Background to EU Directive

Health and Safety (Sharps Instruments in Healthcare) Regulations 2013

These Regulations implement the EU Council Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector. Many of the requirements contained in the Directive already formed part of health and safety law in Great Britain. The new regulations only contain those requirements that are not specifically addressed in existing legislation.

HSE has produced a Health Services Information sheet Health and Safety (Sharps Instruments in Healthcare) Regulations 2013

[1]
to assist employers and employees to understand their legal obligations under the Regulations.

The Directive


. Member states, including the UK, have until 11th May 2013 to ensure that the provisions of the Directive have been implemented into national legislation.

The Directive legislates a framework agreement on the prevention of sharps injuries in hospitals and the healthcare sector (signed in July 2009) by the Social Partners – the European Hospital and Healthcare Employers’ Association (HOSPEEM) and the European Federation of Public Service Unions (EPSU). These two bodies were recognised as European Social Partners by the European Commission in 2006.

Background to the Directive

In February 2005, the European Parliament adopted a resolution on promoting health and safety in the workplace. This included a call on the European Commission to ensure Member States implemented specific preventative measures necessary to protect healthcare workers from injuries caused by needlesticks in view of the risk of infection from serious blood-borne infections, such as Hepatitis B and C and HIV.

In July 2006, the European Parliament adopted a resolution requesting that the Commission submit a legislative proposal on protecting healthcare workers from blood-borne infections due to needle stick injuries.

The European Commission sought the opinion of the EU Social Partners on whether there should be legislation to strengthen the protection of healthcare workers from blood-borne infections due to needlesticks and whether a joint initiative by the Social Partners would be appropriate.

Following this, the Social Partners were invited to work together to agree a framework to prevent needlestick injuries in the healthcare sector. After consultation and a technical seminar on the issue, the Social Partners
informed the Commission of their intention to negotiate on a wider basis covering all types of sharp injuries and not just needlesticks.

Negotiations started in January 2009 and by 2 June 2009 an agreement had been reached. On 17 July 2009, after approval from the European Commission, the framework agreement was signed by the Social Partners.

As a result, on 26 October the Commission published a proposal for a Directive to implement the framework agreement.

On 11 February 2010, the EU Parliament’s Employment and Social Affairs Committee adopted a Motion supporting the adoption by the Council of the proposal Directive.

On 10 May 2010, a Directive was introduced to prevent injuries and blood-borne infections to hospital and healthcare workers from sharp instruments such as needles.

Other information on the Directive

- The Safer Needles Network

  [3]

  and the Partnership for Occupational Safety and Health in Healthcare (POSHH) have agreed advice for the NHS on preparing for implementation of the sharps Directive. The advice is intended to help employers in ensuring that they are ready and compliant once UK legislation is passed. It provides guidance on the practical implementation of the Directive and should be read in conjunction with relevant national legislation and guidance.

- The Royal College of Nursing

  [4]

  has published guidance on the prevention of sharps injuries. The publication, Sharps Safety

  [5]

  covers the law on sharps injuries, including the European Directive and its underlying principles, as well as its requirements on healthcare providers.

- The European Biosafety Network

  [6]

  was established following the adoption of the new European Directive on Sharps Injuries to improve the safety of patients and healthcare and non-healthcare workers. The Network has published guidance

  [7]

  that provides a practical toolkit to aid in the implementation of the Directive on the prevention of sharps injuries in the hospital and healthcare sector.

Link URLs in this page

1. Health and Safety (Sharp Instruments in Healthcare) Regulations 2013
   http://www.hse.gov.uk/pubns/hsis7.htm

2. Official Journal of the European Union
3. Safer Needles Network
   http://www.saferneedles.org.uk/
4. Royal College of Nursing
   http://www.rcn.org.uk/
5. Sharps Safety
6. European Biosafety Network
   http://www.europeanbiosafetynetwork.eu/
7. published guidance
Health and Safety (Sharp Instruments in Healthcare) Regulations 2013
Guidance for employers and employees

HSE information sheet

This information sheet is for healthcare employers and employees. It will help you understand your legal obligations under the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 (the Sharps Regulations).


All employers are required under existing health and safety law to ensure that risks from sharps injuries are adequately assessed and appropriate control measures are in place. The Sharps Regulations build on the existing law and provide specific detail on requirements that must be taken by healthcare employers and their contractors.

This information sheet should be read in conjunction with other information on managing the risks of sharps injuries, and the associated risks of infection from blood-borne viruses. HSE guidance and links to other relevant guidance can be found on HSE’s website.

