



European
Biosafety
Network

**Toolkit for Implementation of European Directive
on Prevention from Sharps Injuries
(Council Directive 2010/32/EU) in Member States**

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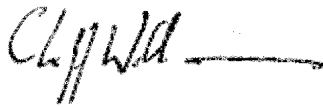
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Prevention of Sharps Injuries in the Hospital and Healthcare Sector
European Biosafety Network Implementation Guidance Toolkit for EU
Council Directive 2010/32/EU

January 2013

Foreword

Directive 2010/32/EU is an example of what can be achieved by the social partners, employers and trade unions, working together to improve the health and wellbeing of workers. The European Biosafety Network believes this toolkit provides guidance on the measures necessary to ensure member states and employers comply with this directive and other European regulations on the management and prevention of sharps injuries.



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Executive Summary of what employers and workers need to do to comply with the Directive:

It is good practice for employers to adopt an integrated approach to establish policies in risk assessment, risk prevention, training, information, awareness raising and monitoring. This should be done in consultation with employees and their representatives.

Employers must ensure that they:

- Are in compliance with all European and domestic health, safety and workplace laws;
- Have workplace processes in place to identify, manage and where possible eliminate all workplace sharps injuries;
- Consult and work with workers and their representatives in the management of sharps injuries;
- Provide all necessary initial and refresher training for workers to ensure they understand their own legal obligations and that they are doing all they can to ensure the safety and welfare of themselves and their fellow workers.
- Have report systems in place to ensure that all sharps injuries are reported and managed.

Workers must ensure their own and other workers safety by:

- Working in partnership and co-operate with their employers in the management of their own and other workers' safety;
- Attend any training provided;
- Understand and comply with the workplace processes and safe systems, including attending any training provided;
- Report all sharps injuries using the procedures put in place by their employers.

Introduction

The Directive recognises that the everyday work of healthcare staff puts them at risk of serious infections, with more than 30 potentially dangerous pathogens, including hepatitis B, hepatitis C and HIV, as a result of sharps injuries. The most common and dangerous of which are injuries with used needles (needlestick injuries). More than one million needlestick injuries are estimated to occur in the European Union each year. Sharps injuries are one of the most common and serious risks to healthcare workers in Europe and represent a high cost for health systems and society in general. Additionally, the emotional impact of sharps injury can be severe and long lasting, even when an infection is not transmitted.

Each Member State is required to bring into force national legislation or legally binding agreements to implement the Directive by 11 May 2013 at the latest. The implementation of the Directive will contribute to achieving the safest possible working environment in the hospital and healthcare sector and is binding between employers and workers. The Directive specifies minimum requirements and Member States are free to adopt additional measures to protect workers. Member States should ensure that national requirements are as clear and effective as possible.

Member States are encouraged to draw up their own tables which will illustrate the correlation between the requirements of the Directive and the transposition measures implemented to comply with it, and to make that document public. Member States shall also determine applicable penalties to be applied when the national provisions to implement the Directive are infringed. The penalties shall be effective, proportionate and dissuasive.

Although the Directive is specifically aimed at the hospital and healthcare sector, the basic principles of risk assessment, elimination and prevention apply to all workers and employers. It will be in the employer's interest to do everything reasonably practical to eliminate hazards regardless of where the exposed worker is employed.

The directive covers all workers that are under the managerial authority and supervision of health care employer/ organisations. This extends not only to staff that are directly employed, but also some self-employed workers. For example, agency and bank nurses, any workers employed by organisations contracted to provide services for health care organisations such as cleaners and other ancillary staff. The agreement also covers any students while they are under the supervision of any health care provider.

Principal Provisions of the Directive

The underlying principles of the directive include:

- A well trained and adequately resourced workforce
- Recognition of the key role of safety representatives in risk prevention, and of employers and workers' representatives working in partnership with regard to implementation and awareness raising of the directive;
- That the employers have a duty to ensure the health and safety of workers, while at the same recognising that employees have a responsibility to look after their own health and safety by complying with the instructions of their manager and attending any training provided;
- Using the hierarchy of controls in assessing the control measures to put in place to eliminate sharps injuries;
- Implementation through an information and consultation process, and in accordance with national laws and collective agreements;
- Achieving the safest possible working environment;
- Promotion of a no blame culture; incident reporting should focus on systemic factors rather than individual errors

