



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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INTRODUCTION

This document provides a practical toolkit to aid the effective implementation of the Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector. It utilises a wide range of practical experiences and best practice together with relevant existing advice and independent studies that have been developed over the years. Further support is available from the European Biosafety Network's previously published Implementation Guidance.

The everyday work of healthcare staff puts them at risk of serious infections from more than 30 potentially dangerous pathogens, including hepatitis B (HBV), hepatitis C (HCV) and HIV, through injuries with contaminated needles and other sharps. The majority of these injuries are preventable with the provision of effective training, safer working procedures and safety-engineered medical devices that shield or retract the needle/sharp after use.

As well as medical staff, downstream workers, such as cleaners, laundry staff and refuse collectors and non-healthcare workers are exposed to injuries from contaminated used medical sharps.

The June 2010 publication of EU Council Directive 2010/32 /EU, on the prevention of sharps injuries in the hospital and healthcare sector, highlighted the importance of consistently implementing mandatory measures to prevent these potentially fatal injuries. Existing legislation has largely been ignored or misinterpreted, and as a result proved ineffective. The Directive must be implemented at national and local level in all member states by 11 May 2013 at the latest.

PART 1: NATIONAL LEVEL

Implementation: Each Member State is required to introduce national legislation or legally-binding joint agreements by social partners to implement the Directive by 11 May 2013. Legislation is considered the effective route to ensuring that the requirements of the Directive are fully applied, not least because in some Member States there are no effective social partners. It is likely that the principal agency responsible for legal transposition of the Directive will be the relevant government department and/or its regulatory or advisory technical agency for health and safety.

The Directive provides 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.

Member States are encouraged to draw up for themselves their own tables which will illustrate the correlation between the requirements of the Directive and the transposition measures of the Member State to comply with it and to make that document public.

Member States shall determine what penalties are applicable when the national provisions to implement the Directive are infringed. The penalties shall be effective, proportionate and dissuasive.

Scope: The Directive covers all workers that are under the managerial authority and supervision of healthcare employer/organisations, including those providing health care in the home, in nursing and care homes, doctor's offices, dentists and other non-hospital settings, and any private or independent healthcare employers. It also covers some self employed workers (such as agency/bank nurses), and any workers employed by employers contracted to provide services for healthcare organisations (e.g. cleaners). The Directive also covers any students whilst they are under the supervision of any healthcare provider.

Not all workers at risk, such as refuse workers and some prison staff, are covered by this Directive. However the basic principles of risk prevention still apply (see below)

Risk management and prevention: The aim of the Directive is to achieve the safest possible working environment by preventing injuries involving medical sharps such as needlesticks. It builds on existing law and regulations setting out an integrated approach to risk assessment explaining what measures should be considered and used to eliminate the risk of sharps injuries. The Directive requires that wherever there is a risk of a sharps injury or infection it must be eliminated.

Each Member State has until May 2013 to comply with the Directive. However they should be taking actions now to ensure they can achieve compliance. The Directive sets out a framework of measures to eliminate or, where this is not currently technically possible, minimise the risks associated with sharps injuries. These measures include:

- Medical devices incorporating safety engineered mechanisms
- Effective training
- Effective working procedures, including disposal of used sharps
- Well resourced and organised workforce
- Local, National and Europe wide reporting mechanisms
- A ban on recapping

These measures should be implemented in a manner consistent with the existing principles of risk assessment. Existing risk assessment requirements are set out in European Directives 89/391, which defines the basic principles of risk assessment, and 2000/54, which specifies how these should be applied to risks related to exposure to biological agents at work. These are:

- Avoid the risks where possible
- Evaluate the risks that cannot be avoided
- Combat the risks at source
- Replace the dangerous with the less dangerous
- Implement a coherent overall prevention policy (safe systems of work)

- Provide appropriate training and instructions for workers

Each Member State should review their existing legislation and guidance, which has been introduced to comply with these existing directives, to ensure they are compliant with the more stringent requirements of the new Directive. In particular they should ensure that it is sufficiently specific and clear on how to apply the principles of risk prevention to sharps injuries as now required by Directive 2010/32/EU. Directive 2010/32/EU requires that wherever there is a risk of a sharps injury or infection it must be eliminated.

