



Phlebotomists
Association of Ireland
AGM & National
Conference

Sarah Ross
European Marketing Manager
12th March 2011

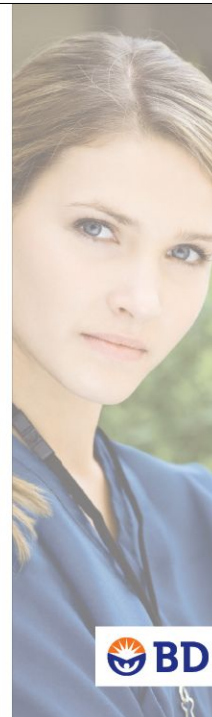


Helping all people
live healthy lives

The EU Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Agenda:

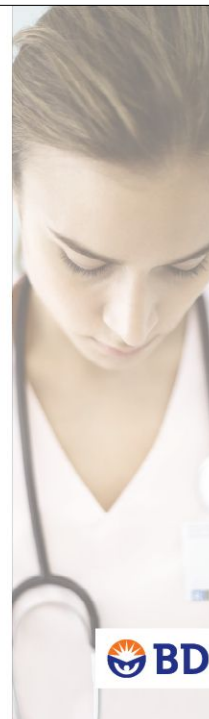
- Why is it Important to Treat Needlestick Injuries Seriously?
- Needlestick Injuries – European Overview
- EU Directive on Prevention of Sharps Injuries in the Hospital and Healthcare Sector
- The European Biosafety Network



Why is it Important to Treat Needlestick Injuries Seriously?

- Thirty-five million healthcare workers globally, suffer two million needlestick injuries (NSI) annually, which may result in infections from potentially dangerous blood-borne virus, such as, Hepatitis B, Hepatitis C and HIV
- The projected two million needlestick injuries are considered to be a low estimate due to a lack of surveillance systems and underreporting of injuries
- On average, research indicates a 40% - 75% underreporting rate of needlestick injuries globally

The Global Occupational Health Network, Newsletter Preventing NSI & Occupational Exposure to Bloodborne Pathogens 2007

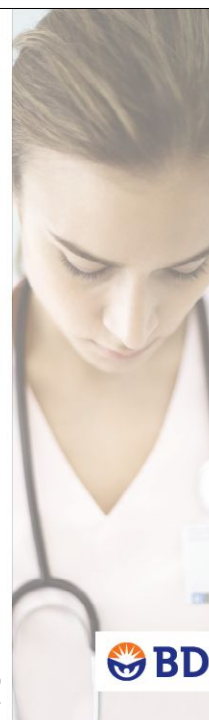


Why is it Important to Treat Needlestick Injuries Seriously?

- The greatest danger of infection comes from procedures using hollow-bore needles such as:
 - Blood collection
 - Intravenous cannulation
 - Percutaneously placed syringes¹
- The World Health Organization estimates the global burden of disease from occupational exposure accounts for:
 - 40% of the Hepatitis B & C amongst healthcare workers
 - 4.4% of the HIV infections among healthcare workers²

1. EU Council Directive 2010/32/EU 10th May 2010

2. The Global Occupational Health Network, Newsletter Preventing NSI & Occupational Exposure to Blood-borne Pathogens 2007



What Can you Contract From a Needlestick?

Viral Infections	Bacterial Infections	Fungal Infections
Hepatitis B	Brucella Abortus	Blastomyces Dermatitidis
Hepatitis C	Corynebacterium Diptheriae	Cryptococcus Neoformans
Hepatitis G	Neisseria Gonhorreae	Sporotrichum Schenkii
Human Immunodeficiency Virus	Leptospira Icterohaemorrhagiae	
Simian Immunodeficiency Virus	Mycobacterium Marinum	Protozoal Infections
Herpes Simiae	Mycoplasma Caviae	Plasmodium Falciparum
Herpes Simplex	Orientia Tsutsugamushi	Toxoplasma Gondii
Herpes Zoster	Rickettsia Rickettsii	
Ebola/Marburg	Staphylococcus Aureus	Tumors
Dengue	Streptococcus Pyogenes	Adenocarcinoma
Creutzfeldt-Jakob Disease	Treponema Pallidum	Sarcoma
	Mycobacterium Tuberculosis	

