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### Converting to Safety-Engineered Medical Devices:

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#### Compliance with the new EU Directive on Sharps Injury Prevention

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In recent years, much work has been done by healthcare worker associations to highlight the danger of sharps injuries, which are described by the European Parliament as “one of the most serious health and safety threats in European workplaces and estimated to cause one million injuries each year”. Sharps injuries are the most frequent occupational hazard faced by healthcare workers, with 45% of these occurring amongst nursing professionals and 40% amongst other medical professionals. A European country study reveals that the highest risk area for the likelihood of needlestick injury is venous blood-drawing (>38%); and that only 20–50% of all needlestick injuries are reported.

Such injuries are particularly dangerous in view of their potential for transmitting life-threatening blood-borne pathogens, including Hepatitis B (HBV), Hepatitis C (HCV) and HIV. Most injuries are from hollow-bore needles used in injection syringes, blood-drawing devices and intravenous catheters – the everyday tools of the healthcare worker trade and the most deadly, as they contain residual blood. Upon suffering an injury from a contaminated needle or sharp, the risk of infection is one in three workers for HBV, one in 30 for HCV and one in 300 for HIV. These injuries have an enormous psychological impact, and potentially serious health impact.

There is now EU legislation for the introduction of compulsory healthcare worker protection requirements. The EU Employment and Social Affairs Ministers adopted a new Directive, which is designed to help prevent healthcare workers from sustaining injuries from medical sharps such as hypodermic needles and blood collection devices. The Directive was published in the Official Journal of the EU in June 2010 and the deadline for implementation into national law in all EU countries was May 2013.

Both the public and private healthcare sectors are affected by the legislation, which is designed “to achieve the safest possible working environment” in hospitals and wherever healthcare activities are undertaken and “by preventing injuries to workers caused by all medical sharps (including needlesticks)”. The Directive specifically mandates better training, better working conditions and the general use of safer medical instruments incorporating sharps protection mechanisms. The Directive confirms employers have a responsibility to protect their employees from sharps injuries and, therefore, compliance is mandatory.

This article discusses the management of risk and cost of needlestick injury treatment in order to help general management, occupational health managers and health and safety heads in public and private sector healthcare organisations address the business case for conversion to safety-engineered medical devices.

#### The Costs Associated with Sharps Injuries

Over the last ten years there have been a number of discussions and studies on the costs associated with sharps injuries. Most identify the costs purely as the expense of treating the injured party, with the typical treatment sum varying between a few hundred and a couple of thousand Euros.

However, these academic papers specifically exclude factors such as staff time off work, the cost of resignations and wasted training investment when staff leave, or greater recruitment costs because of increased staff churn. For serious sharps injuries resulting in infection by a blood-borne pathogen, costs that could be avoided are much higher. The cost associated with each inoculation injury has been estimated to range between €15,000 to €1,000,000 for an injury resulting in transfer of a bloodborne virus.

#### Adopting Safety-Engineered Medical Devices Makes Good Business Sense

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A wide variety of studies demonstrate that the adoption of safety-engineered medical devices, such as catheters and syringes, radically reduces injury levels. Now that the use of safety-engineered medical devices is specifically cited in European law, and despite pressure on health budgets across Europe, many healthcare organisations have already constructed a robust case for conversion to safety-engineered medical devices. Healthcare organisations which have already converted recognise that adoption of safety-engineered medical devices is integral in their efforts to provide a safer working environment for staff, to eliminate the cost of treatment and staff absence, and to avoid damaging and expensive legal action. In general, the cost of introducing safety-engineered medical devices to prevent needlestick injuries is estimated to be roughly a quarter of the cost of treating injuries.

Studies typically see conversion to safety-engineered medical devices as providing a viable return on investment, because their use significantly reduces the risk of sharps injuries and the associated costs, as well as being more attractive to healthcare workers wanting to work for reputable institutions with high quality standards. This is supported by experience in Italy which demonstrates that adoption of safety-engineered medical devices, in conjunction with training and awareness, is extremely effective in reducing sharps injuries (reduction ranges from 63% to 100% depending on the device used), and that adoption of safety-engineered medical devices is both affordable and cost effective.

