

Sharps Injuries in the Operating Theatre

A Practical Guide to Further Reducing the Risks

European Council Directive 2010/32/EU

Implemented by

The Health & Safety
(Sharp Instruments in Healthcare)
Regulations 2013 effective from May 2013

Implications for Healthcare Employers & Employees



Endorsed

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purple surgical

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Foreword

Seventeen years ago, I wrote the original educational guide for Cory Bros. (as Purple Surgical was then known) called "Safe Sharps Management in the Healthcare Environment" and I am privileged to be able to write the foreword for this new guidance.

Certainly, a great deal has changed for the better in the intervening years. Awareness of the risks of sharps injury has increased generally and treatment of many blood-borne infections has improved significantly; reported deaths from HIV acquired through accidental inoculation seem thankfully to be a thing of the past.

However, substantial risks remain and there is no room for complacency. Apart from the human costs of distress, discomfort, potential career restrictions, illness and even death, organisations incur considerable financial and operational costs through sharps injuries, at a time when healthcare expenditure has never been under greater pressure.

Research has also highlighted that while some types of sharps (particularly hollow bore needles) account for large numbers of injuries, the actual incidence of injury associated with some other sharps (scalpel blades, suture needles) is many times higher. While industry has responded and produced a variety of engineered safety devices to prevent injury, the nature of the work in Operating Theatres means that the use of sharp implements cannot always be avoided. This problem is exacerbated by the high pressure and close proximity of colleagues that typifies the theatre environment, so the focus of this guide aims to bring real value to this particularly vulnerable group. Better practice can only be achieved by multiple marginal improvements.

The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 now in place, represents a landmark in protecting healthcare workers. Since the 90's when the original Cory Bros document was written, the emphasis has changed from raising awareness about sharps injuries to active assessment, risk reduction and prevention with the new regulations obliging employers to act and giving employees better rights and protection. In combination with existing Health & Safety law, the regulations leave no doubt about what is required.

Healthcare staff and managers face multiple challenges and time is precious. This practical and comprehensive guide provides all the essential information about the risks associated with sharps and manages to make sense of the principles underpinning new regulations in a simple and informative way. I am sure you will find this document to be an invaluable aid in implementing the new regulations, assuring sharps safety and communicating the key issues to all members of the healthcare team.

Jennie Wilson Healthcare Infection Prevention Specialist and Reader in Healthcare Epidemiology at the University of West London

About Purple Surgical

Purple Surgical was founded in 1909 under the name Cory Bros. (Hospital Contracts) Ltd. Originally a surgical instrument manufacturer, the company became a UK distributor for international manufacturers and introduced a number of innovative product concepts.

In the early 1980s, Cory Bros launched the novel Devon range of Safe Sharps Management products and became the UK market leader in Operating Theatre Sharps Safety by providing high quality user education, training and products.

In 2000, Cory Bros (as the company was known at that time) began manufacturing its own range of Operating Theatre Essentials and Safe Sharps Management products at its own manufacturing facility in Taunton, Somerset.

While the company is probably now best known for its extensive portfolio of laparoscopic products, Purple Surgical continues to be the European sharps safety market leaders and has more than 100 distribution partners worldwide.

Purple Surgical replaced Cory Bros as the company's brand name completely in 2013, in recognition of the international nature of the business.

Purple Surgical remains committed to further reducing sharps injuries in the Operating Theatre through the provision of excellent quality and cost effective products supported by user education and training.

For more information visit www.purplesurgical.com or contact the Customer Service Team on +44(0)1923 839333 or email: mail@purplesurgical.com

About this Guide

This document is intended to provide relevant information and practical guidance to healthcare managers and clinicians with responsibilities for front line operating theatre staff, risk reduction, health and safety and governance.

On 11th May 2013, European Council Directive 2010/32/EU (The Sharps Directive) adopted in May 2010, became UK law

With the 2010 European Directive¹ becoming law in the UK under the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013², from 11th May 2013 employers now have legal duties with regard to sharps safety. Unlike previous guidance from bodies such as the Care Quality Commission, this legislation falls under the Health and Safety at Work Act 1974³ and compliance is mandatory.

Any organisation that does not comply is liable to enforcement action or prosecution, even before an injury occurs, if adequate process is not in place.

The requirements for reducing the risks of sharps injuries, as laid out in this new legislation, are reviewed. Information and facts about the implications and real cost of sharps injuries for both the individual workers and organisations is provided before discussing control measures and risk assessment, drawing on published information from a number of expert, independent bodies.

Particular attention is given to sharps used in the Operating Theatre as this is a significant problem area. This issue is often lost within a mass of general information and broad consideration of hollow bore needle injuries. In many respects, the issues facing operating theatre staff are different from those in other hospital departments and the community so there is merit in focusing on suture and scalpel sharps.

Any organisation that does not comply is liable to prosecution, even before an injury occurs, if adequate process is not in place

The Operating Theatre is a unique environment in many respects; many healthcare professionals work in close proximity, often over long periods, and often under emergency conditions

To provide practical value, a business plan requirement with a financial cost/risk reduction template is provided, in addition to information about specific products designed to prevent sharps injuries in the Operating Theatre. References are provided throughout.

Purple Surgical would like to acknowledge with thanks, the use of materials from the following organisations in preparing this guide: H&SE, RCN, AfPP, Safer Needles Network, Biosafety Network, and the NHS Confederation.

¹ European Directive: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF>

² UK legislation: http://www.legislation.gov.uk/ukSI/2013/645/pdfs/ukSI_20130645_en.pdf

³ Explanatory Memorandum to The Health & Safety (Sharps Instruments in Healthcare) Regulations prepared by the Health and Safety Executive on behalf of the Department for Work and Pensions: http://www.legislation.gov.uk/ukSI/2013/645/pdfs/ukSIEM_20130645_en.pdf

1 Introduction

Sharps injuries come second only to lifting and handling injuries in the order of occupational hazards faced daily by healthcare workers (NAO)⁴. Twenty UK healthcare workers have acquired Hepatitis C and four have died from HIV following sharps injuries (HPA 2012)^{5,6}.

The actual and potential impact of sharps injuries on individuals and organisations is much greater than simply the statistical risk of seroconversion of a blood borne virus. In the past, efforts to reduce sharps injuries have focused on changing behaviours; the emphasis of the new legislation is prevention and there are now specific requirements to be met.

Sharps injuries are recognised as being hugely under reported⁷. They are too often seen as a repellent event that is an occupational risk when working in healthcare. However, the violence of such an injury could not be a greater contrast to the therapeutic intentions of caring healthcare professionals.

Sharps injuries can be painful, shocking, debilitating and stressful for the individual. Initial distress can be followed by weeks of worry and uncertainty while the consequences of such an apparently innocuous event unfold. Sharps injuries can be career ending and can deprive providers of scarce and valuable human resources.

For the organisation, a sharps injury is potentially expensive; assessment, monitoring and treatment following injury costs time and money, not least due to the partial loss of the working contribution of an often scarce and skilled professional. Outside the hospital, the courts may find the employer liable and guilty of failing to protect staff. Past judgements have cost Trusts thousands of pounds in penalties, compensation, costs and fees; litigation insurance and unanticipated corrective action will have cost more still. The cost to reputation and employees' morale is impossible to quantify. As a department, Operating Theatres are the site of more sharps injuries than any other place in the hospital. As a proportion of the number used, the frequency of sharps injuries from suture needles and scalpels are considerably higher than most hollow bore needles.

While any sharps injury reduction strategy starts with avoiding the use of sharps, in theatres the nature of the work often makes this impractical. The opportunity for risk reduction using engineered safety devices (ESDs) are inevitably limited so the problem is best addressed by the provision of protective equipment, staff training and raised awareness.

Sharps safety awareness is neither new nor revolutionary in the UK. Thankfully, sharps disposal practice has improved generally to the benefit of all involved since the introduction of purpose designed sharps containers in the 1980s. There is still room for continuous improvement and no place for complacency; in fact, consequences and implications for managers and organisations have increased from 11th May 2013 with the legal enactment of the "Sharps Directive". Under this law, adequate staff protection from sharps injury is no longer best practice, it is mandatory. Failure to comply leaves employers exposed to the full force of the law.

20 UK healthcare workers have acquired Hepatitis C and four have died from HIV following sharps injuries - Health Protection Agency, 2012

Operating Theatres, not surprisingly perhaps, are the site of more sharps injuries than any other place in the hospital

⁴ **National Audit Office:** A Safer Place to Work - Improving the management of health and safety risks to staff in NHS trusts. Report by Comptroller and Auditor General. HC 623 Session 2002-2003: 30 April 2003

⁵ **Health Protection Agency:** Eye of the Needle 2012 United Kingdom surveillance of significant occupational exposures to blood borne viruses in healthcare workers: December 2012

⁶ **NHS Confederation Briefing:** Protecting Healthcare workers from sharps injuries – what employers and employees need to do from May 2013 to implement new health and safety requirements – May 2013 Issue 13

⁷ **Elder A, Patterson C (2006)** "Sharps Injuries in UK Health Care: a review of injury rates, viral transmission and potential efficacy of safety devices" Occupational Medicine 56:566-74

2 What's New? The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

2.1 What has changed?

On 11th May 2013, The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 No. 645² came into force. This law was required to implement the European Council Directive 2010/32/EU¹, (The Sharps Directive), adopted in May 2010.

