

Eucomed Position Paper - Preventing 'Sharps' Injuries

1 Introduction

This Position Paper has been produced by Eucomed. As the major medical technology industry association in Europe, Eucomed represents both national associations and many of the most important manufacturers. These include most of the major companies manufacturing medical devices which incorporate "sharps", in Europe and worldwide.

2 Executive Summary

The purpose of this position paper is to:

- Raise awareness of the risk of needlestick and other "sharps" related injuries (referred to generally as 'sharps injuries') and the associated risk of infection or contamination of healthcare workers.
- Draw attention to the obligations of the various stakeholders in relation to these risks.
- Emphasise the value of effective training and education, and the implementation of appropriate working practices aimed at reducing these risks.
- Promote both the knowledge and the use of available "sharps protection" technologies

These are issues in which governments, healthcare providers, healthcare workers and industry have a common interest, and the effective solution to which requires that all stakeholders work together. This paper discusses the following aspects of this important subject:

The Clinical Risk

Healthcare workers who use, or may come into contact with, medical devices incorporating "sharps" are at risk of injuries that can lead to serious or fatal bloodborne infections. These include Hepatitis B, Hepatitis C and the Human Immunodeficiency Virus, HIV.

Legal and Ethical Considerations

From the ethical standpoint, employers of healthcare workers do not wish to see unnecessary injuries occurring. Beyond the ethical considerations, there is a growing body of law that requires employers to combat risk at source.

Improving the Situation

These risks can be dramatically reduced through the introduction of improved education and training, the operation of safe working practices and the use of medical devices which incorporate "sharps protection" safety features.

Economic Implications

The cost of “sharps” injuries is significant, both financially and emotionally. The most valuable asset of any healthcare establishment is its people. They need to be protected from the risks of occupational injuries that can leave them out of action for months, or even permanently.

3 The Clinical Risk

The use of conventional needles and other “sharps” is fundamental to medical practice. However, there is an inherent risk of injury whenever a needle or other sharp device is exposed. By far the most common medical devices involved with percutaneous injuries are those incorporating hollow-bore needles ⁽¹⁾.

Published data indicates that in an average hospital, workers incur approximately 30 needlestick or other sharps injuries per 100 beds per year ⁽²⁾.

The data also indicates that the incidence of “sharps” injuries is greatly under-reported. Research shows that as many as 60% of incidents remain unreported ⁽³⁾.

It is not only medical staff that are at risk of injury from needlestick and other “sharps”. A significant proportion of such injuries are experienced by ancillary staff, such as cleaners and laundry workers. Laboratory and other technical support staff are also exposed to risk.

It is clear that a used “sharp” can transmit bloodborne pathogens. Any individual unfortunate enough to suffer a needlestick or other “sharps” injury may, as a consequence, contract illness and diseases that can range from a fever and bacterial infection, through to HIV or Hepatitis C.

Staff are not necessarily infected in every instance of a Sharps injury, but the risk of transmission from a needlestick or other sharps injury, where the needle has been contaminated by an infected patient, is:

- 1 in 3 workers for Hepatitis B
- 1 in 30 workers for Hepatitis C
- 1 in 300 workers for HIV

The Hepatitis C virus (HCV) is ten times more transmissible than HIV and there is currently no vaccine available ⁽⁴⁾.

In addition to the risk of acquiring a seriously debilitating or fatal disease, the psychological impact of a needlestick or other sharps injury can be very significant. Even where subsequent infection does not occur, the victim’s mental suffering should not be underestimated. A lengthy process of diagnostic procedures must be followed before it is known whether a serious disease has been contracted or not.

Healthcare employers, workers or other stakeholders should not have to accept such risks as “part of the job”. There is a great deal that can be done to reduce the risk, and there is both an ethical and a legal obligation to do so.

4 Legal and Ethical Considerations

The ethical considerations in this matter are obvious. No employer or employee wishes to see avoidable risks such as needlestick or other sharps injuries in the workplace.

Beyond the ethical considerations, there is a growing body of related law that applies to healthcare providers.

The EU Council Directive 89/391/EEC concerns the Safety and Health of Workers, and requires that, if risks cannot be totally eliminated, they must be combated at source.

Dangerous practices must be replaced by those that are non-dangerous or less dangerous. Employers are also responsible for adapting their operations to technical progress, by using newer technologies that can reduce or eliminate risk.

EU Council Directive 89/655/EEC deals with Work Equipment and obliges employers to provide a safe working environment. In this context, medical devices are "work equipment" and they must be chosen with a view to avoiding or minimising risk.

More recently, EU Council Directive 2000/54/EC has consolidated European law concerning Biological Agents. Employers must assess risk and prevent workers' exposure to biological risks or, if prevention is not technically practicable, reduce it to the lowest risk level for adequate protection by means of workplace design, engineering control measures, hygiene measures and safe handling of waste. In addition, employers are required to make available their risk assessment information to Competent Authorities upon request.

The Medical Devices Directive, 93/42/EEC, also has direct relevance to this issue. Manufacturers are required to undertake a risk analysis of all medical devices before they are placed on the market. In doing so, manufacturers should take account of the European Standard for risk analysis of medical devices, EN 1441, and for risk management, EN ISO 14971.

The Medical Devices Directive also requires manufacturers to maintain awareness of adverse events reported in relation to their devices, and to take reasonable measures to manage risks that have been highlighted.