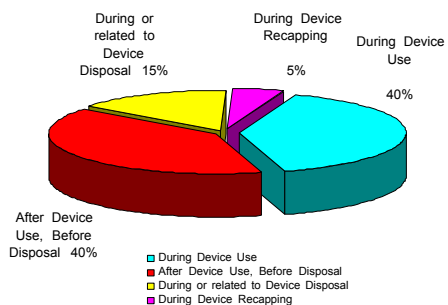
Today there are 30 known pathogens....Tomorrow???

Jagger J, De Carli G, Perry J, Puro V, Ippolito G. Chapter 31: Occupational exposure to bloodborne pathogens: epidemiology and prevention. Wenzel RP; Prevention and Control of Nosocomial Infections 4th ed. Baltimore Md Lippincott, Williams & Wilkins; 2003.

Who, When, Where of Needlestick Injuries

EPINet™—The Exposure Prevention Information Network

Timing of Needlestick Injuries



Who Gets Injured?

Nurse	44%
Doctor	15%
Phlebotomist	5%
Cleaning Staff	5%
Surgery Attendant	5%
Other Attendant	5%
Technologist	4%
Clinical Lab Worker	3%
Other	14%

Data Source: EPINet™ 2008

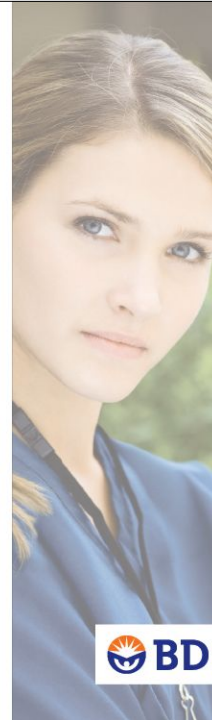


Global Initiative for Healthcare Worker Safety and Occupational Exposure Prevention
International Healthcare Worker Safety Center

Prevalence of Blood-borne Pathogens

	Blood-borne Pathogen Prevalence in General EU Population	Blood-borne Pathogen Prevalence in Patients
HIV	0.05%	0.1%
HBV	0.5%	1.0%
HCV	0.5%	1.0%

Data Source: Shepherd J et al. Wessex Institute of Health Research and Development: 2000
 Ramsay ME. Communicable Disease and Public Health: 1999
 Touzet S et al. European J Gastroenterology and Hepatology: 2000
 Goudeau A. Vaccine: 1990
 PHLS
 DoH. Hospital Episode Statistics 1998/1999

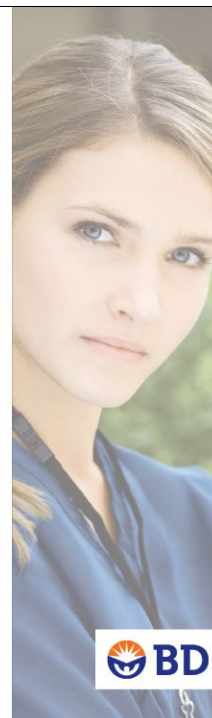


Seroconversion Rates of Blood-borne Pathogens

HBV	30%	1 in 3
HCV	3%	1 in 30
HIV	0.3%	1 in 300

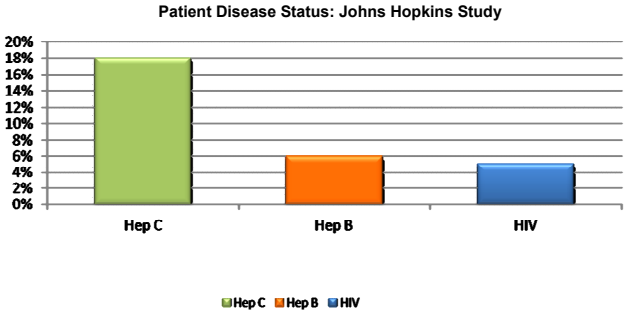
- The greatest seroconversion risk occurs when the skin is pierced by a hollow bore blood filled needle
- Of the 16,374 needlestick injuries registered in Spain from 1996 to 2000, 87% were caused by hollow bore needles