While the Health and Safety at Work Act (HWSA) 1974 already provides much protection for people at work, the Sharps Directive required Member States to provide “effective, proportionate and dissuasive penalties” in the event of any breach of the Directive. Previously, the UK had no legal mechanism under which social partners (employers and trade union representatives) could bring in sufficiently enforceable measures to meet the UK’s obligation under the Directive³. As a result the new UK law was passed and came into effect. The 2013 act requires employers to provide a safe working environment in relation to sharps injuries, together with safe equipment, training, information and instructions on safe systems of work. Other existing legislation applying to sharps safety^{6,8} is shown in Figure 1 below:

The Sharps Directive requires Member States to provide “effective, proportionate and dissuasive penalties” in the event of any breach of the Directive

- **The Control of Substances Hazardous to Health Regulations (COSHH) 2002.**
- **The Provision and Use of Work Equipment Regulations 1998 under which employers are required to select and provide suitable work equipment and provide information and instruction on safe use.**
- **The Management of Health and Safety at Work Regulations 1999 under which employers must carry out suitable and sufficient risk assessments of all significant hazards in the work place. Employers must also provide employees with information on the risks to their health and safety, preventative and protective measures in place and emergency procedures.**
- **The Personal Protective Equipment Regulations 1992 requires employers to assess, select, provide and maintain personal protective equipment. This includes a selection of suitable gloves, aprons and goggles where the risk of exposure to blood-borne viruses cannot be eliminated or reduced effectively through other measures.**
- **Safety Representatives and Safety Committee Regulations 1977 requires employers to consult with safety representatives and allow paid time off.**

Figure 1: Legislation Applying to Sharps Safety in the Work Place

Under the 2013 UK regulations, sharps safety receives more focussed attention and lays out some new requirements for employers and employees. The existing Health and Safety at Work Act gives the courts power to impose significant financial penalties for breaches of the law so there is requirement for additional penalties.

¹ **European Directive:** <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF>

² **UK legislation:** http://www.legislation.gov.uk/uksi/2013/645/pdfs/uksi_20130645_en.pdf

³ **Explanatory Memorandum to The Health & Safety (Sharps Instruments in Healthcare) Regulations** prepared by the Health and Safety Executive on behalf of the Department for Work and Pensions: http://www.legislation.gov.uk/uksi/2013/645/pdfs/uksiem_20130645_en.pdf

⁶ **NHS Confederation Briefing:** Protecting Healthcare workers from sharps injuries – what employers and employees need to do from May 2013 to implement new health and safety requirements – May 2013 Issue 13

⁸ **RCN:** Sharps Safety - RCN guidance to support implementation of the EU Directive 2010/32/EU the prevention of sharps injuries in the healthcare sector - Royal College of Nursing, 2011

2.2 What does the new law say?

Under the UK 2013 regulations, prevention is a priority; the regulations introduce new requirements that need to be implemented. The key requirements can be considered as four components⁹:

- Risk assessment, elimination and prevention
- Raising awareness and monitoring
- Training
- Information

In more specific detail, these apply to both employers and employees⁸:

2.2.1 Employers

Promote the safe use and disposal of medical sharps

- Avoid unnecessary use altogether
- Where the use of medical sharps is necessary, substitute with suitable “safer sharps”
- Prevent the re-capping of needles (with exceptions)
- Place secure containers and instructions for safe sharps disposal close to the work area

Provide information and training for staff

- Provide information about sharps injuries which explains the risks, legal duties of employers and employees, good practice, the benefits of vaccination and support available in the event of an injury
- Work with appointed trade union representatives and other safety representatives in developing and promoting information to workers
- Train employees in the correct use of safer sharps, safe disposal and what to do in the event of injury, and employer arrangements for health surveillance

Respond effectively if an injury occurs

- Have arrangements in place so that employees know how and who to report injuries
- Record and investigate the injury and take appropriate action
- Where an employee has notified an incident in which they may have been exposed to a blood borne virus, ensure they have immediate access to medical advice, and counselling where appropriate
- On medical advice, offer treatment
- In some circumstances advice and treatment may be provided by a suitable qualified non-medical practitioner (Occupational Health Nurse, for example) if provided under the supervision of a registered Medical Practitioner

Review procedures regularly

- Review procedures in place to implement the above. This in effect includes an audit of existing procedures to ensure compliance

2.2.2 Employees

Notification of Injuries

- The new regulations include a duty for an employee who receives a sharps injury whilst performing their work to notify their employer as soon as possible

⁸ RCN: Sharps Safety - RCN guidance to support implementation of the EU Directive 2010/32/EU the prevention of sharps injuries in the healthcare sector - Royal College of Nursing, 2011

⁹ Adams D (2012) Needlestick and sharps injuries: implications for practice. Nursing Standard, 26, 37, 49-57

3 The Cost and Implications of Sharps Injuries

3.1 Infections from Sharps Injuries

More than 20 blood borne infections can be acquired by a sharps injury⁹. Seroconversion rates vary according to pathogens but the risk of infection following a percutaneous injury, especially deep penetrating injuries involving a hollow bore needle or a device visibly contaminated with blood has been estimated at 1 in 3 for Hepatitis B, 1 in 30 for Hepatitis C and 1 in 300 for HIV.

Relative Risk of Seroconversion Following Exposure by Pathogen

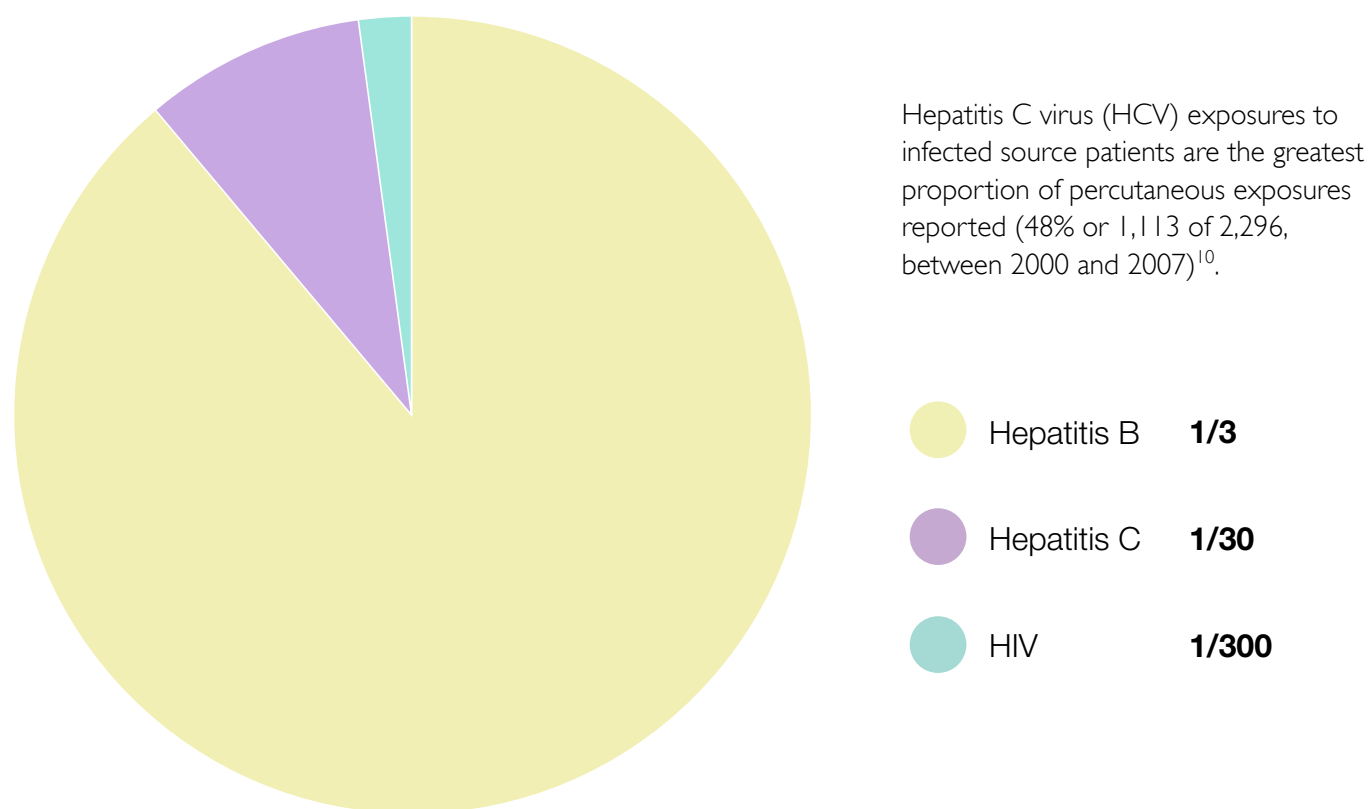


Figure 2: Relative Risk of Seroconversion Following Exposure by Pathogen (HPA 2012)

In 2012, The Health Protection Agency reported that the total number of Hepatitis C virus seroconversions in healthcare workers reported between 1997 and 2011 now stands at 20; 17 cases were reported in England and three in Scotland⁵.

There is no effective post-exposure prophylaxis available for Hepatitis C currently¹¹. 85% of Hepatitis seroconversions occur asymptotically.

At least four UK healthcare workers are known to have died following occupationally-acquired HIV⁵.

Of healthcare workers exposed to an HIV positive source patient between 2002 and 2011, 78% (1048/1336) began HIV post-exposure prophylaxis (PEP) after sustaining a significant exposure. Of these exposures, a third (34%; 221/645) had commenced HIV PEP within an hour of their exposure and 89% (577) within 24 hours⁵.