From the above brief overview of current legislation, it can be seen that there is an obligation on all involved in the provision of healthcare to identify risks and to do whatever they reasonably can to eliminate, or at least reduce, such risks to the extent that is practicable and furthermore to communicate any residual risk to the user.

In this regard, the medical device industry has a proven record of continual improvement through striving to make available products that offer improved patient and healthcare worker safety.

Used properly, in accordance with labelling and instructions, and following standard medical practice, conventional medical devices incorporating "sharps" carry a low level of risk, are effective for their intended use and may be disposed of correctly.

There remain, however, residual risks that can result from unexpected events and conditions or from misuse. A new generation of medical devices, which incorporate additional safety features and that provide higher levels of protection against accidental needlestick injuries, may be appropriate for selection and use in such situations.

The US Needlestick Safety and Prevention Act, which was passed in November 2000, requires that healthcare facilities evaluate and implement the use of needle protection devices. It is currently estimated that over one third of needles used in hospitals in the USA incorporate needle protection features. Within two years it is expected that virtually all needles used in US healthcare facilities will incorporate needle protection.

In Eucomed's opinion, it is important that the competent European authorities take steps (whether by guidance or regulation) to recognize the obligations placed on employers and to encourage the evaluation and use of such technology and other preventive measures

5 Improving the Situation

The available measures to help combat needle-stick and other "sharps" injuries can be divided into three broad areas:

- 1) training and education
- 2) safer working practices
- 3) the use of "sharps protection" technology

5.1 Training and education

Effective training and education regarding related precautions is clearly an important weapon in the war against needlestick and other "sharps" injuries. Such training should be incorporated in all relevant educational programs for healthcare employees. Indeed, personnel that are relatively new to the healthcare environment are amongst those most at risk.

Equally important is the conducting of regular refresher training, as complacency can become a contributing factor with experienced healthcare workers, who can develop the attitude that such risks are "normal" and "expected" for their profession.

Such educational programs should clearly identify the risk of exposure, by reference to the published literature, which is very consistent in this respect. Furthermore, each healthcare facility should have an effective reporting system in order to be able to assess the level of "sharps" related injuries and to measure the benefits of preventative measures taken.

5.2 Safer working practices

In addition to education, each healthcare facility should establish policies and associated procedures to reduce the incidence and severity of the risk. Training and education of staff needs to be reinforced with working policies and procedures that are ingrained and implemented in the day-to-day routine.

Essential risk reduction working policies include:

- the vaccination of staff, including verification of immunisation
- the enforcement of safe working practices, such as not re-shielding needles
- the wearing of gloves
- the immediate disposal of used “sharps” in purpose-designed “sharps” containers

Additionally, should sharps injuries occur, effective procedures need to be in place for reporting, and for effective response and follow-up including post-exposure prophylaxis.

5.3 The use of “sharps protection” technology

Studies have shown that improved education and training and attention to working practices cannot alone eliminate needlestick or other sharps injuries. However, medical device technology exists today to protect medical staff from inadvertent sharps injuries. Medical devices are available with additional safety features to prevent sharps injuries. These include:

- devices that include a needle shielding or retraction that is manually operated or blunting of the needle
- devices with automatic shielding or retraction of the needle, without the need for an additional operation
- needle-free injection systems for certain applications.

EUCOMED believes that a combination of all of the above mentioned preventative actions would significantly reduce the risks from injuries associated with the use of medical devices which incorporate “sharps”

6 **Economic Implications**

“Sharps” injuries impose a significant economic burden on healthcare providers. The cost of follow-up testing and treatment is substantial and is additional to the human costs in terms of anxiety, stress and personal anguish.

Aside from these costs, healthcare providers increasingly face large compensation claims, and serious difficulty in attracting suitable staff and in retaining trained staff. The most valuable asset of any healthcare establishment is its people. They need to be protected

from occupational injuries that can leave them out of action for months, or even permanently, thereby wasting extremely valuable resources.

A lengthy process of diagnostic procedures must be gone through before it is known whether a serious disease has been contracted and, where this is the case, treatment may be required over an extensive period of time and, in some cases, for the remainder of the victim's life.

It is Eucomed's view that, compared with the costs associated with needlestick or other sharps injuries, the benefits obtained from suitable education and training, from risk reduction working practices and from the use of medical devices incorporating additional safety features represent a wise investment.

7 Conclusions

The risk of needlestick and other "sharps" injuries is well documented, and it is widely accepted that the incidence of such injuries is widely underestimated. The cost to the health services of Europe is, therefore, likely to be much greater than is currently recognised.

There is a clear legal and ethical obligation on employers to anticipate and manage risk, and to provide safe working conditions and equipment for healthcare workers.

There are means readily at hand to significantly reduce the risk of needlestick and other "sharps" injuries. These include training and education, appropriate policies and working procedures, and the use of available "sharps protection" technologies.

The cost of adopting these measures is modest compared to the consequences of "sharps" injuries.

These are issues in which governments, healthcare providers, healthcare workers and industry have a common interest, and the effective solution to which requires all of these stakeholders working together to implement the necessary measures.

EUCOMED is eager and willing to work alongside other interested parties in order to eliminate, or at least to significantly reduce, the serious risks associated with "sharps" that have been outlined in this paper.

8 References

- 1 Ippolito and Puro: Device Specific Risk of NSI in Italian HCW. *Jama* 1994; 272: 607-10.
- 2 EPINet 1999, University of Virginia.
- 3 CDC / NIOSH Alerts on NSI
- 4 CDC / SIROH Reports