These principles have resulted in a well-proven “hierarchy” which employers should adhere to when implementing safety measures to eliminate sharps injuries. According to the World Health Organisation this hierarchy should be applied as follows:

1. Elimination - eliminating the unnecessary use of sharps by implementing changes in practice;
2. Engineering Controls - providing medical devices incorporating safety-engineered protection mechanisms;
3. Safe Systems of Work - 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;
4. PPE - the use of Personal Protective Equipment (gloves, masks, gowns, etc);
5. Vaccination – vaccination, in particular for hepatitis B, shall be carried out in accordance with national law and/or practice of the Member State.

Although the Sharps Directive is specifically aimed at the health sector, European Directives 89/391 and 2000/54 apply to all sectors. This means that the basic principles of risk prevention as outlined above apply to all workers. All employers are required to do everything reasonably practical to eliminate hazards regardless of where that worker is employed.

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.

Surveillance centres in each Member State are currently in discussion about standardising the reporting of sharps injuries to ensure a common European approach to data collection and surveillance. The EBN would like the European Commission and the European Agency for Safety and Health at Work to establish a European Observatory on sharps injuries.

Surveillance Systems: All cases of suspected occupational exposure to blood or body fluid from patients infected with HIV, hepatitis C virus or hepatitis B virus, and all incidents where post-exposure prophylaxis (PEP) for HIV has been started (whatever the HIV status of the source), should be reported to the appropriate Member State regulator or national

surveillance scheme.

The anonymity of the healthcare worker should be maintained throughout the process.

The scheme should aim to record:

- the numbers of workers being exposed to these viruses;
- the circumstances contributing to occupational exposures;
- the clinical management of those exposures, including HIV exposures and the use of PEP;
- the side effects of HIV PEP and outcomes;
- evaluate the introduction and effectiveness of safer devices.

Workers representatives or employers in Member States interested in devising a format for collecting their data comprehensively might wish to refer to the EBN or one of the national unions or clinical associations who have experience in this area.

National studies have been established in some Member States already on the prevalence and causes of needlestick and sharps injuries, using the EPINet™ surveillance system. This is an international computerised database for recording data about needlestick injuries and body fluid exposure. Further information about this system can be found at www.med.virginia.edu.

Information and awareness-raising through national coalitions: An ideal way to disseminate information and raise awareness about sharps injuries and the preventative measures in the Directive is to bring together government departments, regulators, workers organisations, employers, manufacturers and clinicians and technical experts into a country coalition, such as the UK Safer Needles Network. This is not an alternative to employer-worker social partnership but an effective way to bring all interest groups together in a non-adversarial atmosphere to target and focus resources where they are most needed. In some Member States this may not be possible and the responsibility for information and awareness-raising will inevitably fall to government agencies, trades unions and medical and nursing associations.

Any coalition group, or individual workers organisations, should be clear about their objectives and set out a strategy for achieving them within an agreed timescale, together with key messages, target audiences and an action plan with measurable deliverables. Media campaigns, websites, online social networking, lobbying, seminars, roadshows and conferences are all effective means of getting the message out about the dangers of sharps injuries and the need for governments to make changes to legislation to implement the Directive. Empirical evidence and data are helpful in demonstrating the need for behavioural change and sometimes this information is readily available through national and international surveillance programmes and reporting systems, such as EPINet™, in Member States. Where this is not the case then surveys and questionnaires of staff practice and experience are useful ways to establish the scale of the problem and thus the need for change. Examples of best practice and the traumatic experiences of those who have suffered a sharps injury are also very effective ways of communicating information and raising awareness.

Cost effectiveness: Any change in practice towards safer systems or work need to be justified and explained to employers, regulators and government departments. If the government department, its regulatory or advisory technical agency for health and safety, and employers are not convinced about the need for change any short term cost implications can be a barrier to rapid compliance with the Directive.

PART 2: LOCAL LEVEL

At the national level, a coalition of interest groups is a good way to achieve change and similarly at the local and workplace level a working group of all parties – eg workers representatives, employers, clinicians, occupational health and infection control specialists – needs to be established to manage the process of implementing the Directive including responsibility for:

- Risk assessment
- Education, training, information and awareness-raising
- Implementation
- Reporting
- Funding and procurement
- Monitoring and reporting

Risk Assessment: Employers are required to undertake regular risk assessments of all situations where there can be a sharps injury or infection. A risk assessment is a careful examination of what, in a workplace, could cause harm to people, so that measures can be identified that eliminate, or if that is not practical, minimise the risk of harm. Therefore when prevention of workers' exposure to biological agents is not possible, the risk of exposure must be limited to as low a level as necessary in order to protect the health and safety of the workers concerned. In the light of the results of the risk assessment the number of workers likely to be exposed needs to be kept as low as possible, with the design of work processes and use of engineering controls avoiding or minimising the release of biological agents into the workplace.