Which employers must take action on the Sharps Regulations? - regulations 3 and 4

The employer's duties in the Sharps Regulations only apply if you are either:

- an employer whose primary work activity is the management, organisation or provision of healthcare (a healthcare employer); or
- a contractor working for a healthcare employer and your staff may be at risk of a sharps injury while on the premises of or working under the management and supervision of the healthcare employer (for example laundry workers, caretakers, cleaners, waste disposal workers, bank nurses and locum doctors). However, a contractor's duties will only apply to the extent of their control of work involving medical sharps.

Health Services Information Sheet 7

The main healthcare employer and their contractors must co-operate and share information to ensure that risks of sharps injuries are adequately controlled and that they have the appropriate arrangements to comply with the Sharps Regulations, as required by the Management of Health and Safety at Work Regulations 1999.

For most healthcare employers and their contractors it will be clear that the Regulations apply to them. The Annex at the end of this information sheet provides examples where further clarification is likely to be helpful.

How do the Sharps Regulations change my responsibilities for managing the risks from the use of sharps?

Effective safe management of sharps, across all sectors, flows from the existing health and safety legislation. In particular, the need to assess the risks, provide appropriate information and training, and consult with employees. The Sharps Regulations build on the existing law and provide specific detail on requirements that must be taken by healthcare employers and their contractors. These are:

Use and disposal of medical sharps

The Sharps Regulations follow the principles of the hierarchy of preventative control measures, set out in the Control of Substances Hazardous to Health Regulations (COSHH). However, they require that employers consider the additional risk control measures below:

Avoid the unnecessary use of sharps - regulation 5(1)(a)

Needles, scalpels etc will remain essential tools for effective medical care. However, the employer should ensure that sharps are only used where they are required. For example, organisations that have reviewed the use of sharps have identified staff using needles to carry out tasks for which they are not required (for example collection of urine samples from catheter bags). Needle-free equipment is available for certain procedures and should be used, where it is reasonably practicable to do so.
Where it is not reasonably practicable to avoid the use of medical sharps, the Sharps Regulations require employers to:

Use safer sharps (incorporating protection mechanisms) – regulation 5(1)(b)
The employer must substitute traditional, unprotected medical sharps with a ‘safer sharp’ where it reasonably practicable to do so. The term ‘safer sharp’ means medical sharps that incorporate features or mechanisms to prevent or minimise the risk of accidental injury. For example, a range of syringes and needles are now available with a shield or cover that slides or pivots to cover the needle after use. The following factors should be considered:

- the device must not compromise patient care;
- the reliability of the device;
- the carer should be able to maintain appropriate control over the procedure;
- other safety hazards or sources of blood exposure that use of the device may introduce;
- ease of use (taking into account the existing clinical practices commonly in use by the relevant health professionals – but not assuming custom and practice is safest);
- is the safety mechanism design suitable for the application? The following are relevant:
  - if activation of the safety mechanism is straightforward, it is more likely to be used;
  - if the safety mechanism is integral to the device (ie a separate accessory) it cannot be lost or misplaced;
  - for many uses a single-handed or automatic activation will be preferable;
  - an audible, tactile or visual signal that the safety mechanism has correctly activated is helpful to the user; and
  - the safety mechanism is not effective if it is easily reversible.

‘Safer sharps’ do not necessarily remove all risks associated with the use of a sharp. For example, a needle shield is activated after a procedure is completed, but a sharps injury to the healthcare worker can occur during the procedure (eg when a patient moves unexpectedly) and a ‘safer sharp’ will not prevent this.

For some procedures, there may be more than one person involved in handling, sterilising or otherwise dealing with the sharps. The employer’s COSHH risk assessment should consider all these aspects, and identify the appropriate equipment, safe procedures, personal protective equipment (PPE) and immunisation required at each stage.

Involving the end users of the equipment and their representatives in the selection of safer sharps will help ensure that they use the new equipment safely, and any reduction in the number of sharps injuries is maintained for longer.

If a suitable safer sharp is not available to reduce the risk of injury, the employer should ensure that safe procedures for working with and disposal of the sharp are in place.

In some circumstances, patients may provide needles (for example, for administration of insulin) which they expect a healthcare worker to use and the employer has not had an opportunity to ensure that it is a suitable ‘safer sharp’. The employer’s risk assessment should identify if their employees may be faced with such a request, and make arrangements to ensure that employees have safe systems of work and the appropriate information, training and equipment to deal with this situation.

Prevent the recapping of needles – regulation 5(1)(c)
Injuries can occur after a needle has been used if the healthcare worker holds the needle in one hand and attempts to place a cap on the needle with the other hand (so-called two-handed recapping).