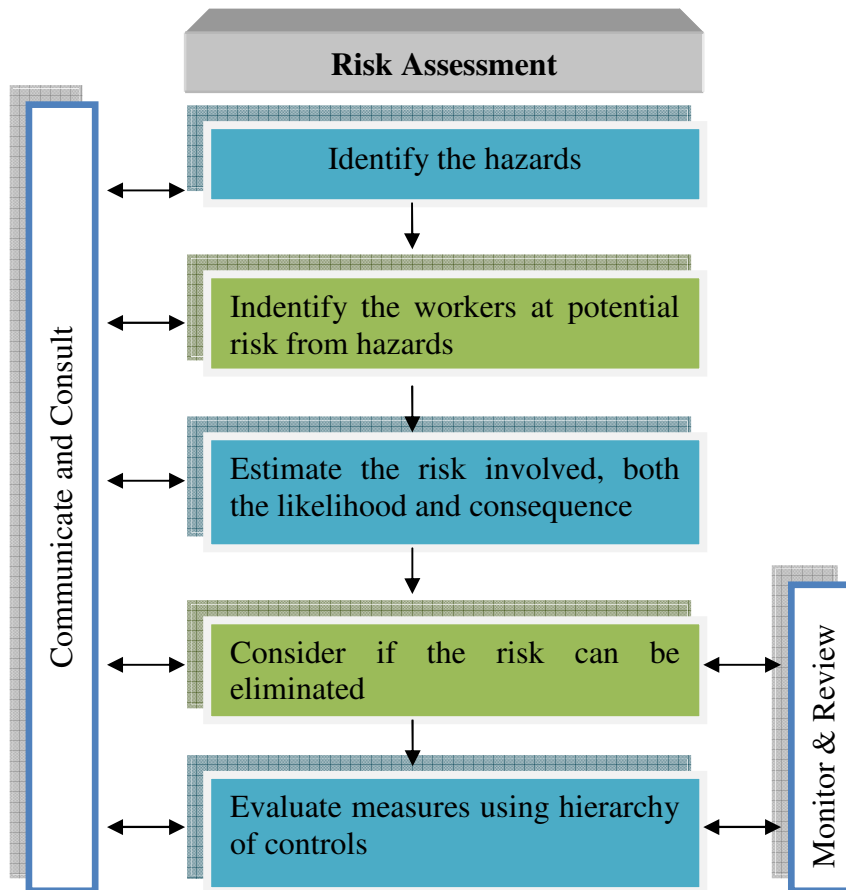
The directive says that risk assessments must be carried out to assess the risk of exposure to blood-borne infections from sharps injuries, and where there is a risk of exposure, employers need to identify whether exposures can be eliminated.

The sharps directive (2010/32) says where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection, workers' exposure must be eliminated by taking the following measures, without prejudice to their order:

- Specifying and implementing safe procedures for using and disposing sharp medical instruments and contaminated waste;
- Eliminating the unnecessary use of sharps by implementing changes in practice and *where the risk assessment deems it necessary* providing medical devices incorporating safety engineered mechanisms
- Providing sharps disposal equipment as close as possible to those areas where sharps are being used or found;
- Banning the practice of recapping

Measures to be applied in the light of risk assessment include:

- Safe systems of work by developing an overall prevention policy
- Appropriate vaccination (eg hepatitis B vaccine)
- Information and awareness raising
- Training in the correct use of medical devices
- Employers to release workers who are required to attend training
- Employers to revise reporting procedures
- Local national and European-wide reporting systems
- Workers to report immediately any accident or incident involving sharps
- Policies and procedures to be in place in case of a sharps injury occurring.



Step by step guide to risk assessment and implementation of the directive. Engagement of senior management and workers’ representatives.

There needs to be commitment from the top, which means senior management. However as the directive makes clear, partnership working with workers’ representatives are key to the successful implementation of the directive, and safety representatives play a key role in the successful implementation of the directive. Employers and trade unions may want to consider jointly appointing sharps advocates who would be responsible for overseeing the project.

Risk assessments should be conducted in compliance with existing European legislation (89/391 and 2000/54). The European Commission has produced guidance to help member states comply with this legislation. This lists the following steps:

1. Identify the hazards
2. Identify the workers at potential risk from those hazards
3. An estimation of the risk involved in terms of both the likelyhood and consequence
4. Consider if the risk can be eliminated; and if not
5. Make a judgement on whether measures to prevent or reduce the injury need to be introduced.

