



European
Biosafety
Network

**Prevention of Sharps Injuries in the
Hospital and Healthcare Sector**

**Implementation Guidance for the EU
Framework Agreement, Council Directive
and Associated National Legislation**

Introduction

This document has been drafted by the European Biosafety Network, a newly constituted organisation which has been established with the principal object of eliminating sharps injuries throughout the European Union. The European Biosafety Network was established following the final adoption of the new European Directive on sharps injuries with a key commitment to improve the safety of patients and healthcare and non-healthcare workers. The Directive was drafted by the European Commission and adopted by the European Council of Ministers. It incorporates the EU Framework Agreement on sharps injuries, negotiated by the EU social partners EPSU and HOSPEEM, and also responds to a European Parliament report on needlestick injuries.

The Network is open to national and European professional institutions, representative associations, unions and other interested organisations committed to the elimination of sharps injuries throughout the EU. This will be achieved by promoting best practice and providing guidance and assistance to Member States and the European Commission on the legislative implementation of the European Union Council Directive on sharps injuries and to ensure maximum compliance and coverage for all relevant workers and sectors. The Network's objectives include establishing measures, at EU level, aimed at increasing the education and training of healthcare and non-healthcare workers and promoting safer practices as well as providing the necessary safety engineered technologies.

The Network is hosting the 1st European Biosafety Summit in Madrid on 1-2 June 2010 at the offices of the Spanish General Council of Nursing. This first EU Biosafety Summit is an important public expression of the European social commitment to the prevention of risks associated with blood-borne diseases, which have a huge impact on the health of the workers and the citizens of European Union.

Key Points for Implementation

- Each Member State is required to introduce national legislation or legally-binding agreements to implement the Directive. Legislation is considered the effective route to ensuring that the requirements of the Directive are fully applied.
- The Agreement and the Directive provide the framework to put in place and implement adequate and practical preventative measures before the publication of the required national legislation. National implementation negotiations should begin immediately so that these serious occupational risks are reduced as soon as possible.
- The Directive specifies minimum requirements and Member States are free to adopt additional measures to protect workers. They should be encouraged to do so to ensure that the national requirements are as clear and effective as possible.
- Risk assessment shall be conducted for all situations where there is potential for injury or exposure to blood or other potentially infectious material. Where the results of the risk assessment reveal a risk of exposure, this must be controlled, by:
 - Elimination - eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment,
 - Safe Procedures - specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste. The practice of recapping shall be banned with immediate effect.;
 - Engineering Controls - providing medical devices incorporating safety-engineered protection mechanisms;
 - PPE - the use of Personal Protective Equipment (gloves, masks, gowns, etc).
- Independent studies show that a combination of training, safer working practices and the use of medical devices incorporating safety-engineered protection mechanisms can prevent the majority of needlestick injuries. ¹Studies have also demonstrated that failure to implement any one of these three elements results in a significantly reduced impact. ² Similarly, attempts to implement safety-engineered medical devices only in certain areas or on certain patients would be neither practicable nor effective.
- The highest risk procedures include blood collection, IV cannulation and percutaneously placed syringes. Small amounts of blood can result in potentially life threatening infection. Hollow-bore needles contain more blood and therefore carry more risk than solid needles.
- The incidence of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) is significantly higher in the hospital population than in the general population. Additionally, patients will be treated before it is known that they are carrying a serious blood-borne infection, so it is not feasible to reliably segregate patients on the basis of risk and universal sharps injuries prevention measures are therefore, appropriate.

Prevention of Sharps Injuries in the Hospital and Healthcare Sector

Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation

1 Background and Implementation

The European Social partners in the hospital and healthcare sector, HOSPEEM (*European Hospital and Healthcare Employers' Association*) and EPSU (*European Public Services Union*) signed a Europe-wide framework agreement (the Agreement) on the prevention of sharps injuries on 17 July 2009, which has been incorporated into the proposal for a Council Directive (the Directive) – COM (2009) 577 final (26 October 2009).

The Agreement and the Directive recognise 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 needlestick injuries. Needlestick injuries are a very serious occupational hazard for healthcare workers. More than one million needlestick injuries are estimated to occur in the European Union each year. Needlestick 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 a serious infection is not transmitted. Healthcare workers and their families can suffer many months of anguish as they wait to discover whether they have contracted a potentially fatal infection.

