. Nevertheless it does offer some additional protection, particularly to downstream workers.

Although the study was restricted to LMWHs similar assessment can and should be applied to other products presented in prefilled syringes, including epoetins and granulocyte colony-stimulating factor preparations.

The HSE states that employers must undertake a risk assessment for all handling of sharps; they must also procure safer devices if these are available so the risks are avoided in the first place. The HSE has shown that it is likely to prosecute organisations that fail to take these precautions, as the case against Worcestershire Acute Hospital in 2007 showed.[11]

Hopefully once the Directive is fully implemented into UK law this will encourage all suppliers of LMWHs and similarly presented products to provide them with fully compliant safer needle devices.

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