⁵ Health Protection Agency: Eye of the Needle 2012 United Kingdom surveillance of significant occupational exposures to blood borne viruses in healthcare workers: December 2012

⁹ Adams D (2012) Needlestick and sharps injuries: implications for practice. Nursing Standard. 26, 37, 49-57

¹⁰ Health Protection Agency: Eye of the Needle 2008

¹¹ Thomas WJC Murray JRD The incidence and reporting rates of needle-stick injury amongst UK surgeons. Ann R Coll Surg Eng 2009; 91: 12-17

3.2 The Incidence of Sharps Injuries in the Operating Theatre

Approximately 100,000 sharps injuries occur in UK hospitals each year. It has been estimated that 4% of healthcare workers sustain 1-6.2 sharps injuries each year¹².

The Operating Theatre is a unique environment in many respects; many healthcare professionals work in close proximity, often over long periods, and often under emergency conditions.

According to the CDC, 27% of all percutaneous injuries are sustained in the Operating Theatre. Of these, 43% were due to suture needles (CDC)¹³ with scalpel injuries contributing the majority of the remainder (18% according to Vose)¹⁴.

20% of injuries in all hospital settings are caused by suture needles; 8% are caused by scalpels¹⁵.

It has been estimated that cuts or needlestick injuries occur in as many as 15% of operations¹⁶. The higher risks are associated with longer, more invasive and high blood loss operations. The majority are self-inflicted but as many as one quarter are caused by other members of the team.

Scalpel injuries represent a multi-faceted risk as they cause mechanical injury and expose both the injured worker and the patient to the risk of acquiring blood borne infection¹⁷. Depth of injury and whether the device causing the injury has been in the patient's artery or vein are known to increase risks of infection⁷.

According to the CDC, **27%** of all percutaneous injuries are sustained in the Operating Theatre

Scalpel injuries represent a multi-faceted risk as they cause mechanical injury and expose both the injured worker and the patient to the risk of acquiring blood borne infection

Data on the number of percutaneous injuries sustained by healthcare workers as a result of scalpels are scarce as under reporting is a major problem; some estimates are that only 1 in 10 sharps injuries are reported^{6,18}.

The incidence rate of puncture injury per 100,000 devices was seen to be 662 for scalpels compared to 476 for all other types of sharp instrument combined. Although accounting for the highest number of reported injuries, almost 50%, disposable syringes and needles had an incidence of only 3.2/100,000 devices.

⁶ NHS Confederation Briefing: Protecting Healthcare workers from sharps injuries – what employers and employees need to do from May 2013 to implement new health and safety requirements – May 2013 Issue 13

¹² Trim JC Elliot TSJ A review of sharps injuries and preventative strategies. Journal of Hospital Infection Volume 53, Issue 4, Pages 237-242, April 2003

¹³ CDC workbook: http://www.cdc.gov/sharpsafety/pdf/sharpsworkbook_2008.pdf - Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program

¹⁴ Vose J G, McAdara-Berkowitz J Reducing Scalpel Injuries in the Operating Room. AORN JOURNAL December 2009, Vol90, No 6

¹⁵ Perry J, Parker G, Jagger J. EPINET report: 2003 percutaneous injury rates. Adv Expos Prevent 2005;7:42-5

¹⁶ Al-Benna S Needlestick and sharps injuries amongst theatre care professionals. Journal of Perioperative Practice December 2010/Volume 20 Issue 12 440-445

¹⁷ Watt AM et al: Scalpel injuries in the operating theatre – Editorial BMJ 2008;336:1031

¹⁸ Au E, Gossage JA, Bailey SR. The reporting of needlestick injuries sustained in theatre by surgeons: are we underreporting? J Hosp Infect 2008; 70: 66-70

Incidence of Injury by Type of Sharp per 100,000 Devices

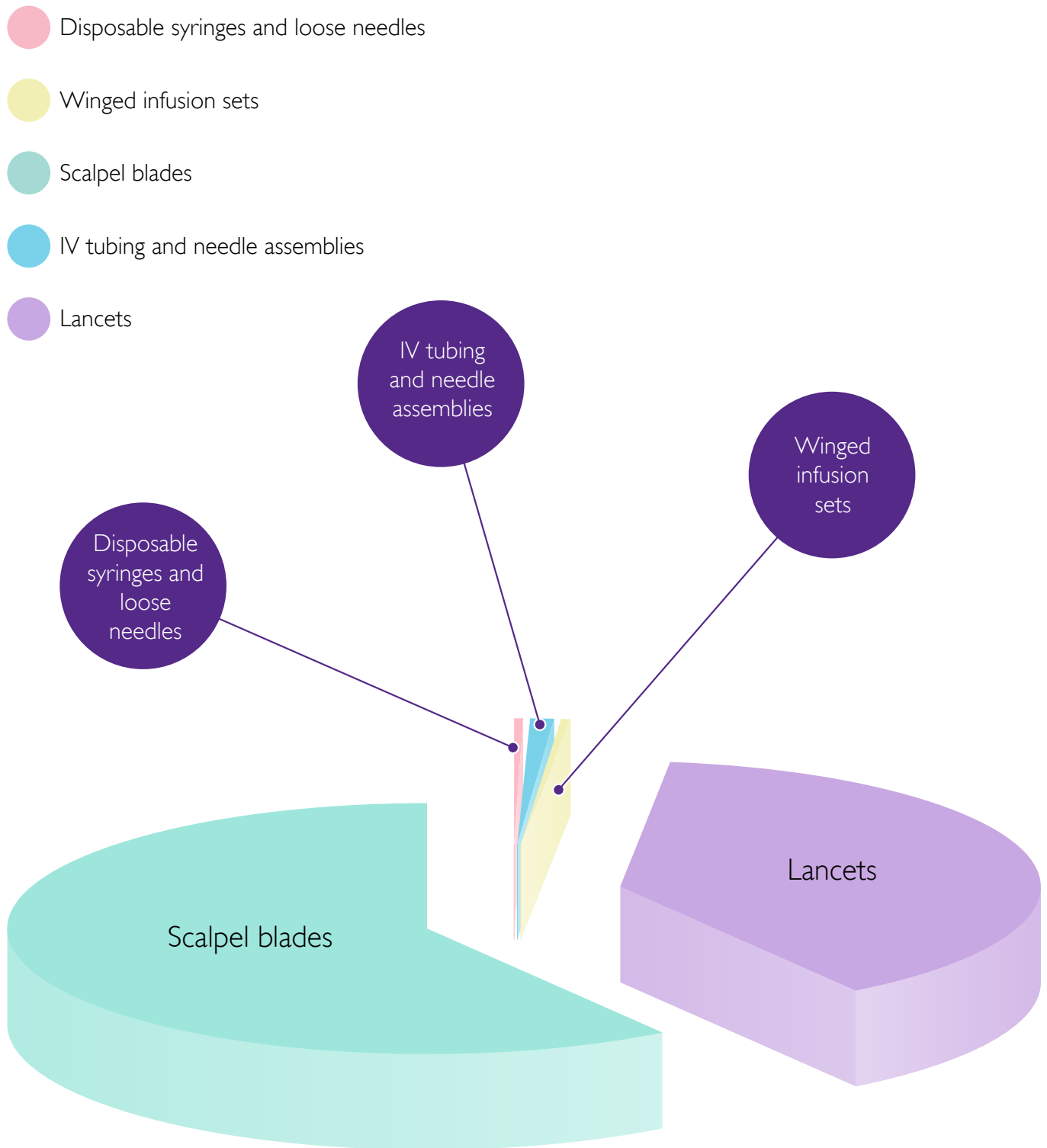


Figure 3: The Incidence of Injury by Type of Sharp (Data from Eisenstein¹⁹)

Scalpels also cause injury to skin and connective tissue and injuries from scalpels are likely to be more severe¹⁴. A US study showed that 6.4 sharps related blood and body fluid exposures occurred per 1,000 procedures, equivalent to 2.6 per 1,000 surgical hours²⁰.

¹⁴ Vose J G, McAdara-Berkowitz J Reducing Scalpel Injuries in the Operating Room. AORN JOURNAL December 2009, Vol90, No 6

¹⁹ H. C. Eisenstein and D. A. Smith Epidemiology of reported sharps injuries in a tertiary care hospital Journal of Hospital Infection (1992) 20, 271-280

²⁰ Myers DJ, Epling C, Dement J, Hunt D. Risk of sharp device-related blood and body fluid exposure in operating rooms. Infect Control Hospital Epidemiol. 2008;29 (12):1139-1148

3.2.1 Incidence by Job Category

Data from the Health Protection Agency (2012)⁵ shows doctors and nurses account for the highest number of reported injuries and the incidence of injuries from solid needles amongst doctors is notably high:

Occupational Exposure by Type of Exposure and Occupation, 2002-2011

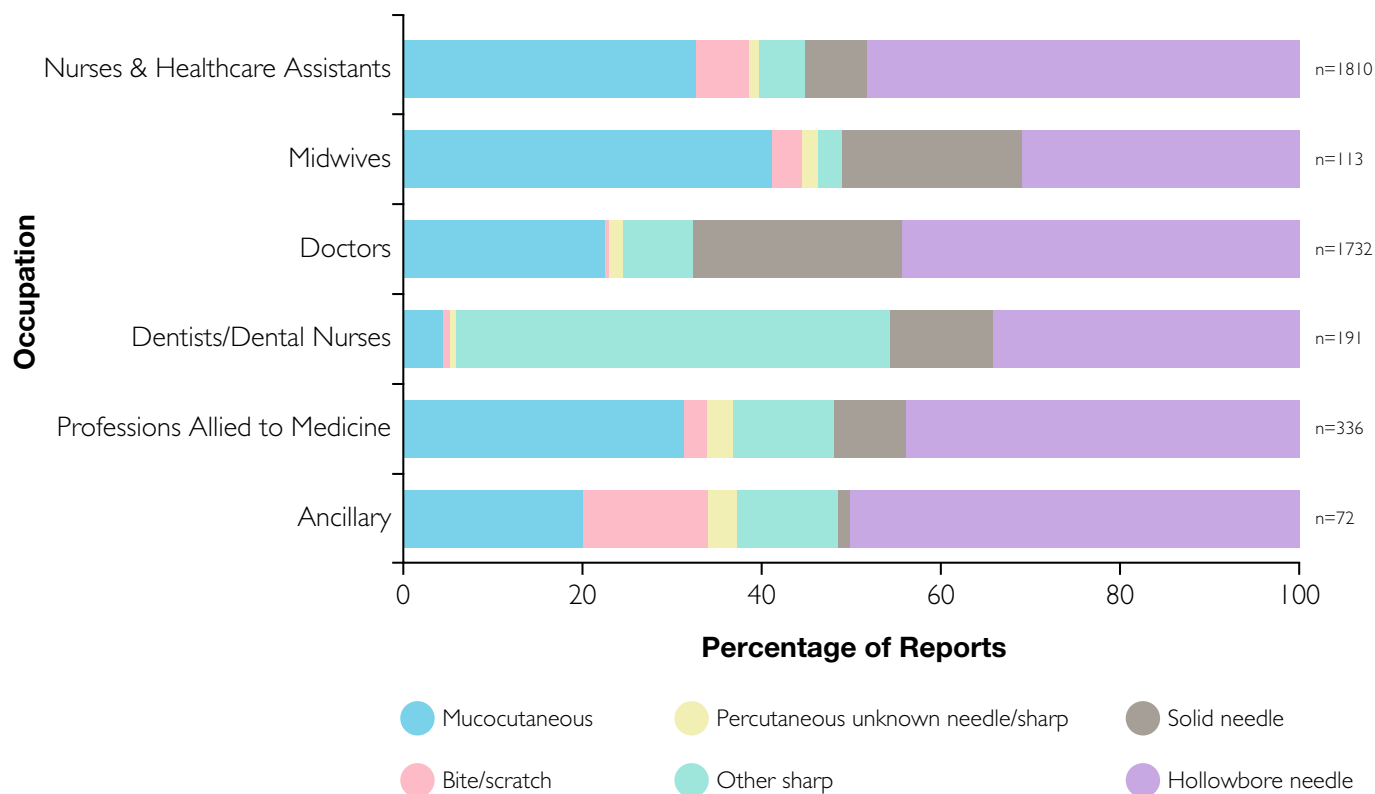


Figure 4: Occupational Exposure by Type and Occupation (HPA)

Previous studies (Jagger 1998)²¹ produces the following data reporting injuries by job category:

Job Category	Percentage of Total Needlestick Injuries
Surgeons	59.1
Theatre Nurses	19.1
Anaesthetists	6.2
Circulating Nurses	6.0
Medical Students	3.1
ODAs	0.8
Others	5.7

Table 1: Percentage of Sharps Injuries by Job Category

⁵ Health Protection Agency: Eye of the Needle 2012 United Kingdom surveillance of significant occupational exposures to blood borne viruses in healthcare workers: December 2012

²¹ Jagger J, Bentley M, Tereskerz P A study of patterns and prevention of blood exposures in OR personnel. AORN J. 1998 May;67(5):979-81, 983-4, 986-7 passim.

Figure 5 below indicates that although there has been a decreasing trend in the number of ward exposures, the number for Operating Theatres shows an increase.

Occupational Exposures by Location of Exposure, 2002 - 2011

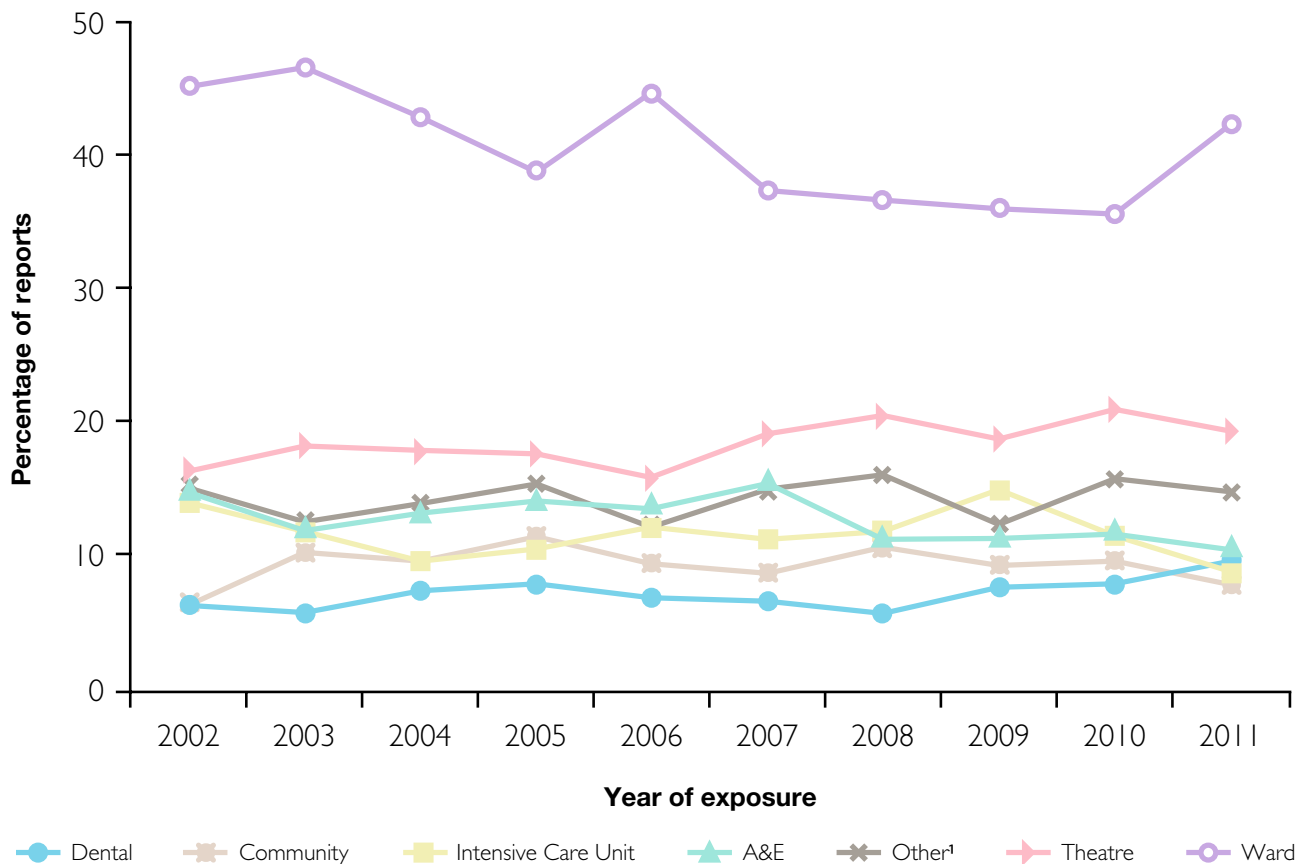


Figure 5: Occupational Exposure by Location of Exposure (HPA)

3.2.2 Under Reporting

It is well recognised that the problem relating to sharps injuries is more significant than it may initially appear due to consistent under reporting, particularly by surgeons¹⁸. Elder and Patterson (2006)⁶ estimated that only 1 in 10 sharps injuries are reported.

73.2% of surveyed surgeons who responded had received a sharps injury in the previous year; **52%** had not reported any of the injuries as required under trust policy

Kerr (2009) reported a study²² across three UK district general hospitals in which 73.2% of surveyed surgeons who responded had received a sharps injury in the previous year; 52% had not reported any of the injuries as required under trust policy. In another study (Thomas 2009)¹¹ 44% had had a sharps injury over the previous 6 months; one surgeon admitted to more than 10.

Various reasons have been given for under reporting: perceived low risk of infection; the policy and procedure is seen as cumbersome and time consuming; disruption to the operating list²³. McCann found only 19% of surgeons followed local protocols even though 35% of participants had at least one injury that caused significant anxiety.

⁶ NHS Confederation Briefing: Protecting Healthcare workers from sharps injuries – what employers and employees need to do from May 2013 to implement new health and safety requirements – May 2013 Issue 13

¹¹ Thomas WJC Murray JRD The incidence and reporting rates of needle-stick injury amongst UK surgeons. Ann R Coll Surg Eng 2009; 91: 12-17

¹⁸ Au E, Gossage JA, Bailey SR. The reporting of needlestick injuries sustained in theatre by surgeons: are we underreporting? J Hosp Infect 2008; 70: 66-70

²² Kerr HL, Stewart N, Pace A, Elsayed S. Sharps injury reporting amongst surgeons. Ann R Coll Engl 2009; 91: 430-432

²³ McCann P Needlestick injury management – what's the solution? Ann Coll Surg Engl 2009; 91: 627

3.3 The Cost of Sharps Injuries

In today's healthcare environment, cost considerations have to be central to adopting any new practice, particularly when additional spending is involved. In reality, besieged managers operating within constrained budget silos often find cost can override practice development.