Each Member State is required to bring into force national legislation or legally binding agreements to implement the Directive within two years following its publication. The Agreement (annexed to the Directive) and the Directive will contribute to achieving the safest possible working environment in the hospital and healthcare sector and are binding between employers and workers. The Directive specifies minimum requirements and Member States are free to adopt additional measures to protect workers. The Agreement and the Directive provide the framework to put in place and implement adequate and practical preventative measures in anticipation of the publication of the required national legislation. National implementation negotiations should begin immediately so that serious occupational risks are reduced as soon as possible.

2 Purpose and scope

This document (the Guidance) provides important guidance on the practical implementation of the Agreement and the Directive and needs to be read in conjunction with them and relevant national legislation and guidance. The purpose of these documents is to achieve the safest possible working environment by preventing injuries to workers caused by all medical sharps, including needlesticks, and protecting workers at risk. It provides for an integrated approach, establishing policies in risk assessment, risk prevention, training, information, awareness-raising and monitoring, and for response and follow-up procedures. The Directive applies to any person employed by an employer including trainees and apprentices (full-time, part-time or temporary contract), in the healthcare sector, including related services and activities. Subcontracted or agency workers also fall within the scope of the agreement.

3 Principles

The principles which must be observed when taking action include:

- the vital role of a well-trained, adequately resourced and secure workforce in preventing risks;
- 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 consultation on the choice and use of safe equipment, identifying how best to carry out training, information and awareness-raising processes.
- the responsibility of each worker to take care of his or her own safety and the duty of the employer to ensure the health and safety of workers in every aspect relating to their work;
- to never assume that no risks exist;
- the hierarchy of measures concerning the safety and health protection of workers in the Directive, i.e. to avoid risk, to evaluate remaining risks which cannot be avoided, to combat risks at source and to reduce risks to a minimum;
- the importance of a combination of several measures (see 5 below) for achieving the safest possible workplace environment;
- promoting a 'no blame' culture. Incident reporting should focus on systemic factors rather than individual mistakes and systematic reporting must be considered as accepted procedure.

4 Assessment of risks

Risk assessment procedures shall be conducted in compliance with articles 3 and 6 of Directive 2000/54/EC and Articles 6 and 9 of Directive 89/391/EEC. They must cover all situations where there is potential for injury or exposure to blood or other potentially infectious material. The Directive also states that any risk assessment must take into account how well resourced and organised the workplace is.

Directive 2000/54/EC (safety of workers exposed to biological agents) states:

"Where prevention of workers exposure is not possible, the risk of exposure must be limited to as low a level as necessary in order to adequately protect the health and safety of the workers concerned, in particular by the following measures which are to be applied in light of the results of the risk assessment:

- a) keeping as low as possible the number of workers likely to be exposed;
- b) design of work processes and engineering control measures so as to avoid or minimise the release of biological agents into the workplace."

The highest risk procedures include blood collection, IV cannulation and percutaneously placed syringes. Small amounts of blood can result in potentially life threatening infection. Hollow-bore needles contain more blood and therefore carry more risk than solid needles. Therefore, whenever a hollow-bore needles is used on a patient there is a significant risk to healthcare workers.

It is important to note that the incidence of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) is significantly higher in the hospital population than in the general population. Additionally, patients will be treated before it is known that they are carrying a serious blood-borne infection, so it is not feasible

to reliably segregate patients on the basis of risk and universal sharps injuries prevention measures are therefore, appropriate.

5 Elimination, prevention and protection

The Directive states that employers must comply with the hierarchy of controls as set out in European Directives 89/391 and 2000/54.

Where the results of the risk assessment reveal a risk of exposure, this must be controlled, by:

- Elimination - eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment,
- Safe Procedures - specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste. The practice of recapping shall be banned with immediate effect. These procedures shall be regularly reassessed and shall form an integral part of the measures for the information and training of workers;
- Engineering Controls - providing medical devices incorporating safety-engineered protection mechanisms;
- PPE - the use of Personal Protective Equipment (gloves, masks, gowns, etc).

Directive 89/655/EEC (Minimum safety and health requirements for the use of work equipment by workers at work) in Article 3.2 says that where risk cannot be eliminated the employer shall take appropriate measures to minimise the risks.

Appropriate measures to minimise the risks would include the provision by employers of safer needle devices and sharps containers. Independent studies show that a combination of training, safer working practices and the use of medical devices incorporating sharps protection mechanisms (safety-engineered devices) can prevent the majority of needlestick and sharps injuries¹. Studies have also demonstrated that failure to implement any one of these three elements results in a significantly reduced impact.² Similarly, attempts to implement safety-engineered medical devices only in certain areas or on certain patients would be neither practicable nor effective.