Although adoption of safety-engineered medical devices does have an additional initial investment implication, that cost is not insurmountable. A European study, for instance, found that "the direct cost increase [of using safety-engineered medical devices] was €0.558 per patient in the emergency department and €0.636 per patient-day in the hospital wards", but that "proper use of [safety] engineered devices to prevent percutaneous injury is a highly effective measure to prevent these injuries among healthcare workers."

One Spanish study also found that "savings in sharps injuries care outweigh additional costs of certain [safety] engineered sharps injury prevention devices." A Swedish study reported that "the expected number of injuries [in Sweden] that could be avoided by introducing safety-engineered medical devices was estimated at 3,125 and the corresponding expected cost offset at €850,000."

In Spain, five of the autonomous regions have now made the use of safety-engineered medical devices a legal requirement. Evidence of the country's leading role in this respect is found in a study conducted some years ago, by the General Council of Hospitals, which identified some €30 million/year in savings from conversion to safety-engineered medical devices.

Most organisations, private and public, however, will also be motivated by the ethical duty to provide staff with a safer working environment, something that often improves staff loyalty, motivation, productivity and recruitment. There is a growing body of evidence in the UK that what is good for staff is good for patients, with a recent report on NHS health and well-being stating that "organisations that prioritised staff health and well-being performed better, with improved patient satisfaction, stronger quality scores, better outcomes, higher levels of staff retention and lower rates of sickness absence". For private medical laboratories in particular, the whole brand image of a safer environment also plays a role in attracting patients.

#### **Leading the Conversion to Safety- Engineered Medical Devices**

Medisch Centrum Haaglanden (MCH), a leading clinical teaching hospital in The Hague, is dedicated to the highest standards of patient care, as well as to providing its staff with the best working environment. Occupational Health at MCH has always monitored needlestick injury, and desired increased staff safety, as well as greater comfort for patients.

This led to the Oncology and Nuclear Medicine departments at one of its two locations, MCH Westeinde, converting in July 2007 to the exclusive use of a safety-engineered medical intravenous device – a closed IV catheter system. Used for peripheral venous access, the all-in-one safety-engineered medical system is designed to reduce needlestick injury by using passive needle-shielding technology – where the shielding mechanism automatically activates without any need for manual activation by the practitioner - that does not compromise the insertion techniques. It is also designed to reduce insertion attempts and limit healthcare workers' exposure to blood with its innovative blood-containment system that helps minimise blood leakage from the catheter hub.

MCH chose an extremely secure system, where the needle becomes 'sealed off' after intravenous insertion. The needle lies slightly flatter on the skin than other products, and the cannula adapts more closely to the patient's movements, reducing the risk of phlebitis.

Following the successful conversion of the Oncology department, the Intensive Care unit at MCH Westeinde is also planning to start using all-in-one safety-engineered medical IV systems. Word of mouth, and increased awareness of the importance of safety, is also leading to safety product trials being set up in other departments. The main priority is staff safety, but safety and infection prevention come hand in hand.

The new EU Directive specifically requires each hospital to undertake a risk assessment process, which MCH already has in place, in the form of a specific Hazardous Incidents and Critical Occurrences Risk Inventory. Any needlestick incident is thoroughly investigated internally, and corrective actions are implemented as required (MCH recently replaced its sharps containers with safer units). In order to be compliant with the new Directive, MCH only needed to make minor adjustments and developments, as the hospital is already on track to implement a total safety policy in the near future.

## Conclusion

Forward-thinking healthcare organisations in both public and private sectors, such as Medisch Centrum Haaglanden, that have chosen to convert to safety-engineered medical devices have recognised a compelling business case for conversion to safety-engineered medical devices straight away. Their reasoning usually combines economic, risk and ethical factors. They understand that NSI costs can be substantial, when treatment, lost working time and staff turnover are taken into account. They have constructed a business case for conversion to safety-engineered medical devices that is at least cost-neutral, if not delivering actual savings. And finally, these leading healthcare organisations want to create an environment for staff and clinicians that provides proper protection against injuries that are, at best, distressing, and at worst, can ruin careers and destroy lives.

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