1. Hernandez Navarrete MJ et al. Occupational exposures to blood in biological material in healthcare workers. Medicina Clinica Barcelona 2004

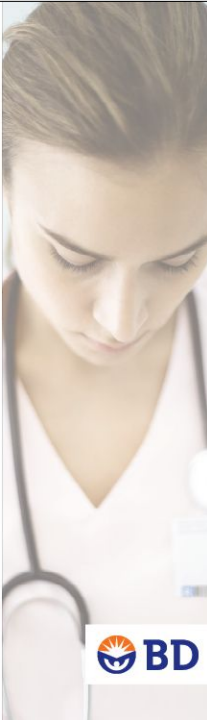


Do you Know the Prevalence of Blood-borne Pathogens in Your Hospital?

- A study of the Johns Hopkins Hospital Emergency Room determined the prevalence of the HCV, HBV and HIV in blood samples from 2,523 patients. Twenty-nine percent were infected with one of the three viruses. Of those patients:



Kelen GD, Green GB, Purcell RH, et. Al. Hepatitis B and Hepatitis C in Emergency Department Patients. N Engl J Med. 1992;326:1399-1404



Needlestick Injuries

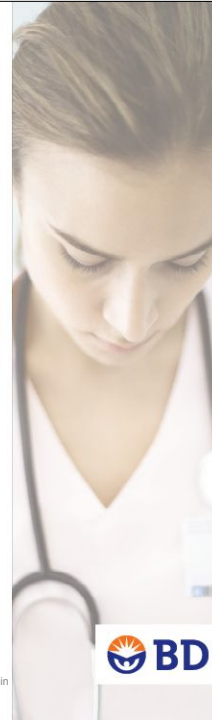
European Overview



European Overview

- An estimated **1 million needlestick injuries** occur in Europe each year¹
- An estimated **60% - 80%** of needlestick injuries go unreported²
- The prevalence of both Hepatitis C & HIV is growing fast:
 - The WHO reports HIV approaching 50 million cases globally
 - Five million Europeans infected with Hepatitis C
 - Many people who contract Hepatitis C often remain symptom-free for many years, many cases remain undiagnosed, potentially creating additional risks of cross-infection²

1. Clin Perfm Qual Healthcare 1999 Apr-Jun; 7(2):88-91 Underreporting of Percutaneous Exposure Accidents In Teaching Hospitals in Spain
 2. The Global Occupational Health Network, Newsletter Preventing NSI & Occupational Exposure to Bloodborne Pathogens 2007

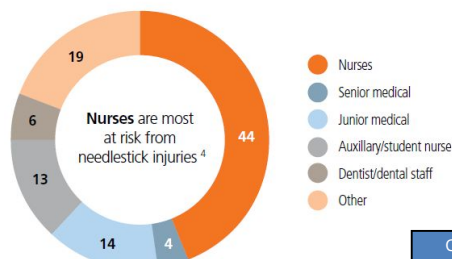


Who, When, Where of Needlestick Injuries

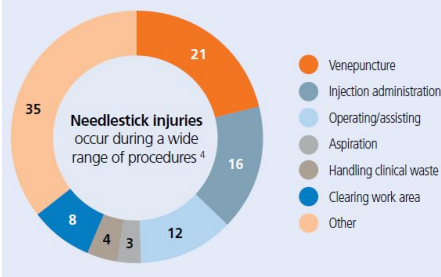
In the EU more than one million needlestick injuries occur every year³