It is also important to note that as well as safeguarding the safety of healthcare staff and making this a more attractive profession, these measures have been proven to be cost effective.³

As the Directive stipulates managers should consult with workers' representatives on the choice and uses of safety-engineered devices, identifying how best to carry out training, information and awareness-raising processes. In Spain there are already four regions where sharps prevention measures, including the mandatory use of medical devices incorporating safety-engineered needle protection, is required by law. In supporting the implementation of these measures the Spanish Nurses Association has found that it is very important that the staff that will use the devices are involved in the selection process.

When considering safety-engineered medical devices the following selection criteria should be applied:

- The device must not compromise patient care;
- The device must perform reliably;

- The safety mechanism must be an integral part of the safety device, not a separate accessory;
- The device must be easy to use and require little change of technique on the part of the health professional;
- The activation of the safety mechanism must be convenient and allow the care-giver to maintain appropriate control over the procedure;
- The device must not create other safety hazards or sources of blood exposure;
- A single-handed or automatic activation is preferable;
- The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual sign to the health professional;
- The safety mechanisms should not be easily reversible once activated.

In the Annex to Directive 89/655/EEC, which specifies the minimum requirements, it states:

2.8 “Where there is a risk of mechanical contact with moving parts of work equipment which could lead to accidents, those parts must be provided with guards or devices to prevent access to danger zones or to halt movement of dangerous parts before danger zones are reached.”

Comprehensive user training is pivotal to the introduction of safety-engineered medical devices. Experience has shown that when this is done well, in combination with safer working procedures, the implementation of the safety measures is much more effective.

6 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;
- Raise awareness by developing activities and promotional materials in partnership with representative trade unions and/or workers’ representatives;
- Provide information on support programmes available.

7 Training

Workers shall receive training on policies and procedures associated with the prevention and management of sharps injuries during induction for all new and temporary staff and at regular intervals thereafter. Training shall include:

- The correct use of medical devices incorporating sharps protection mechanisms;
- 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 importance of immunisation and how to access immunisation services;
- The reporting, response and monitoring procedures and their importance;

End of guidance

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- ¹ a) Advances in Exposure Prevention; vol. 3, no. 4; Libourne study GERES day_09/2001
 b) D. Adams*, T.S.J. Elliott, 'Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study' *Journal of Hospital Infection* (2006) 64, 50e55
 c) *Four-year surveillance from the Northern France network, Am J Infect Control. 2003 Oct;31(6):357-63. Tarantola A, Golliot F, Astagneau P, Fleury L, Brucker G, Bouvet E; CCLIN Paris-Nord Blood and Body Fluids (BBF) Exposure Surveillance Taskforce.*
 d) Cullen BL, Genasi F, Symington I, Bagg J, McCreaddie M, Taylor A, Henry M, Hutchinson SJ, Goldberg D, 'Potential for reported needlestick injury prevention among healthcare workers in NHS Scotland through safety device usage and improvement of guideline adherence: an expert panel assessment' (2006), *Journal of Hospital Infection*, 63: 445-451.'
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 f) *Louis N, Vela G, Groupe Projet. Évaluation de l'efficacité d'une mesure de prévention des accidents d'exposition au sang au cours du prélèvement de sang veineux. Bulletin Épidémiologique Hebdomadaire 2002 ;51 : 260-261.*
- ² D. Adams*, T.S.J. Elliott, 'Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study' *Journal of Hospital Infection* (2006) 64, 50e55
- ³ a) A. Wittmann, F. Hofmann, B. Neukirch, Ch. Thürmer, N. Kralj, S. Schroebl, K. Gasthaus; 'Blood-borne viral infections: causes, risks and prevention strategies', Bergische Universität Wuppertal, May 2005
 b) US General Accounting Office, Impact assessment regarding Needlestick Safety and Prevention Act; Nov 17, 2000
 c) Evaluation of the Efficacy of a Measure to Prevent Accidental Needlestick Injuries by Using Safety Needles for Venous Blood. Louis Nicole (1), Vela Gilles (2) and the Project Group Cellule d'Hygiène [Hygiene Unit], Centre Hospitalier 06401 – Cannes cedex Département d'Ergonomie [Department of Ergonomics], Centre Hospitalier Cannes
 d) 2004 Center for Disease Control Sharps Safety Workbook, USA - Cost of Needlestick Injuries