However, in the case of sharps safety, a more extensive cost/benefit analysis which includes other factors beyond additional equipment costs clearly indicates the need to prevent injuries at every marginal opportunity. For the full benefits to be obtained, it is essential to consider the full resource impact and cost implications for the whole healthcare organisation, not simply the Operating Theatre department in isolation.

Indeed, if a truly complete analysis is to be undertaken, full social cost should be included such as the cost of benefits and loss of taxation through reduced earnings.

The National Audit Office produced a summary of such consequences (Table 2 below) to take into account when assessing the impact of health and safety accidents⁴.

...in the case of sharps safety, any more extensive cost/benefit analysis which includes other factors beyond additional equipment costs clearly indicates the need to prevent injuries at every marginal opportunity

Consequences for Employers	Consequences for Individuals
Tarnished reputation	Reduced capacity for work
Poor functioning of management teams	Reduced quality of life
Delayed service delivery	Need for redeployment
High staff turnover	Need for re-training
Loss of key, experienced staff	Reduced earning capacity
Unplanned managerial time spent reacting to incidents	Temporary disability
Court fines	Permanent disability
Legal costs	Early retirement
Compensation claims	Affect on staff morale
Increased insurance contributions	Death

Table 2: The Impact of Health and Safety Accidents

3.3.1 Costs to the Organisation

Treatment costs

Employers have a legal and moral duty to treat injured staff and the 2013 regulations are specific about what should be done. (See 2.2.1 Employers)

NICE produced a National Costing Statement in March 2012²⁴ which showed indicative costs relating to responding to sharps injuries:

Description	Unit Costs	Notes
Blood Test	£3 per test	National Schedule of Reference Costs Year: 2009-10
Administration costs relating to recording and reporting injury	£12 per hour	Band 3 Admin Assistant
Contact with occupational health professional	£21 per hour	Band 6 OH Nurse
Post-exposure prophylaxis drug cost	£32.64 per day (£456.96 for 14 days, £913.92 for 28 days)	Assuming use of Truvada (£418.50 per pack; 14 days supply) and Kaletra (£76.85 per pack; 28 days supply) – based on UK CMO Expert Advisory Group recommendations
Follow-up appointments	£184 per appointment (£1,104 for 6 appointments)	2011-12 National Tariff. 4 x weekly appointments are recommended when post-exposure prophylaxis is administered. Follow-up appointments are recommended after 3 and 6 months

Table 3: Indicative Costs Associated with Responding to Sharps Injuries (NICE 2012)

Adams and Elliot (2006) estimated financial costs associated with seroconversion to be £7,298 for HCV, £938 for HIV and £607 for HBV²⁵

Adams and Elliot (2006) estimated financial costs associated with seroconversion to be £7,298 for HCV, £938 for HIV and £607 for HBV²⁵

Penalties

Under Health and Safety Legislation, courts may impose fines and award compensation. Magistrates can fine organisations up to £20,000. For more serious breaches, Crown courts can impose unlimited fines and award unlimited compensation.

This is not a theoretic risk; there have been a number of cases where healthcare bodies have incurred penalties and costs relating to sharps injuries:

²⁴ NICE: National Costing Statement: Infection Prevention and control (March 2012)

²⁵ Adams, D, Elliot TS Financial costs associated with the initial treatment of a health care worker who has seroconverted to Hepatitis B,B or HIV following needle stick injury. J of Hospital Infection. 64, Suppl 1, S31 (quoted in Adams 2012)

- In 1998, a health authority paid an out of court settlement of £465,000 to a junior doctor who developed a psychiatric illness following a sharps injury, even though the incident did not lead to any physical infection. (National Audit Office⁴)
- In 2002, a healthcare worker received an award of £58,000 for a needlestick injury suffered in 1997. While assisting a Consultant Anaesthetist a Senior Operating Departmental Assistant was injured when a tray of needles flipped over. One stuck in his arm, and in attempting to shake it off it penetrated his toe, through his shoe. The needle was contaminated and the assistant suffered severe shock and trauma. (National Audit Office⁴)
- In 2007 Worcester NHST was fined £12,500 and costs of £9,000 following infection of a healthcare worker with HCV following a sharps injury²⁶
- In 2008 Kettering General Hospital paid a healthcare worker £6,500 compensation in an out of court settlement after she was injured by sharps left in a plastic bag²⁷
- In 2009 the significant case of Fryers v Belfast Health and Social Care resulted in the High Court of Justice in Northern Ireland awarding £3,000 compensation to a hospital worker at the Royal Victoria Hospital who sustained a needlestick injury. The worker was injured by a used needle that had been thrown into a yellow clinical waste bag. Treatment and a series of blood tests confirmed that there was no risk of developing an infection. However, Mr Fryers went on to develop an adjustment disorder as a result of the stress caused by the injury²⁸

Table 4: Penalties and Costs Imposed on Health Organisations Following Sharps Injuries

These costs do not include significant legal fees incurred while defending the charges.

Operational

At a time of scarce resources, potential or actual infection with HIV or blood-borne Hepatitis viruses will make valuable qualified staff unavailable to work in any branch of surgery short term or even permanently. As a minimum, staff may require time away from work to attend occupational health appointments and raised anxiety reduces performance. Additional department costs may include locum and agency staff.

At a time of scarce resources, potential or actual infection with HIV or blood-borne hepatitis viruses will make valuable qualified staff unavailable to work in any branch of surgery short term or even permanently

3.3.2 Costs to the Individual

At least four UK healthcare workers are known to have died following occupationally-acquired HIV and the consequences of acquiring HCV and HBV are life threatening and debilitating.

The immediate impact of a sharps injury is pain and revulsion and distraction from the task in hand but the longer term consequences may be much more serious. In addition to the anxiety and mental stress caused, infection may end the careers of certain types of staff.

⁴ **National Audit Office:** A Safer Place to Work - Improving the management of health and safety risks to staff in NHS trusts. Report by Comptroller and Auditor General. HC 623 Session 2002-2003: 30 April 2003

²⁶ **Health & Safety Executive Press Release:** Hospital fined after health worker infected with Hepatitis C, 6 October 2010 Release No: WM177/10. <http://www.hse.gov.uk/press/2010/coi-wm-17710.htm>

²⁷ <http://www.thompsons.law.co.uk/ntext/compensation-needlestick-injury.htm>

²⁸ **Thompsons Solicitors** Health & Safety News Spring 2010 Issue No 9 <http://www.thompsons.law.co.uk/ltxt/dload/health-safety-news-009.pdf>

4 Developing a Safe Sharps Strategy

In order to implement an effective safe sharps strategy, it is essential to have commitment from senior management in order to secure the prerequisite funding and resources. Factual information to support the process of securing this buy-in by illustrating the real and potential costs to organisations of sharps injuries has been provided in this guide.

Sharps Safety Stakeholders

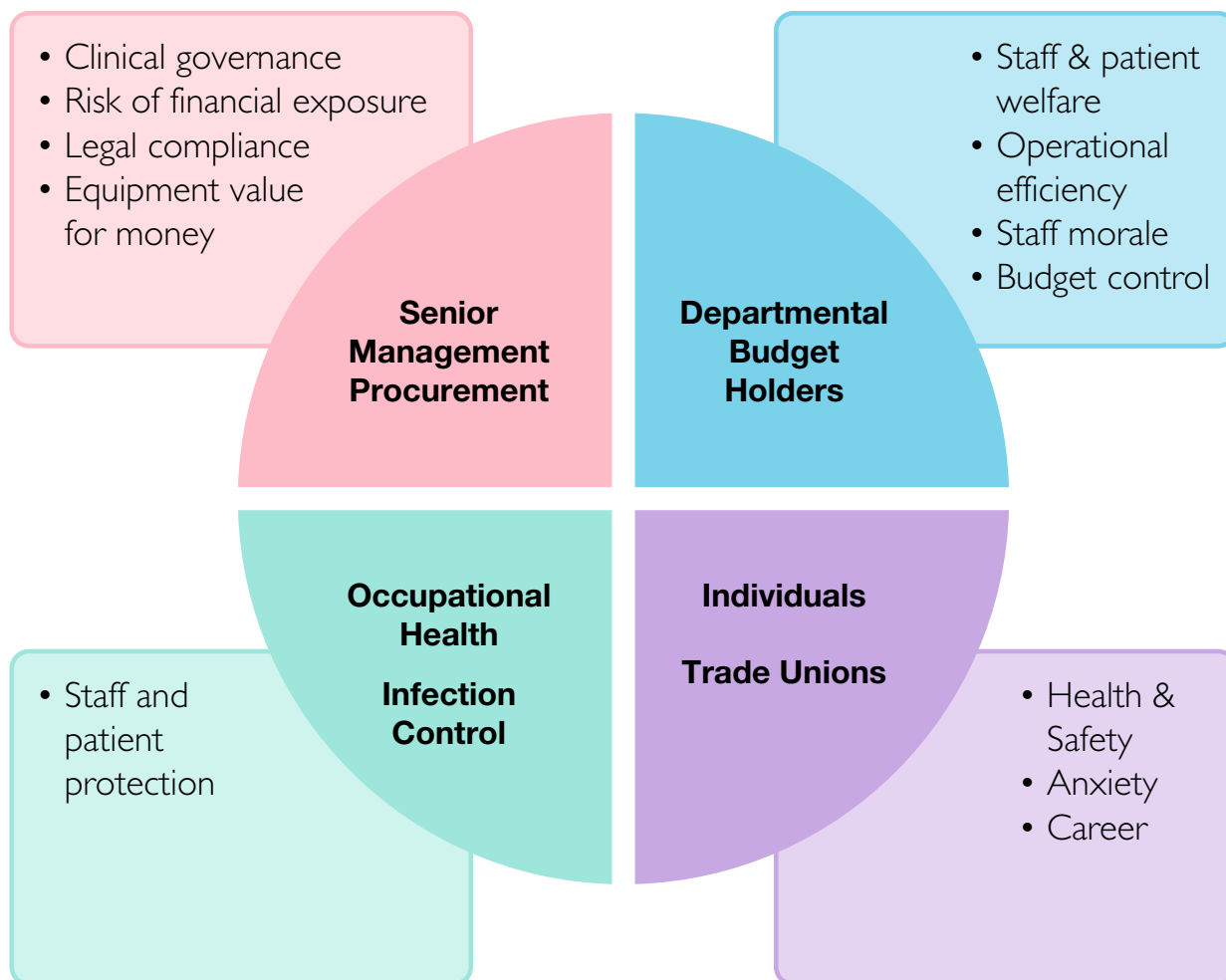


Figure 6: Sharps Safety Stakeholders (Purple Surgical 2013)

Previously, the focus of intention for sharps injury reduction has been on changing individual behaviour to reduce sharps accidents. Under the EU Sharps Directive and the 2013 UK law, prevention of exposure is a priority.