Needlestick injuries are a common occupational hazard for healthcare workers³

Frequency (%) of needlestick injuries by profession



Frequency (%) of needlestick injuries by procedure



Cullen BL. *et al* 2006. Total number of injuries over a 6-month period = 952. Other represents a collection of other groups where each other group accounts for <3% of all injuries

European Overview

- Figures from UNISON and The Royal College of Nursing estimate that **100,000** needlestick injuries occur annually in the UK alone
- The costs associated with each needlestick injury can vary considerably, but are significant. The provision of post exposure prophylactic (PEP) alone can be several thousand Euros per case
- For an injury resulting in transfer of a serious blood-borne virus it has been estimated that in certain cases, the cost could be as high as **EUR1,000,000**¹

1. Protecting European Healthcare Workers from Medical Sharps Injuries April 2007



European Overview

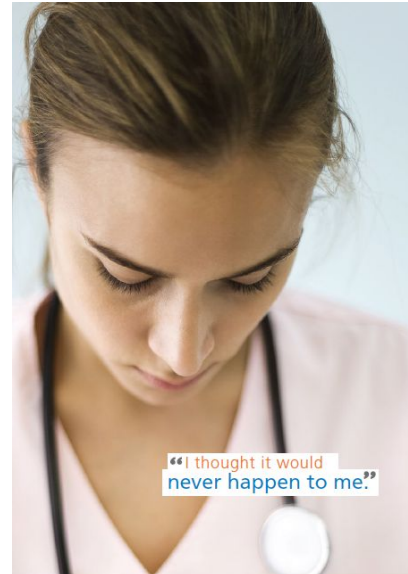
- In Germany, the estimated number of needlestick injuries per year in hospitals is **500,000**¹
- It is estimated that in Sweden 3,215 needlestick injuries could be avoided by introducing safety devices; correspond to a saving of **€850,000** in investigation costs alone²
- Needlestick injuries are estimated to cost each NHS Trust **£500,000** per year³

1. Hofmann F et al. Needlestick Injuries in Healthcare. Gesundheitswesen
2. Glengard AH Persson. Costs Associated with sharps injuries in Swedish Hospitals February 2009
3. Are your sharps policies and procedures up to scratch. Bevan Brittan February 2011



Impact of Needlestick Injuries

- Needlestick injuries not only represent a high cost burden, they also cause severe distress¹²³
- Even when a serious infection is not transmitted, the emotional impact of needlestick injuries can be severe and long-lasting
- Healthcare workers and their families suffer many months of anguish as they wait to discover if they have contracted a potentially fatal infection¹²³



1. European Biosafety Network June 2010
2. Wicker S et al Prevalence and Prevention of Needlestick Injuries 2008
3. Are your sharps policies and procedures up to scratch. Bevan Brittan February 2011

Surgeon Settles HIV High Court Action

RTÉ News

Wednesday 26th January 2011



A surgeon who contracted HIV from a patient has settled his High Court action for damages.

He said his **'life stopped'** the day he was diagnosed.

The High Court was told the action against the hospital and the Attorney General was settled but no details of the settlement were disclosed.

The surgeon claimed there was a failure to adopt risk management, infection control policies, training and educational programmes by the hospital concerned.

The defendants denied the claims. The man was forced to stop working as a surgeon after his diagnosis and has suffered from depression along with the physical symptoms of HIV.

He has to undergo combination therapy for life for his condition.

He and his wife were extremely distressed and depressed about the future and feared for the prospect of having children.

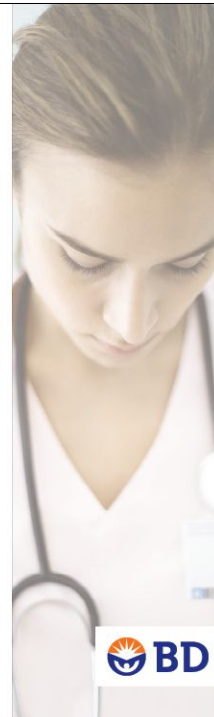
EU Directive on the Prevention of Sharps Injuries in the Hospital and Healthcare Sector



Why The EU Directive?