Needles must not be recapped after use unless the employer’s risk assessment has identified that recapping is itself required to prevent a risk (eg to reduce the risk of contamination of sterile preparations). In these limited cases, appropriate devices to control the risk of injury to employees must be provided. For example, needle-blocks can be used to remove and hold the needle cap and so allow safe one-handed recapping.

Place secure containers and instructions for safe disposal of medical sharps close to the work area – regulation 5(1)(d)
Regulation 7(6)(c) of COSHH requires systems to dispose of contaminated waste safely. The Sharps Regulations supplement this by requiring that clearly marked and secure containers be placed close to the areas where medical sharps are used. Instructions for staff on safe disposal of sharps must also be placed in those areas.

In many healthcare facilities sharps bins can be placed next to the healthcare worker so they can drop the used sharp straight into it. For example, in wards this can be achieved by placing the sharps container on the dispensing trolley.

However, some healthcare workers do not operate in premises in which they have control, for example paramedics or healthcare workers working in a patient’s home. In these cases, the employer’s risk assessment should select appropriate sharps, specify safe working procedures and provide suitable portable
sharps containers and means for collection and replacement of those.

Information and training

The Sharps Regulations supplement existing requirements to provide health and safety information and training for staff by requiring that it includes those matters listed below (from Schedule 1 and 2 of the Sharps Regulations), to the extent that they are relevant to the employee’s work.

The information provided to employee – regulation 6

Information may be provided in many forms, including safe operating systems, safety guides, posters, information on internal staff websites. The employer must work with any appointed safety representatives in developing and promoting the information to be given to workers (regulation 6(2) and (3)). This provision recognises the role of union and other safety representatives in helping to raise awareness of the risks from medical sharps.

The information provided to employees must cover:

- the risks from injuries involving medical sharps;
- relevant legal duties on employers and workers;
- good practice in preventing injury;
- the benefits and drawbacks of vaccination; and
- the support available to an injured person from their employer (see requirements on accident follow-up below).

Employee training – regulation 6(4)

Training should be in an appropriate form to ensure that your employees know how to work safely and without risks to health with the specific sharps equipment and procedures that they will use. Guidance on ensuring that employees receive appropriate health and safety training is available in Health and safety training: A brief guide INDG345 (www.hse.gov.uk/pubns/indg345.htm).

Under the Sharps Regulations, the training provided to employees must cover:

- the correct use of safer sharps;
- safe use and disposal of medical sharps; and
- what to do in the event of a sharps injury (see requirements on accident follow-up below);
- the employer’s arrangements for health surveillance and other procedures.

Arrangements in the event of injury

The Sharps Regulations require employers to take specific actions in the event of a sharps injury. This means they need to have procedures in place to ensure that they can respond effectively and in a timely manner when an injury occurs.

Injured employee’s duty to notify their employer of a sharps accident – regulation 8

An employee who receives a sharps injury at work must notify their employer as soon as practicable. The employer will need to ensure they have sufficiently robust arrangements to allow employees to notify them in a timely manner, including where the employee works, out-of-office or away from the employer’s premises.

As set out above, an employee’s training must be clear about the requirements for notifying and on the employer’s procedures for follow-up. This will include who and how they should notify and what information is likely to be useful.

Recording and investigating the incident – regulation 7(1)

Employers must make a record of the sharps injury when they are notified of it, whoever provides that notification. They must investigate the circumstances and causes of the incident and take any action required. The injured person is required to provide sufficient information to their employer to allow them to carry out this investigation.

The record of the injury should include who was injured, and when and where the incident occurred. If possible, the summary record should contain sufficient detail to identify what type of sharps was involved, at what stage of a procedure or post-procedure/disposal of the sharp the injury occurred, and the severity of the injury. If the employer has an existing accident book or other recording system, it will be appropriate to use this for the record of sharps injuries.

The extent of the accident investigation should be proportionate to the potential severity of the incident. For example, where an employee has injured themselves with a clean needle as they take it out of the packet it will usually be sufficient to record the details and ensure they receive any first aid required. Injuries involving used needles will involve more analysis and an appropriate record should be kept of the findings of the investigation.

The purpose of the investigation should be to establish whether the employer’s existing risk control measures are adequate. It should look at underlying and root causes as well as the immediate factors that led to the individual incident. Investigations should be conducted with accident prevention in mind, not placing blame. An investigation of a significant sharps injury may involve expertise from health and safety, occupational...
Health and infection control teams (where available). Any lessons to be learned should be applied across an organisation (if appropriate), not just in the location or department where the accident occurred.