Each workplace should have a member of staff trained in risk assessment and management. The assessment should be carried out in consultation with workers' representatives, and where required staff with the relevant technical expertise. Risk assessment must be fully documented and authorised and feed into written plans in the workplace to eliminate, prevent and protect workers from risks. They must also be routinely updated. In order to avoid a huge administrative burden and duplicated effort, a standardised risk assessment matrix for medical sharps injuries has been developed by a leading academic and expert on needlestick and sharps injuries, Professor Andreas Wittmann of the University of Wuppertal, Germany. This serves to simplify the analysis using a standardised approach. The matrix and conclusions of the analysis are provided as Appendix 3.

Wherever there are exposed sharps there is a risk of infection. The principle of following Standard (Universal) Precautions means never assuming that there is no risk. If every patient is assumed to be potentially infected with a blood-borne infection, the same precautions to prevent exposure should be used for every procedure. 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. Body fluids, excretions and secretions must always be handled as if they are infectious. The most effective precautions must always be stringently and consistently applied to protect patients and staff.

It is important when assessing which safety controls to introduce to a workplace to adhere to the basic principles of risk prevention, and the hierarchy of controls. In summary these are:

1. Elimination
2. Engineering Controls
3. Safe Systems of Work
4. PPE (Personal Protective Equipment)
5. Vaccination

For more information on the highest risk procedures go to Appendix 2, and on the effectiveness of safety engineered devices, Appendix 1.

Needles should never be re-sheathed. Re-sheathing needles is a common cause of needlestick injury. The ink mark on an index finger or thumb after inaccurate re-capping of a pen illustrates how easily re-sheathing needlestick injuries occur. Re-capping of needles has been banned in the EU.

Cuts and grazes should be covered with waterproof dressings. Non-intact skin is a potential route of entry for blood-borne transmissible agents through contact with infected body fluids. Personal protective equipment (PPE) should be worn when dealing with blood or body fluids.

Education, training, information and awareness-raising: Employers are legally responsible for providing training on all health and safety issues, including sharps injuries, and it is the duty of workers to attend the training that is provided for them. 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 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

Refresher training should be made available on a regular basis.

As well as instructing staff in correct procedures, training raises awareness of the dangers associated with sharps injuries. Other awareness raising techniques include posters, leaflets, electronic mailings and bulletins.

It also helps if staff are fully engaged in decisions that affect their safety. That is why we recommend that workers representatives and clinicians are part of any committee set up to manage risk prevention of sharps injuries. In addition the new Directive makes it clear that workers representatives are consulted over any decisions affecting workers safety, including the choice and selection of sharps devices.

Implementation: Some employers will argue that the cost of implementing some safety measures, such as safety engineered medical devices are too expensive, and that the extent

of the risk does not justify the cost. As pointed out above, cost benefit analysis has been undertaken on specific workplaces, such as acute hospitals, which indicate that there can actually be cost savings as a result of the universal introduction of safer medical devices. However, in order to overcome resistance it may be agreed to trial safety devices in procedures where the risks are highest. Any such local assessments would need to be completed well in advance of the legislative deadline of 11 May 2013 to allow adequate time for full compliance to be achieved. Once implemented it is important to review the results of any new safety measures. In addition all safety procedures should be kept under review and in particular when there are:

- Any new incidents or injuries are reported
- Changes to staff, working environment, equipment used etc

Reporting: Accurate reporting of sharps injuries is essential, to ensure that incidents are appropriately managed. It also enables employers to accurately assess the level of risk, and what measures they must take to eliminate that risk. The Directive requires all member states to revise local, national and European procedures. Currently it is widely accepted that there is large scale under reporting of sharps injuries. Therefore workers representatives should ensure that employers locally have the appropriate reporting procedures in place and that staff are trained so that they know how to complying with them.

Funding and procurement: In assessing what is necessary and reasonably practical, employers are likely to measure the risk (likelihood and consequence) of an injury, against the cost of any safety measures. However cost alone is not sufficient justification for failure to introduce safety measures. Employers would have to demonstrate that the cost is sufficiently high, and the level of risk so low, that the safety measure is not reasonably practical. This is clearly not so in this case where the initial cost is modest and the overall impact is to reduce costs and substantially improve occupational safety. It is important that workers challenge and have access to visibility of any procurement and costing data that is being used by employers to justify their decisions. For more information on cost effectiveness please see Appendix 1.