A European Parliament Report in 2010 described needlestick injuries as:

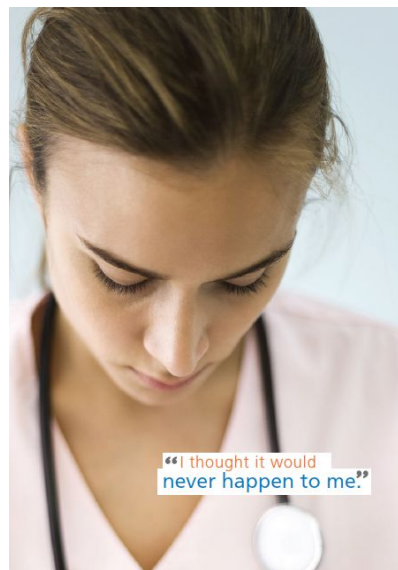
“...one of the most serious health and safety threats in European workplaces...”



European Parliament Preventing Needlestick Injuries in the Healthcare Sector February 2010

Why The EU Directive?

- Sharps injuries are a common and serious risk to European healthcare workers, representing high costs for both healthcare systems and society
- Over 1 million sharps injuries occur each year across the EU
- The process of developing legislation specifically to address the risk of working with medical sharps in the EU began over five-years ago; with the final publication of The Directive on 1st June 2010



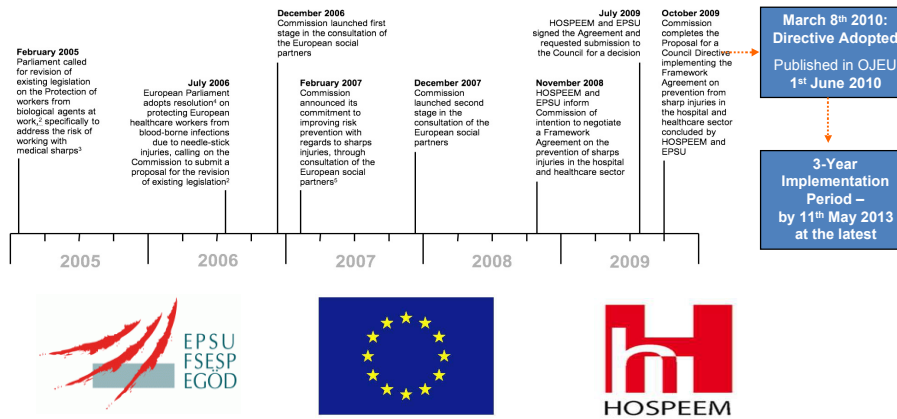
EU Council Directive on the Prevention of Sharps Injuries in the Hospital & Healthcare Sector: Council Directive 2010/32/EU

- Prepared by the European Commission, the proposal is designed to give legal effect to the Framework Agreement on Prevention from Sharps Injuries in the Hospital & Healthcare sector signed in July 2009 by the recognised European social partners:
 - European Hospital & Healthcare Employers' Association (HOSPEEM)
 - European Federation of Public Services Unions (EPSU)
- The process of developing legislation specifically to address the risk of working with medical sharps started in 2005



EU Council Directive on the Prevention of Sharps Injuries in the Hospital & Healthcare Sector: Council Directive 2010/32/EU

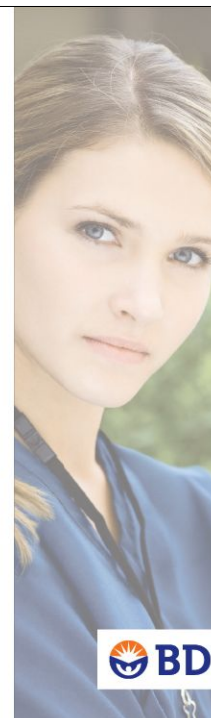
Evolution of the Directive:



EU Council Directive on the Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Key Provisions:

- Purpose
- Scope
- Principles
- Risk Assessment
- Elimination, Prevention & Protection
- Information & Awareness Raising
- Training
- Reporting
- Response & Follow-up



EU Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Purpose:



- To achieve the safest possible working environment
- To prevent workers from injuries with all medical sharps – including needlestick injuries
- To protect workers at risk
- To set up an integrated approach, establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring
- To put in place response and follow up procedures

1. Clause 1 Purpose of the EU Council Directive 10th May 2010

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Scope:

- Applies to all workers in the hospital and healthcare sector, as well as those under the managerial authority and supervision of the employers
- Employers will need to ensure that subcontractors follow the provisions in the Directive

EU Council Directive 2010/32/EU 10th May 2010

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Principles:

- Lays down the principles that must be observed when actioning the Directive, including the importance of:
 - Training
 - Preventing exposure
 - Role of health and safety representatives
 - Employers and workers responsibilities
 - Development of health and safety policy practice, **never assuming that no risk exists,**
 - Evaluating and reducing risk
 - Need for action - effectiveness of awareness-raising measures, importance of combining measures for optimal effect and incident reporting procedures

EU Council Directive 2010/32/EU 10th May 2010

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Risk Assessment:

- Assessments should be conducted in all situations where there is a danger of infection
- Any risk assessment must take into account the organisation of the workplace and its resources:
 - Includes exposure determination and understanding the importance of a well resourced and organised working environment
 - The aim is to keep the number of workers likely to be exposed to a minimum
- Aims to identify how exposure can be eliminated and promote the consideration of alternative systems, such as safety engineered devices

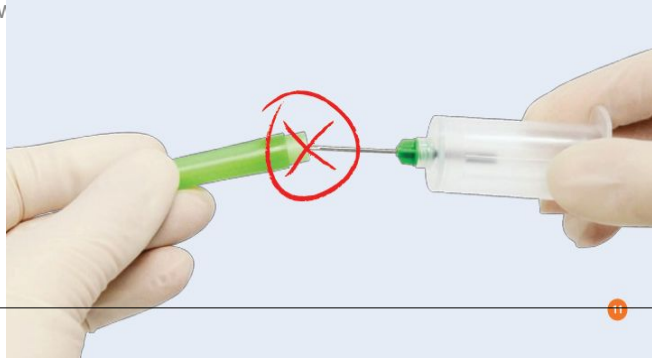
In a hospital environment it is not possible to segregate patients based on risk as many will be treated before it is known they are carrying serious blood-borne pathogens
Therefore, universal sharps injury prevention measures are appropriate

EU Council Directive 2010/32/EU 10th May 2010

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Elimination, Prevention and Protection:

- Sets out measures to avoid risk including safe procedures for using and disposing of medical sharps
- Eliminating the unnecessary use of sharps
- **Recapping of needles to be banned with immediate effect**
- Use of safety engineered devices
- Use of personal protective equipment, for example, wearing gloves
- Training, conducting health surveillance procedures and the benefits and draw



Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Information and Awareness-Raising:

- Employers have a responsibility to ensure that managers and healthcare workers are aware of:
 - The risks of handling sharps
 - Legislation and policies
 - Good practice and safe systems of work regarding the prevention of needlestick injuries
 - The importance of recording needle stick injuries
 - Provision of support programmes

Managers should confer with staff regarding training, changing working practices and choice of safety engineered devices

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Training:

- Employers must organise and provide regular **mandatory** training for healthcare workers. Training should include:
 - The correct use of safety devices and mechanisms
 - Induction for all new and temporary staff
 - The risks associated with blood or fluid exposure
 - Standard safety procedures – including a ban on recapping
 - The importance of reporting, response and monitoring procedures