In the case of an injury where there may have been exposure to a blood-borne virus or other significant infection, the investigation may also involve establishing the infection status of the source patient (where it is possible to identify the individual). If this information is known, it should be handled in accordance with appropriate requirements for patient confidentiality. If it is promptly shared with the medical professional who is treating the injured person, it can greatly assist with ensuring they receive the right treatment or that they do not take unnecessary prophylaxis or anti-viral treatments.

Treatment and follow-up of a sharp injury – regulation 7(2)
The employer must ensure that, when notified of any incident in which an employee has been injured by a sharp that has or may have exposed them to a blood-borne virus, the employee:

- has immediate access to medical advice;
- has been offered post-exposure prophylaxis and any other medical treatment, as advised by a doctor; and
- the employer has considered whether counselling would be appropriate for the employee.

Advice for doctors on the appropriate treatment and follow-up for an exposure to blood-borne viruses, including current post-exposure prophylaxis regimes, is provided by the Department of Health.

In some circumstances, an occupational health nurse or other suitably qualified and supervised practitioner may provide the assessment and treatment for an employee injured by a sharp. This service will be adequate to comply with the requirement for the advice to be provided by a doctor if:

- it is provided within a practice supervised by a registered medical practitioner; and
- it is carried out in accordance with the appropriate established operating procedure of that practice.

If staff work out-of-hours and/or on premises where there is not an occupational health service available to them, the employer must ensure they have sufficiently robust arrangements that will allow employees to access treatment in a timely manner. The training they provide staff should be clear as to where they should go for treatment.

Review procedures regularly – regulation 5(2)
The Sharps Regulations follow the same principles as any successful health and safety management regime, including reviewing procedures to ensure their continuing effectiveness. However, the Regulations specifically require employers to review, at suitable intervals, the procedures that are in place to implement the following risk control measures:

- use of medical sharps at work is avoided so far as is reasonably practicable;
- when medical sharps are used at work, safer sharps are used so far as is reasonably practicable;
- needles that are medical sharps are not capped after use at work unless the risk of injury to employees is effectively controlled by use of a suitable appliance, tool or other equipment;
- in relation to the safe disposal of medical sharps that are not designed for re-use:
  - written instructions are available for employees; and
  - clearly marked and secure containers are located close to areas where medical sharps are used at work.

A suitable review would involve gathering information on:

- the degree of compliance with the relevant procedures (if the procedures are not being followed there is usually a reason why, such as lack of training, or a genuine practical problem with the procedure itself);
- any areas where procedures are absent or inadequate. New 'safer sharps' may have become available for certain applications or guidance may have been issued from a relevant authoritative body;
- consultation with the relevant staff and their representatives; and
- injury and incident data.
Annex: Further clarification on when the Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 apply

The following have been raised as examples where some further clarification of the application of the Sharps Regulations would be helpful. However, it is important to remember that existing legal requirements still apply, whether or not the Sharps Regulations apply. For example, the need to follow the COSHH hierarchy.

Contractors
A contractor whose employees work at different times at healthcare premises and non-healthcare premises (for example, a cleaning firm) is not required to comply with the Sharps Regulations when their staff are working at a non-healthcare premises (eg an office). However, the existing requirements to ensure risks from sharps injuries are controlled apply. This means that if cleaners at non-healthcare premises may encounter drug litter or other unsafely disposed of used needles, the employer should assess the risk and provide the appropriate controls.

Healthcare workers providing care to people at their homes
The Regulations apply to employers whose primary activity is to organise, manage and provide healthcare, including where their employees provides care for people in their own homes. They do not place any duties on the person receiving care, their family members/cohabitees or their appointed attorney. The employer’s risk assessments and arrangements to comply with the Regulations will need to take account of the circumstances that their employees work in, including arrangements for any lone workers.

Residential care homes
Whether the Regulations apply will depend on the nature of the care provided by the home. They will apply if the primary purpose of the home is to provide healthcare. They will not apply if the main purpose of the home is limited to only providing residential care. The residents of either type of home will not have any duties under the Regulations.

Bank nurses and other agency workers contracted to work in healthcare
The employment status of an individual bank nurse or agency worker will depend on their exact circumstances. However, if they are employed by an employer whose main activity is the provision of healthcare or they are employed by an agency that provides services to that main healthcare employer, the Regulations will apply to risks of sharps injuries that arise from their work.

Clinical placement, student assistantship, elective, internship or other workplace training
The employment status of an individual student or trainee while they are on placement in a hospital or other healthcare premises will depend on their exact circumstances. The Regulations will apply to the healthcare employer who is responsible for providing their training. If there is no employment the student is deemed to be an employee of the employer providing the training by virtue of the Health and Safety (Training for Employment) Regulations 1990.