APPENDIX 1: FUNDING AND COST EFFECTIVENESS

FUNDING: Each Member State, together with the Commission, agrees on one or more Operational Programmes for European Social Fund (ESF) funding for the 2007-13 period. Operational Programmes set the priorities and objectives for ESF intervention. The Operational Programmes are implemented through individual projects run by participating organisations known as 'beneficiaries'. Potential beneficiaries in ESF actions should contact the ESF Managing Authority - usually a department of employment or technical agency of government - in their own Member State (A list of managing authorities and detailed information on the ESF in each Member State is available at (http://ec.europa.eu/employment_social/esf/members/be_en.htm)). If there is still available funding in the Member State Budget for the current period, then beneficiary organisations can apply for funding now in order to prepare for the implementation of the Sharps Directive which must be in place by May 2013.

Although some safety devices can be more expensive, many are only marginally more expensive than conventional devices. Any change in practice towards safer systems or work, or increase in costs in the short term, will need to be justified and explained to employers, regulators and government departments. If the government department and/or its regulatory or advisory technical agency for health and safety and employers are not convinced about the need for change, and any short term cost implications, then that can be a barrier to the necessary changes required by the Directive.

One of the key ways to persuade employers and Member States of the need to prepare for and effectively implement the Directive is to prepare a business case and/or to undertake a cost benefit analysis of the changes required to prevent sharps injuries. Financial considerations are not an excuse for Member States not fully implementing the Directive, and there are legal precedents (eg in Scotland in 2004) that state that cost alone cannot be used as a reason for not adopting engineering controls or changing work practices to comply with European health and safety Directives.

Cost benefit analyses have been undertaken on specific workplaces, such as acute hospitals, which indicate that there can actually be cost savings as a result of the universal introduction of safer medical devices. Furthermore, independent European academic studies have investigated the issue of cost effectiveness of medical devices incorporating sharps protection mechanisms. These studies explore the overall costs of managing needlestick injuries and assess the cost of purchasing devices incorporating sharps protection mechanisms against the overall financial benefits of reducing injuries. They conclude that investments to prevent needlestick injuries will achieve overall economic savings.

The EBN can assist with previous examples or providing contacts for specialist health economists to use in Member States. Below is set out an adaptation of a generic business case which was originally drafted for the UK by the Chair of the Safer Needles Network, Dr Paul Grime, in 2006.

GENERIC BUSINESS CASE FOR INVESTMENT IN SAFER SYSTEMS OF WORK: There are many competing priorities for investment of scarce resources and any proposal for change must therefore be sufficiently robust and persuasive to attract attention, to merit serious consideration and to secure successful acceptance. This document outlines the financial, legal and regulatory case for employers to invest in safer systems of work to protect staff, patients and visitors.

Safer systems of work include:

- Data recording systems for surveillance of exposure incidents to facilitate organisational learning and risk reduction
- Regular education and training for workers in safer systems of work
- Provision of medical devices incorporating safety engineered protection mechanisms

The arguments presented here can be adapted and supplemented with local data and information, for example on locally reported exposure incidents and outcomes, to substantiate a local business case.

Cost Considerations; Direct cost comparisons for introducing new systems often show an adverse cost variance, which sometimes discourages employers from even considering investments to protect staff and patients, particularly in the current financial climate. However, such comparisons often do not take account of several important points:

1. Savings on payments for clinical negligence for implementing measures to protect patients and staff.
2. Possible savings due to changes in usage patterns of the mix of available devices (e.g. straight needles vs winged cannulae for blood collection). Calculations are inevitably based on past usage figures, which may well change with the introduction of safer systems of work.
3. Possible larger retrospective discounts calculated on a sector or larger geographical rather than a specific workplace basis, such as a prison or hospital, if a number of workplaces are introducing new systems simultaneously.
4. Savings from the reduction in the rate of exposure incidents. For example, an acute hospital in the UK with 5,000 staff can spend around £100,000 annually on managing exposure incidents, including the costs of blood tests, lost staff time and post-exposure prophylaxis, but excluding litigation costs. A recent large study commissioned by the Scottish Executive demonstrated that 41% of sharps injuries could probably and 14% could definitely be prevented by the use of safety devices. Applying these figures to a hospital with 5,000 staff gives estimated annual savings of £14,000 - £42,000.
5. Employers have sometimes rejected business cases for introducing safer systems of work on cost grounds, only to make the proposed changes subsequently in response to adverse incidents that could have been prevented by safer systems. As well as being more costly to deal with, such incidents attract attention from regulators, litigation,

prosecution and damaged reputation for the employers concerned. Safer systems of work protect patients, visitors and staff, and reduce the risk of further legal action.