- 1. Identify the hazard:** In most situations within a hospital or healthcare environment there is a potentially serious occupational health risk whenever a needle or other sharp is used on a patient. There will be varying degrees of exposure to blood-borne viruses (BBVs). The main BBVs of concern are hepatitis B/C and HIV.

Accidental injury by a sharp implement, such as a hollow bore needle contaminated with a BBV can lead to transmission of the virus. While the risks of contracting a BBV are variable, the anxiety of having to go through blood tests and possible treatment can cause a worker a great deal of stress.

- 2. Decide who might be harmed and how:** There are many types of health care and hospital work that can expose individuals to the risk of sharps injuries. They include:

- clinical work - clinical procedures such as phlebotomy, cannulation, vaccination, acupuncture and surgical procedures
- ancillary services – cleaning, portering, hospital laundry and sterile supplies
- diagnostic and laboratory work
- mortuary work.

Groups that carry out the majority of procedures using sharps are those most at risk. These include: nurses, operating departmental practitioners (ODPs), phlebotomists, physiotherapists, doctors, health care assistants and laboratory technicians. In addition, cleaning staff will have a high exposure to risks if sharps are not properly disposed of. Community-based, as well as acute staff, may be injured by inappropriate use or non-disposal of sharps. There are also specific environmental regulations in place to cover the disposal of hazardous health care waste such as sharps in a community setting (DH, 2011).

Injury can occur with a wide range of items, but those with a higher risk of injury include:

- hollow bore hypodermic needles
- IV cannulae
- winged steel needles (*butterfly*)
- phlebotomy needles.

- 3. An estimation of the risk involved in terms of both the likelihood and consequence:** Employers are required by *Directive 2010/32/EU and other relevant community legislation* to do everything reasonably *practicable* to eliminate hazards. When considering the frequency of sharps injuries, it is important to note that numerous studies and surveys have demonstrated that there is a very significant *under-reporting of these injuries*ⁱ. Therefore, the documented number of cases cannot be viewed as indicative of the scale of the problem.

As outlined above in assessing the level of risk employers must consider the likelihood and the severity of injury. Below is a standard risk matrix tool, used by Professor Andreas Wittmann of the University of Wuppertal, Germany to perform a generic risk assessment for needlestick injuries. This assessment considers the degree of risk for medical devices that incorporate needles, based on the typical frequency of injury and amount of blood exposure (severity).

Generic risk matrix for medical devices incorporating needles

RISK by amount of blood exposure per device	Critical		Infusion devices	Blood collection devices	
	Serious		IM Injection devices	Lancets	
	Medium	Acupuncture	(Blood splashes) Spinal injection devices Subcutaneous Injection devices		Surgical devices
	Low	No patient contact		Heparin injection devices	Insulin injection devices
		Seldom	Sometimes	Often	Frequently
	FREQUENCY of NSI in health care settings				

Risk classification

Risk is not acceptable. Action to address risk is very urgently required.

Risk is not acceptable. Action to address risk is required.

Risk is acceptable. Standard precautions appropriate.

Where safety devices do not exist for a specific application the use of double gloving, vaccination against Hepatitis B and proper information and training for the staff is recommended.

! Important note regarding the high risk (red) category:

There are specific health care settings and situations where the probability that patients will be carriers of blood-borne pathogens will be predictably high. In all cases where this is likely, the risk classification should automatically be considered high (red) regardless of the type of sharps device being used.

4/5 Consider if the risk can be eliminated &

Make a judgement on whether measures to prevent or reduce the injury need to be introduced

An employer has a responsibility to take all practical measures to eliminate the risk of injury. Wherever sharps are used there is a risk of injury. Therefore the only way to eliminate sharps injuries is to eliminate the use of sharps. However this may not always be reasonably practical. Employers, workers' representatives & sharps champions (if appointed) should compare what they are doing now with the requirements of the directive, and prioritise the further controls that need to be put in place. As the directive states, these controls should be prioritised in compliance with the hierarchy of controls, as set out in EU directive 89/391. EU Directive 2000/54 set out how these should be applied to the exposure of biological agents such as sharps injuries. These were summarised by the *International Labour Organisation/World Health Organisation* as follows:

- i. **Elimination, or Substitution**, - eliminating the unnecessary use of sharps by implementing changes in practice;
- ii. **Engineering Controls** - providing medical devices incorporating safety-engineered protection mechanisms;
- iii. **Administrative Controls, or Safe Systems of Work**, - specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste.
- iv. **Work Practices** – universal precautions and the practice of recapping shall be banned with immediate effect.
- v. **PPE** - the use of Personal Protective Equipment (gloves, masks, gowns, etc);

Information and Awareness-Raising

The employer shall take the following appropriate measures to raise awareness amongst workers and their managers:

- Highlight the risks of handling sharps;
- Give guidance on existing legislation and local policies;
- Promote good practices and safe systems of work regarding the prevention of sharps injuries;
- Promote the importance of recording sharps injuries;
- Provide information on available support programmes.
- Raise awareness by developing activities and promotional materials in partnership with representative trade unions and/or workers' representatives.