Safety representatives should be consulted and fully involved in all discussions and initiatives to reduce sharps related injuries. A steering/working group, possibly a sub-group of the Health and Safety committee, should be established to look at the implementation of the Directive across the organisation. The steering group should have the authority to make decisions on purchasing equipment, and be involved in the monitoring and review of the risk assessment process.

There is broad agreement that using a Hierarchy of Control is the best way to implement measures to prevent sharps injuries. Reducing sharps injuries requires adoption of a multiple of measures, each providing a marginal improvement to achieve a greater total outcome.

In reality, it is difficult if not impossible to eradicate the use of all sharps, especially from within the Operating Theatre department so risk assessment is both a central tool and a legal requirement for sharps injury prevention.

4.1 Hierarchy of Control

The Hierarchy of Control model is useful when considering options within a specific department. Within Operating Theatres, the first level measure, Elimination of Hazard (sharps) is difficult, however; so other measures should be considered.

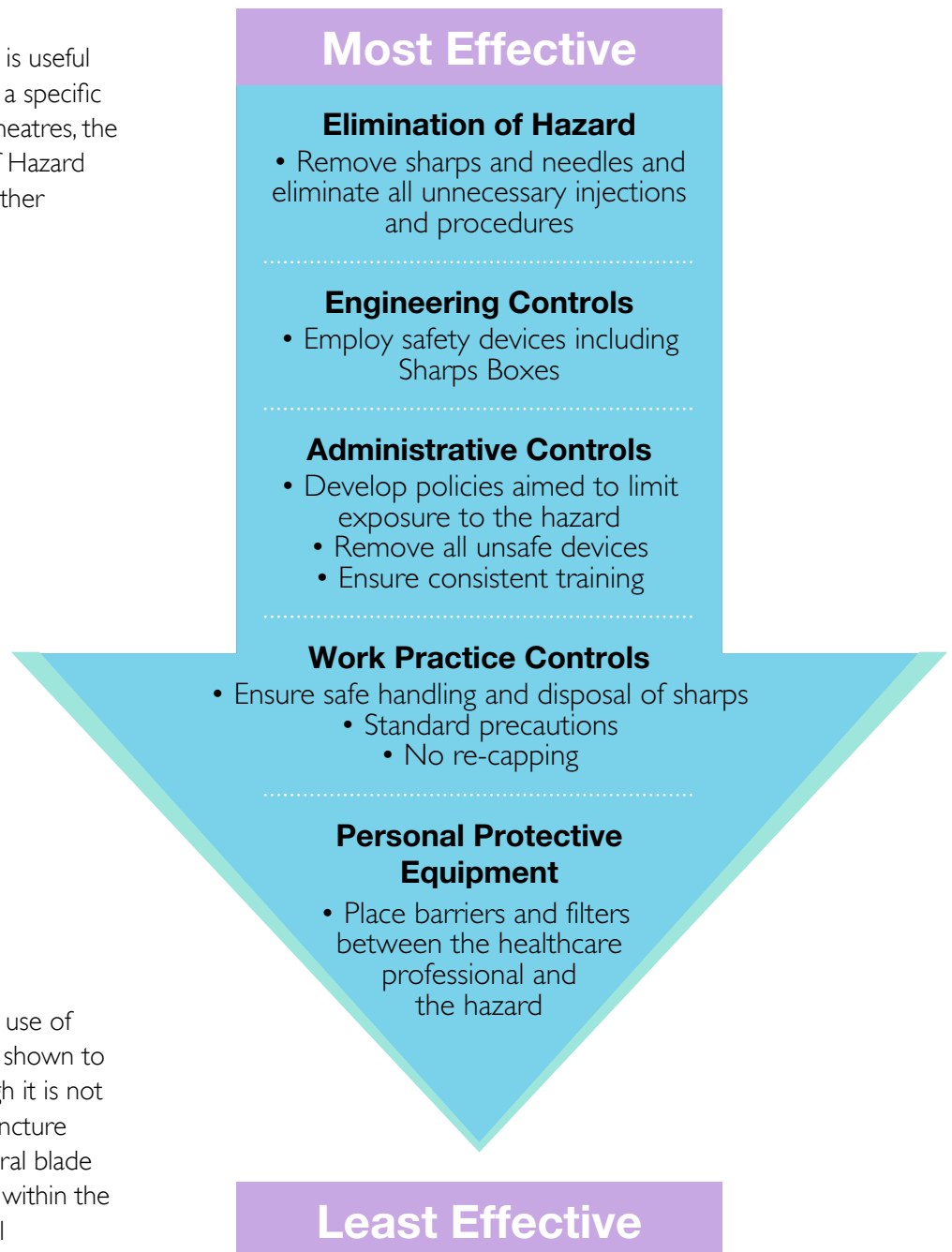


Figure 7: Hierarchy of Control
(After Foley and Leyden 2002²⁹)

Engineering Controls include the use of “double gloving” which has been shown to provide some protection although it is not acceptable to all users. Sterile puncture resistant Sharps Boxes with integral blade removers and needle containers within the operating field are another useful engineering control.

The quality, suitability, ease of use and effectiveness is a critical consideration when attempting to achieve marginal improvement and buying on price alone should be avoided. Devices which do not contain needles effectively or do not work consistently may actually lead to additional accidents and so prove counterproductive. For example, cheap cardboard Sharps Pads do not always adequately contain sharps, particularly when wet.

Other engineering controls to consider are retractable blades and blunt needles.

Administrative Controls (consistent training of all staff) and Work Practice Controls (use of scalpel shields and neutral transfer zones) should also be considered.

A number of products designed for Safe Sharps Management in the Operative Theatre are shown in Section 5: Risk Reduction Products to Consider.

²⁹ **Foley M, Leyden AT** (2002) American Nurses Association: independent Study Module Needlestick Safety and Prevention www.who.int/occupational_health/activities/1/anaim.pdf quoted in Adams (2012)

4.2 Risk Assessment

A simple model of risk assessment used in RCN guidance is provided by the Health & Safety Executive³⁰ and shown in Figure 8 below:

How to Assess the Risks (HSE)

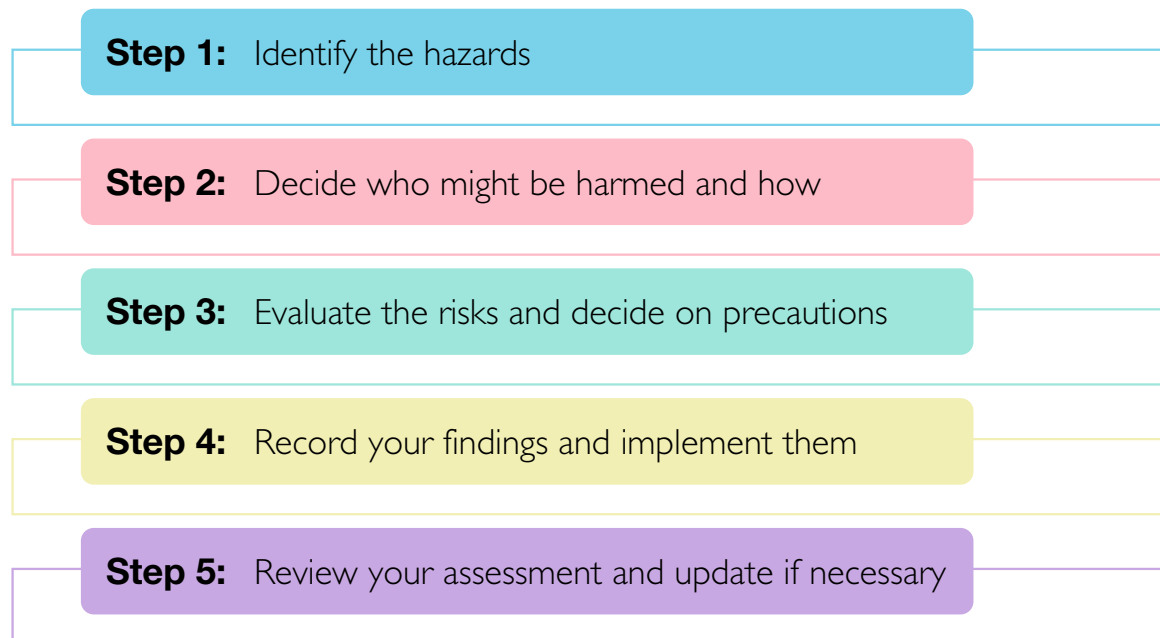


Figure 8: How to Assess the Risks (HSE 2011)

4.2.1 Step 1: Identify the hazards

The first step to work out is how sharps injuries can occur. Review accident and ill-health records to see if these identify any less obvious hazards. Sharps not only include scalpels, suture needles and hollow bore needles but also bone fragments, instruments and glass ampoules.