All healthcare workers should receive training on the policies and procedures associated with sharps injury prevention

EU Council Directive 2010/32/EU 10th May 2010

Provisions of the Directive on Prevention of Sharps Injuries in the Hospital & Healthcare Sector

Reporting:

- Covers the adaptation of existing procedures for accident reporting and the obligation of workers to report incidents involving sharps

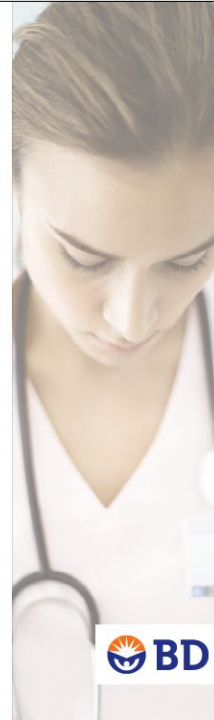
Response and Follow-up:

- Details policies and procedures that should be in place when a sharps injury occurs, in accordance with national/regional legislation. Sets out employers' obligations regarding the care of the injured worker, including:
 - The provision of necessary medical tests
 - Health surveillance
 - Investigation of the cause of the injury
 - Counselling
 - Rehabilitation and continuing employment
 - Compensation and confidentiality

EU Council Directive 2010/32/EU 10th May 2010

EU Directive Key Points

“...in achieving the **safest** possible workplace a combination of planning, awareness-raising, information, training, **prevention** and monitoring **is essential**...”



EU Council Directive 2010/32/EU 10th May 2010

EU Directive on the Prevention of Sharps Injuries in the Hospital and Healthcare Sector

Implementing the EU Directive



 **BD** Helping all people live healthy lives

Implementing The EU Directive

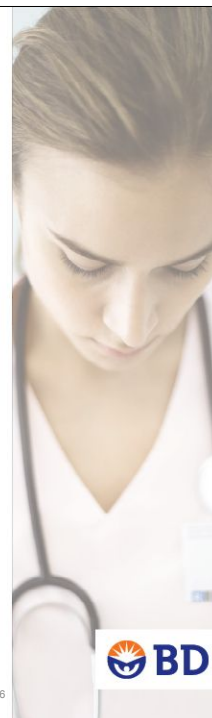
- Start thinking about conversion now - conversion to safety engineered devices is beneficial in a number of important ways
- Overall, the implementation of needle stick prevention measures has been shown, through independent studies, to be a cost-effective investment
- The implementation of improved training, safer working practices (including disposal of used devices) and the provision of medical devices incorporating safety-engineered protection mechanisms is proven to prevent the majority of needlestick injuries
- Standardisation is best – universal implementation of medical devices incorporating sharps safety mechanisms is appropriate because it is not possible to reliably segregate patients or procedures on the basis of risk



Reducing Needlestick Injuries – Impact of safety Engineered Devices

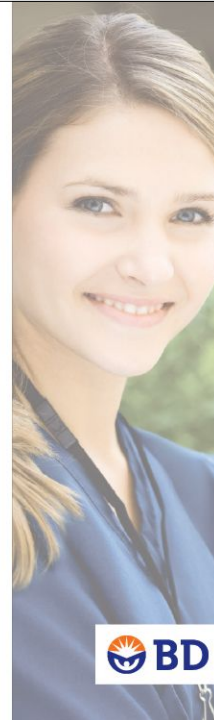
Independent studies have shown that training, safer working practices and the use of safety engineered devices can prevent more than 80% of needlestick injuries

“...In the UK, an expert panel concluded that 56% of all percutaneous injuries and **80% of venepuncture and injection administration injuries**, could probably have been prevented through the use of safety devices ...”