Training

Training shall be provided on policies and procedures associated with the prevention and management of sharps injuries during induction for all new and temporary staff (including sub-contractors) and at regular intervals thereafter. Training shall include:

- Induction for all new and temporary staff;
- The risk associated with blood and body fluid exposures;
- Preventative measures including standard precautions, safe systems of work (including the ban on recapping) and, the correct use of sharps bins and disposal procedures;
- The correct use of medical devices incorporating sharps protection mechanisms;
- The importance of immunisation and how to access immunisation services;
- The reporting, response and monitoring procedures and their importance.

Reporting

The Directive requires there should be local, national and Europe wide systems of reporting in place. Each Member State will have its own requirement for reporting sharps injuries and these mechanisms must include local, national and Europe wide systems. Currently there is often lack of clarity and information about the need to report and as a result there is significant under reporting of sharps injuries. Workers are required, and should therefore be encouraged, to report any accident or incident involving sharps to the employer and/or to the person in charge or responsible for safety and health at work.

Workers' representation

The directive says that employers and workers' representatives shall work together at the appropriate level to eliminate and prevent risks, protect workers' health and safety and create a safe working environment including the use of equipment (including sharps safety devices), training and information and awareness raising. To this end employers' should consider appointing safety representatives and other workers' representatives to local work place steering groups set up to implement the directive. Trade unions and employers may also consider jointly appointing sharps champions to drive through the changes necessary to implement the directive

Employers must familiarise themselves with the functions of safety reps as set out in European Directive 89/391 and any relevant member state laws and regulations.

“Things can still go wrong”

If these guidelines are adopted then reasonable steps will have been taken to prevent a sharps injury but things can still go wrong. If a worker does sustain an injury then appropriate support as prescribed in the Directive should be given to the individual concerned. The wording of the Directive addressing response and follow up actions after an injury is contained at clause 10 of the Framework Agreement which, for ease of reference, is detailed below:

Clause 10: Response and follow up

Policies and procedures shall be in place where a sharp injury occurs. All workers must be made aware of these policies and procedures. These should be in accordance with European, national/regional legislation and collective agreements, as appropriate.

In particular, the following action shall be taken:

- The employer takes the immediate steps for the care of the injured worker, including the provision of post exposure prophylaxis and the necessary medical tests where indicated for medical reasons, and appropriate health surveillance in accordance with clause 6(2)(c).*
- The employer investigates the causes and circumstances and records the accident/incident, taking – where appropriate, the necessary action. The worker must provide the relevant information at the appropriate time to complete the details of the accident or incident.*
- The employer shall, in cases of injury, consider the following steps including counselling of workers where appropriate and guaranteed medical treatment/ Rehabilitation, continued employment and access to compensation shall be in accordance with national and/or sectoral agreements or legislation.*
- Confidentiality of injury, diagnosis and treatment is paramount and must be respected.*

Appendix

Member state specific guidance

United Kingdom: The Partnership of Occupational Safety and Health in Healthcare (NHS Staff Council sub group on health and welfare) has produced its own guidance on the implementation of the guidance within the United Kingdom. This can be found at <http://www.nhsemployers.org/HealthyWorkplaces/LatestNews/Pages/Guidance-on-implementing-sharps-directive.aspx>.

ⁱ HSE (Health & Safety Executive) Board Paper (HSE/08/60 dated 25 September 2008 estimated that only 40,000 out of 85,000 needlestick injuries were reported.

Effectives of measures to prevent needlestick injuries among employees in health professions (p.24) (Prepared for German Ministry of Labour and Social Affairs) dated 2006 said the rate of under-reporting ranged from 26% to 90%.

Elder A Patterson C (2006) "Sharps Injuries in UK health care: a review of injury rates, viral transmission and potential efficacy of safety devices" Occupational Medicine 56:566-74 estimated that only 1 in 10 needlestick injuries were reported