Legal and Regulatory Considerations: A plethora of statutes, regulations and national and international legislation compel employers to protect staff, patients and visitors through safer systems of work

Summary

- Whilst the financial situations of hospitals and Member States cannot be ignored all current priorities must be balanced;
- There are well documented cases of health care workers acquiring blood-borne virus infections through occupational exposure. At least 4 UK nurses are known to have died from occupationally acquired HIV. Given the high population prevalence of hepatitis C, the rising incidence of HIV and the increasingly interventional nature of healthcare, it is not inconceivable that it could happen again. It is likely that it would be the senior managers and employers who would be answerable to any claim brought against an employer for corporate manslaughter;
- The costs of investing in safer systems of work are often calculated on a worst case scenario. Although some financial investment is likely to be required in the short term, the costs of rejecting the opportunity to make the workplace safer, to comply with national and international legislation, guidance and employers' obligations to staff, patients and regulators, are not inconsiderable and likely to be greater in the longer term.

APPENDIX 2: HIGH RISK PROCEDURES

The highest risk procedures involving sharps include blood collection, IV cannulation and percutaneously placed syringes. Small amounts of blood (sometimes not even visible to the naked eye) can result in potentially life threatening infection. Hollow-bore needles contain more blood and therefore carry more risk than solid needles. Epidemiological studies on the incidence, frequency and sero-conversion of blood-borne viruses should be utilised in the risk assessment process.

Assessment of the risk of blood-borne virus (BBV) transmission

Average estimated seroconversion risks from published studies and reports are:

- 0.3 per cent for percutaneous exposure to HIV-infected blood¹
- 0.1 per cent for mucocutaneous exposure to HIV-infected blood
- 0.5-1.8 per cent for percutaneous exposure to HCV-infected blood with detectable RNA^{2 3}
- 30 per cent for percutaneous exposure of a non-immune individual to HBeAg positive source.

Factors that may increase the risk, and influence management of the incident are:

- percutaneous injury rather than mucous membrane or broken skin exposure
- injury with a device from a source patient's artery or vein
- blood exposure rather than exposure to blood-stained fluid, diluted blood (for example in local anaesthetic solution) or other body fluid
- injury from hollow bore rather than solid bore needle
- injury from wide gauge rather than narrow gauge needle
- deep rather than superficial injury⁴
- no protective equipment used (like gloves, double gloves, eye protection)
- first aid measures not implemented (washing, bleeding)
- HCV RNA detectable in source patient on most recent blood test
- high viral load of HIV in source patient⁵
- HBeAg detectable in source patient blood

¹ Tokars JI, Marcus R, Culver DH, Schahle CA, McKibben PS, Bonden CI et al. Surveillance of HIV infection and zidovudine use among health care workers after occupational exposure to HIV-infected blood: the CDC Cooperative Needlestick Surveillance Group, (1993). *Ann Intern Med*; 118:913-9

² Ramsay ME. Guidance on the investigation and management of occupational exposure to hepatitis C (1999), *Commun Dis Public Health*; 2 258-62

³ Jagger J, Puro V, De Carli G. 'Occupational transmission of hepatitis C virus' (2002), *JAMA*; 288(12): 1469-71

⁴ Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R et al. 'A case-control study of HIV seroconversion in healthcare workers after percutaneous exposure' (1997). *N Engl J Med*. 337: 1485-1490

⁵ Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R et al. 'A case-control study of HIV seroconversion in healthcare workers after percutaneous exposure' (1997). *N Engl J Med*. 337: 1485-1490

- exposed person not or inadequately immunised against hepatitis B
- source patient co-infected with more than one BBV.

When a body fluid exposure occurs and is reported, the first priority is to assess how likely it is that the incident will result in blood-borne virus transmission, and then take steps to reduce that risk as far as possible. The initial assessment and management has to be based on the information available at the time.

APPENDIX 3: INTRODUCTION OF SAFETY-ENGINEERED DEVICES

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.

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.

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.

RISK ASSESSMENT MATRIX AND ANALYSIS

Ref. Prof Dr A Wittman, University of Heidelberg, Germany. May 2011

Directive 2010/32/EU requires that formal risk assessments are performed of all activities where medical sharps are used, and that wherever there is a risk of injury or infection it must be eliminated by means of training, improved working practices and the introduction of safety-engineered medical devices. The following table summarises the blood exposure risks relative to the use of different types of medical devices.