Employers and the medical school/academic institution will need to exchange information to ensure that the risks to the students are adequately controlled. The academic institution is not required to comply with the Regulations at the premises of the school or other academic institution itself.

Clinical trials in the pharmaceutical sector
Clinical trials cover a wide range of studies, some of which involve sharps, for example injections of a trial pharmaceutical or collection of blood samples.

Where employees of a healthcare employer (whether in a hospital or other premises) carry out trials involving sharps on behalf of a clinical research organisation/pharmaceutical company the Regulations will apply.

Where employees of a pharmaceutical company or research organisation carry out trials, the main activity of their employer is not the management, organisation or provision of healthcare and therefore the Regulations will not apply. However, if they enter healthcare premises to carry out the trial, especially if they make use of the host’s facilities (eg sharps waste disposal), the requirements of the existing legislation to co-operate and exchange information will apply.

Pharmacies
High-street pharmacies are primarily retail businesses so the Regulations do not apply. However, if the primary activity of a community pharmacy is to provide healthcare then the Regulations will apply. Pharmacies that are part of a hospital and/or an NHS-run service will be employed by a healthcare employer and the Regulations will apply to them.

Medical staff working in prisons, schools or other non-healthcare workplaces
If an employer’s primary activity is the management, organisation or provision of healthcare it does not matter where their staff work, these Regulations will apply. For example, the Regulations will apply:

- in Scotland, to medical staff providing care in prisons employed by NHS Scotland;
• medical staff employed by an independent medical service who provide primary and occupational healthcare to workers on offshore platforms;
• a healthcare business supplies an occupational health nurse to attend a non-healthcare company’s premises to administer vaccinations for the company’s employees, the healthcare business will be subject to the Regulations, but the company will not;

while the Regulations will not apply to the following:

• school nurses employed directly by the school;
• medical staff providing care in prisons, employed by the prison itself.

Non-healthcare contractors to a healthcare employer
Businesses that are contracted to provide non-healthcare services to healthcare employers, such as catering and building or plant maintenance, will only be required to act if those who work for them on the healthcare employer’s premises may be exposed to medical sharps while they are working there.

Such a risk should have been identified in a risk assessment. The term ‘medical sharps’ does not include kitchen knives or utility knives, as these are not used to carry out specific healthcare.

Further information

For further information on managing the risks from sharps injuries, general health and safety advice, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

This publication is available at:

You can find more advice at:

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Protecting healthcare workers from needlestick injuries

The Safer Needles Network is aimed at those concerned with reducing needlestick injuries and bloodborne exposures.

Needlestick accidents occur when healthcare workers jab themselves or a colleague with a needle, or other sharp medical device, which is contaminated with potentially infected blood.

Second only to back-injuries as a cause of occupational injury amongst NHS workers, an ongoing RCN surveillance project suggests that as many as 100,000 needlestick accidents occur in the UK every year.

More about the Safer Needles Network »
Read about our Research »

Welcome to the new Safer Needles Network website. We hope that you find it interesting, informative and easy to use. We welcome your views. Please contact us at saferneedles@saferneedles.org.uk

Current News

Psychiatric consequences of needlestick injury
11 APR 2013

Second hospital embroiled in sharps row
4 APR 2013

Question raised in Parliament on needlestick injuries
3 APR 2013

Secondary legislation on sharps laid before Parliament
27 MAR 2013

HSE publishes sharps regulation guidance
14 MAR 2013

EPSU/Hospeem regional seminar report released
21 FEB 2013

HSE issues consultation report:
8 FEB 2013

NHS Supply Chain Demonstration Days
29 JAN 2013

Department of Health issues sharps alert
24 JAN 2013

HSENI launches consultation for EU Directive
8 JAN 2013

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Feature Articles

Articles relating to research and issues surrounding needlestick injuries.

Registration open for European Biosafety Summit
23 FEB 2012

Revised 2011 version of the 'Blue Book' chapter on Needlestick
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'To the point' report by Debra Adams published
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7 JUN 2010

Council of the European Union adopts rules on sharps
11 MAY 2010

EU-OSHA guidance on risk assessment and needlestick
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Prevention of Sharps Injuries in the Hospital and Healthcare Sector

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. Studies have also demonstrated that failure to implement any one of these three elements results in a significantly reduced impact. 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


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 needle 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 89/665/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 injuries. Studies have also demonstrated that failure to implement any one of these three elements results in a significantly reduced impact. 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.

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


   c) Evaluation of the Efficacy of a Measure to Prevent Accidental Needlestick Injuries by Using Safety Needles for Venous Blood: Louis Nicole (1), Vola 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

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