4.2.2 Step 2: Decide who might be harmed and how

For each hazard you need to be clear about which groups may be impacted, not everyone in the department is exposed to the same or equal risks. Some staff such as trainees, locum or agency workers may have particular needs; patients should be included.

4.2.3 Step 3: Evaluate the risks and decide on precautions

Having identified the hazards, it is necessary to decide what to do to mitigate them. The law requires that everything 'reasonably practicable' is done to protect people from harm. This is best done by comparing current practice with best practice; consider any controls already in place and how work is organised and determine what is required to meet the standard. Consider:

- a) Can the hazard be eradicated altogether?
- b) If not, how can the risks be controlled so that harm is unlikely?

³⁰ <http://www.hse.gov.uk/pubns/indg163.pdf> Five steps to risk assessment – HSE – June 2011

When controlling risks, apply the principles below, if possible in the following order:

- Introduce a lower risk option (e.g. switch to less hazardous alternatives)
- Prevent access to the hazard (e.g. contain sharps safely in rigid sterile boxes prior to the final count)
- Organise work to reduce exposure to the hazard (e.g. train staff to use neutral transfer zones, avoid staff working under undue time pressure, provide equipment to find lost sharps safely)
- Issue personal protective equipment (e.g. clothing, footwear, goggles etc.)
- Provide welfare facilities (e.g. first aid and washing facilities for removal of contamination)

Failure to take simple precautions can cost considerably more if an accident does happen. Finally, involve staff, to ensure that proposed changes will work in practice and won't introduce any new hazards.

The European Biosafety Network³¹, provides a useful guide to Step 3: Evaluate the risks

Risk by amount of blood exposure per device and injury severity	Critical		Infusion devices	Blood collection devices	
	Serious		IM injection devices	Lancets	
	Medium	Accupuncture	Blood splashes; spinal injection devices; subcutaneous injection devices		Surgical devices
	Low	No patient contact		Heparin injection devices	Insulin injection devices
		Seldom	Sometimes	Often	Frequently
Frequency of sharps injury in healthcare settings					

Risk classification:

Risk is not acceptable. Action to address this is very urgently required
Risk is not acceptable. Action to address this is required
Risk is acceptable. Standard precautions are appropriate

Figure 9: Generic Risk Assessment for Medical Devices Incorporating Needles and Sharps (EBN)

4.2.4 Step 4: Record your findings and implement them

Risk assessment findings should be formally recorded. The HSE “do not expect a risk assessment to be perfect, but it must be suitable and sufficient.” (HSE) It is necessary to be able to demonstrate:

- A proper check was made
- Who might be affected was considered
- All the obvious significant hazards have been dealt with, taking into account the number of people who could be involved;
- The precautions are reasonable, and the remaining risk is low; and
- Which staff or their representatives were involved in the process

³¹ European Biosafety Network: Toolkit for Implementation of European Directive on Prevention of Sharps Injuries (Council Directive 2010/32/EU) in Member States – January 2013

Risk Assessment and Policy Templates can be downloaded from the HSE website: www.hse.gov.uk/index.htm

It is important to prioritise what has the biggest impact on reducing injuries and to introduce temporary measures if implementation of a more comprehensive solution is likely to take time.

4.2.5 Step 5: Review your risk assessment and update if necessary

Few workplaces stay the same; new equipment or procedures can lead to new hazards so assessment needs to be conducted on an on-going basis. The risk assessment should periodically be reviewed against staff feedback, accidents and near misses.

5 Risk Reduction Products to Consider

5.1 Introduction

Sharps injuries in theatre occur during the procedure and afterwards during disposal.

Unlike many other healthcare settings, in theatre there is also a requirement to use a sharps instrument several times and injuries frequently occur when sharps are passed between surgeon and colleague.

At the end of the procedure there is a need to account for all sharps used as part of the protocol to ensure nothing is left inside the patient. Sharps need to be isolated so that they can be placed into the sharps container, separate from other contaminated materials destined for clinical waste disposal.

In the event of dropping a sharp or a count discrepancy, it can be difficult to locate and pick up sharp implements, particularly very small needles or wet blades.

As a result, it is worth considering products which meet a number of specific needs:

- Containment and disposal
- Blade removal
- Safe instrument transfer
- Sharps recovery

Given the lack of standard procedures and variety of products available, clear, simple instructions are useful. A statement of which blades can be used, easy-to-follow instructions and user training are strongly recommended. Training of this type should be provided, at no charge, by suppliers whom should also be able to provide experience based advice.

Usability factors are important so practical evaluation by the clinical users of a potential new product is essential. The ease of use is important for reducing stress and the risk of accidents.

5.2 Sharps Containment and Disposal

Sterile Sharps Pads and Sharps Boxes are used during theatre procedures to store used sharps temporarily while allowing them to be easily counted at the end of the operation, prior to safe disposal in a sharps bin. A wide range of sizes are available to suit a variety of different procedures since the type, number and sizes of sharps will vary.

Sharps Pads and Sharps Boxes must close securely to ensure safe handling during disposal. The closing mechanism should ensure that the device will not open if dropped or is left in a temporary location prior to disposal.

Factors to consider:

- Accidental opening of the pad or box
- Pads opening after short time duration
- Dislodgement of sharps from the adhesive or magnetic surface
- Needle penetration of the pad or box

When closed, the two sides should overlap to ensure no accidental sharps migration leaves a sharp exposed.

Products should ensure that sharps are held securely, so that they cannot be dislodged and lost or cause injury, whilst remaining visible for counting at the end of a procedure.

To accommodate user preference and clinical indication, a variety of formats to capture the sharps should be made available. Adhesive strips allow sharps (needles and blades) to be stuck directly onto their surface so the sharps lie flat and are clearly visible. Magnetic surfaces in boxes have a lower strength than adhesive strips and are adequate for most uses with the exception of retaining hypodermic needles. Small strips of magnetic material can be used in combination with other adhesive systems and are generally used for storing blades. Thick foam pads or narrow foam strips are designed for needle insertion. Foam strips require needles to be inserted horizontally so usually both ends of the needle are visible. Foam pads allow needles to be inserted vertically with the blunt end protruding sufficiently for it to be obvious. Large suture needles will not become dislodged, even when a suture is still attached.

The ability of the user to see all sharps clearly is very important to ensure the counting is quick and accurate. The most popular background colour is black as this provides a good contrast to see sharps under theatre lighting. Sharps Boxes should be yellow in colour, consistent with the international bio-hazardous waste identification system. With good product design and careful use, sharps should never penetrate through the container. Boxes offer much better protection than pads which are frequently reported as being penetrated from within and re-open due to adhesive failure.



Sharps Safety Stations™

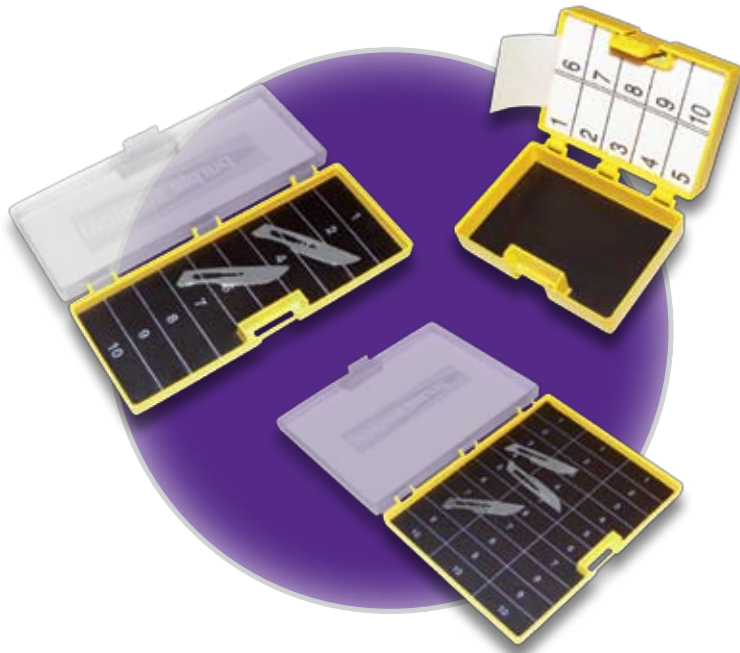
Safety Rating



These sterile rigid boxes combine several devices conveniently and include a scalpel blade removal device and a blade shield to rest scalpels whilst in use. They have a positive locking mechanism which allows re-opening for re-counting. Quality is important and can be demonstrated by deep overlapping edges which avoid accidental migration of sharps and 3 strong hinges. They are available in a number of formats including lift out foam blocks with adhesive backing, fixed foam blocks, foam strips and magnetic and adhesive surfaces for use according to the procedure involved and end user preference.

Sharps Safety Stations™ contain an integral mechanism to improve the safety and ease of removing blades from scalpel handles. Closed blade removers contain the blade as it is removed giving increased protection, particularly against blades breaking or jumping during removal. When using closed blade removers the blades are normally counted in to the container, rather than at the end of the procedure. Not all blade removers will work for all sizes of blades and using an inappropriate size may be hazardous. Advice should be sought from the manufacturer.