Risk by Device Type

The most appropriate criteria for assessing the safety risks associated with different types of devices would appear to be a combination of the likelihood of the presence of sufficient blood to cause a serious infection and the typical frequency of injury for that device type. A risk analysis matrix serves as a simple and practical tool to determine the appropriate preventive measures.

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

Required preventative actions:

Use of Safety Devices essential, vaccination against Hepatitis B and proper information and training for staff obligatory
Use of Safety Devices required, vaccination against Hepatitis B and proper information and training for staff obligatory
Training for staff obligatory to achieve the highest possible safety level. Eliminate use of sharp if alternative available.

* Where safety devices do not exist we recommend the use of double gloving, vaccination against Hepatitis B and proper information and training for the staff.

Conclusions

Life threatening risks are faced by health care staff as well as a range of other workers who may be exposed to needles and other sharps during and following their use. Using a standard risk analysis matrix it is concluded that significant and potentially life-threatening risks are present in the vast majority of cases where needles and sharp surgical devices are used. Use of safety-engineered devices, vaccination against hepatitis B and proper information and training for staff are essential measures to effectively manage the risks and ensure compliance with the Directive 2010/32/EU.

It is no coincidence that where effective legislation has already been introduced (the USA and parts of Spain) it was determined that the only way to ensure effective prevention of injuries was by mandating the universal implementation of all of these measures.

Non-exhaustive list of medical devices to which the EU Directive 2010/32/EU applies:

Blood drawing devices

Intravenous catheters

Sub-cutaneous catheters

Devices for:

- Intradermic injections
- Hypodermic injections
- Intramuscular injections
- Intravenous injections
- Arterial injections
- Arterial blood gas sampling
- Arterio-venous fistulae access
- Implanted chamber access
- Infusion pump access
- Wound and cutaneous care
- Medication reconstitution
- Chemotherapy mixing
- Radionuclide delivery

Lancets

Scalpels

Stitching and sewing devices

Pen injectors

APPENDIX 4: LEGISLATIVE BACKGROUND

Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU was published on 1 June 2010.

89/391/EEC Council Directive, of 12 June 1989, on the implementation of measures aimed at promoting the improvement of workers' health and safety at work establishes general preventive measures for the protection of their health and safety. It lays down the minimum requirements as regards, among other things, risk assessment and information, as well as training and consultation. In particular, Article 6 of the Directive establishes the general prevention principles which are mainly: to avoid risks, to combat risks at source and to replace what is dangerous with what entails little or no danger. Apart from Directive 89/391/EEC, some specific directives are also applicable to the prevention of infection risks of healthcare personnel as well.

Directive 2000/54/EC of the European Parliament and of the Council, of 18 September 2000, on the protection of workers against the risks of exposure to biological agents at work (seventh specific Directive pursuant to Part 1 of Article 16 of Directive 89/391/EEC) includes provisions aimed at preventing such risks and establishes the minimum specific requirements in this field. It also lays down the duties of employers as regards risk prevention. More specifically, in any activity entailing a risk of exposure to biological agents, the characteristics, the degree and the duration of the exposure of workers shall be established with a view to assessing the risks posed to their health and safety and identifying the adequate measures to be adopted. Directive 89/655/EEC of the Council, of 30 November 1989, concerning the minimum health and safety requirements for the use of work equipment by workers at work (second specific Directive pursuant to Part 1 of Article 16 of Directive 89/391/EEC) (amended by Directives 95/63/EC and 2001/45/EC) is aimed at improving the safety of workers who use work equipment, such as hospital medical equipment. Employers should use work equipment on the basis of the working conditions and the risk posed to workers with a view to eliminating or minimising such risks.

Directive 89/656/EEC of the Council, of 30 November 1989, concerning the minimum health and safety requirements for the use by workers of personal protective equipment (third specific Directive pursuant to Section 1 of Article 16 of Directive 89/391/EEC) establishes that personal protective equipment shall be used when risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization. All personal protective equipment shall be appropriate for the risks involved, without it leading to any increased risk. In addition, they must be appropriate to the existent conditions at the workplace and fit the user correctly.

It should also be highlighted that Annex I, Part II of Directive 93/42/EEC of the Council, of 14 June 1993, concerning medical devices, lays down that the devices and manufacturing process must be designed in such a way as to eliminate or reduce, as much as possible, the risk of infection to the patient, the user and third parties. The design shall allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. Any marketed product must have previously obtained the EC label certifying its compliance with the essential requirements of this Directive.