Implementing the EU Directive

- The selection of the most suitable devices for a given application, as well as the assurance of appropriate quality, performance and support is important
- The effective training of users in the use of safety engineered devices is a vital part of the implementation



There is No Time to Delay

There is No Time to Delay

Delaying implementation of safety measures means healthcare workers remain at risk

May 2013

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	



EU Directive: Management Responsibilities

“...the HSE has an ability to prosecute organisations that do not comply with the requisite standards...”⁷

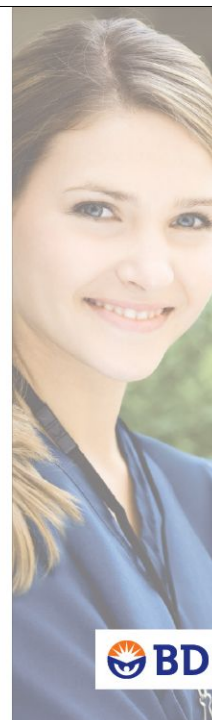
The Care and Quality Commission (CQC) and the Health and Safety Executive (HSE) are expected to enforce the new legislation.⁷ Organisations found to be non-compliant run the risk of receiving significant financial penalties, public warnings, compliance notices and even forced closure of services.⁷

7. Are your sharps policies and procedures up to scratch. Bevan Brittan February 2011



The Majority of Needlestick Injuries Are Preventable

- Independent studies have shown that most needlestick injuries are preventable which the implementation of:
 - Safety education
 - Safer working practice
 - The use of medical devices incorporating needle protection technology



The European Biosafety Network



European Biosafety Network

- The European Biosafety Network was established following the adoption of the new European Directive on Sharps Injuries with a commitment to improve the safety of patients and healthcare workers
- The founding partners of the Network are the Spanish General Council of Nursing and the British public services union UNISON
- The Network will be an inclusive organisation made up of all those national and European professional institutions, representative associations, unions and other interested parties committed to the prevention and elimination of sharps injuries throughout the European Union
- The Network will focus on promoting and encouraging the early legislative implementation of The Directive in Member States by raising awareness, providing guidance, the dissemination of information and effective reporting and monitoring



1st European Biosafety Summit Madrid June 2010



Jose Martinez Olmos, Spanish Secretary-General of Health is welcomed to the conference by Prof Dr Máximo González Co-Chair of the European Biosafety Summit and President of the Spanish General Council of Nursing (CGE)

Dr Máximo González Jurado opens the Summit



Cliff Williams, Co-Chair of the European Biosafety Summit and Regional Secretary of UNISON addresses the Summit

European Biosafety Network: Key Recommendations for Safety Devices

- The device must not compromise patient care
- The device must perform reliably
- The safety device must be an integral part of the device, not a separate accessory
- The device must be easy to use and require little change in technique on the part of the HCW
- The activation of the safety shield 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 preferred
- The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual; sign to the HCW
- The safety mechanism should not be easily reversible once activated



European Biosafety Network: Tools & Resources

- Call for Action
- Implementation Guidance for the EU Framework Agreement, Council Directive & Associated National Legislation:
 - Provides key recommendations when considering safety engineered devices
- Look on-line for the resources:
 - <http://www.europeanbiosafetynetwork.eu/>



European Biosafety Summit Dublin, 1st June 2011

The European Biosafety Network and the Irish Nurses and Midwives Organization will be hosting the European Biosafety Summit on Wednesday 1 June 2011. The Summit is a 1 day event and will be held in the Coach House, Dublin Castle.

A number of keynote speakers, including the Irish Minister for Health and Children, the European Commissioner for Employment, Social Affairs and representatives from European Member States will address the audience.

The European Biosafety Summit will highlight the impact of sharps injuries and report on progress within the Member States and across Europe towards implementation of the Sharps Directive and its transposition into national legislation. The Summit will discuss components of a practical toolkit for implementation and a Blueprint for Action drafted by the European Biosafety Network.





Phlebotomists
Association of Ireland
AGM & National
Conference

Sarah Ross
European Marketing Manager
12th March 2011