Some products have segmented areas or numbered sections to facilitate counting. They should be selected carefully to ensure the range of sharps used in the surgical procedure will fit neatly into the spaces provided to avoid potential miscounting or added confusion.



Sharps Counts

Safety Rating



These are more simple, rigid, sterile boxes available in various formats. Clear lid options enable visualisation of contained sharps for counting. Ideally, these should include a positive locking catch mechanism.

However, some unlockable boxes have a simple snap open and shut catch of varying design and strength and require a small force or manipulation to reopen.

These should be avoided if possible. It is very important that the hinges are strong to avoid separation during handling and closure. A 3 hinge design is the best option.



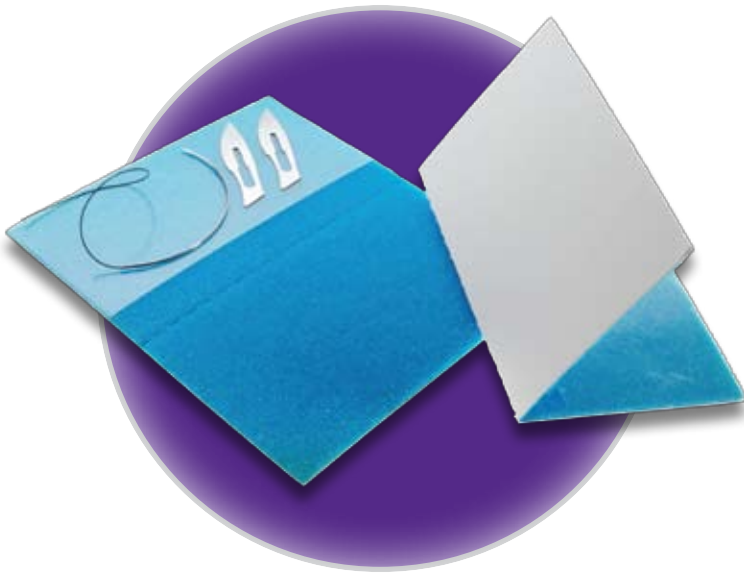
Puncture-Proof-Pad

Safety Rating



This product provides protection against penetration of contaminated sharps, even when wet, while being used in the same way as a standard cardboard Sharps Pad.

Other improvements include overlapping edges to avoid sharps migration, two clasps to aid secure closure and an optional fold-flat edge to accommodate hypodermic syringes and scalpel handles.



Sharps Pad

Safety Rating



Sharps Pads are the most basic means of containing sharps and have been marketed for several decades. Constructed from cardboard with a foam and adhesive lining, they are folded and pressed together to close.

Particular care should be taken to avoid sharps penetrating the pad when pressing the two halves together to close, particularly when wet. Sharps Pads are held closed by adhesive and not intended to be reopened; this should not be attempted if injury is to be avoided.

Hypodermic needles should not be placed in Sharps Pads with their hubs protruding as there is a high risk of them being accidentally dislodged.

Pads	Boxes
✓ Simple in design and easy to use	✓ Contain more safety features than pads
✓ Low in weight and volume	✓ Most are able to fully contain hypodermic needles
✗ Not designed to re-open	✓ Very difficult to penetrate with a needle
✗ Some are easier to penetrate with a needle	✓ Can be reopened and some can lock shut
✗ They may not fully enclose hypodermic needles	
✗ Some have no protection around the edges	

Figure 10: Sharps Pads v Sharps Boxes

The quality of Sharps Pads and other products currently available is highly variable in terms of inconsistent product performance, as suppliers have looked to save costs. This is reflected in cheap mouldings, material thickness and adhesive properties. Locking and other integral mechanisms may not work reliably; adhesives may be inadequate to ensure lasting closure or too aggressive, so tending to stick to operators gloves during use. It is therefore important to performance evaluate products that may appear similar.

5.3 Scalpel Blade Removal

User preference largely determines whether to use a standalone scalpel blade remover or an integral device included on a Sharps Safety Station™. A number are available from different suppliers but correct usage is essential if accidents are to be avoided so training should be provided by your supplier:



Removal using fingers

Safety Rating

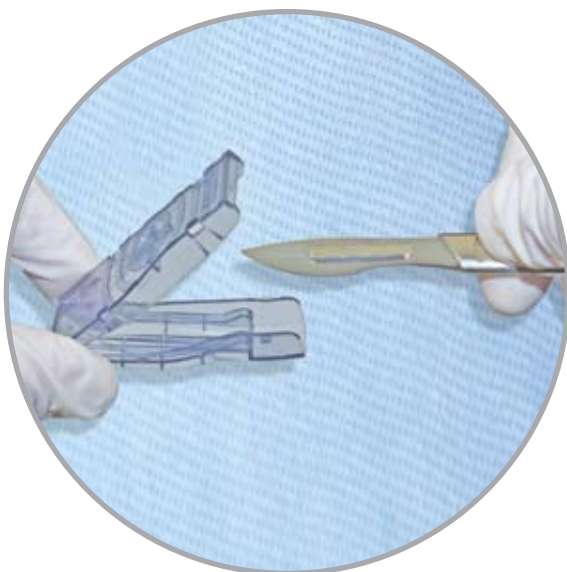
✗ ✗ ✗



Removal using forceps

Safety Rating

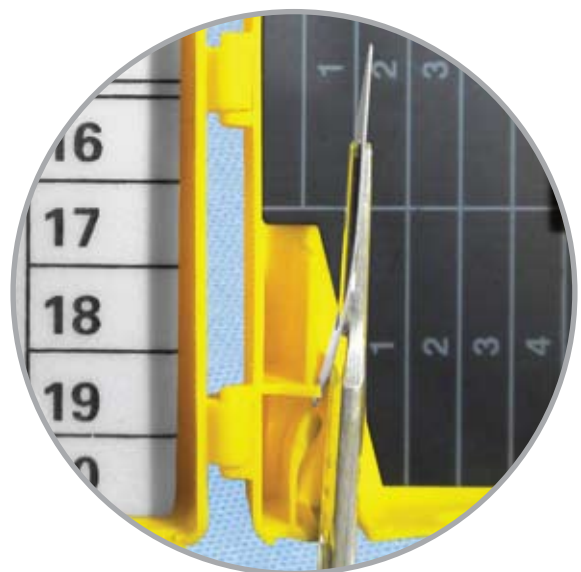
✗ ✗



Hand held blade remover

Safety Rating

✓

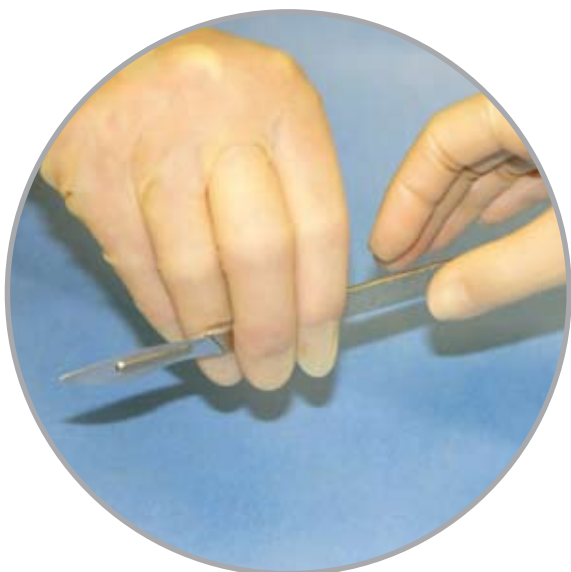


Sharps Safety Station™

Safety Rating

✓ ✓ ✓

5.4 Safe Instrument Transfer



Hand to Hand Transfer

Safety Rating



Avoiding hand to hand transfer of sharp instruments is an obvious means of reducing accidents as this is a frequent cause of third party injury.

When operating at speed under stressful conditions with focused attention elsewhere, without the correct training and products, sharps injuries are almost inevitable.



Kidney Dish Transfer

Safety Rating



Often Kidney Dishes are used to hold instruments while they are being passed to and from the surgeon but instruments can fall out disrupting the case and dishes take up space on the stand or side table.



Sharps Passing Tray

Safety Rating



Greater stability while passing instruments can be achieved by using a purpose designed product such as a Sharps Passing Tray. This product is designed to accommodate a wide range of instruments and shield points during transfer.

An alternative approach is to create a neutral zone which is stationary within the sterile field where the instrument can be put down and picked up, within comfortable reach of both the surgeon and assistant. To increase security, particularly if the transfer surface is not completely level (e.g. the patient's torso), a flexible sterile Magnetic Mat or Magnetic Drape can be used.

Magnetic Mats are heavy duty mesh reinforced mats, approximately 30cm x 40cm in size, which are autoclavable for multiple use. Magnetic Drapes are single use, lightweight and available in different sizes.



Magnetic Drape

Safety Rating



Magnetic Mat

Safety Rating



Safe zones are also created by using Scalpel Shields. These hold the scalpel handle vertically for ease of handling and shroud the blade which also avoids damage to drapes and the compromising of sterility.



Scalpel lying on sterile table

Safety Rating



Scalpel Shield

Safety Rating



5.5 Sharps Recovery

It is sometimes said that it is easier to find something when you are not looking for it and unfortunately this applies to sharps, particularly when they have been dropped onto the operating theatre floor. Searching for lost sharps, particularly very fine needles, is challenging and uncomfortable and dropped sharps can easily be forgotten. It is much better to utilise a magnetic retrieval device which a circulating team member can use to “sweep” the floor should a metallic sharp be dropped.



Bending down on the floor

Safety Rating



Golden Retriever

Safety Rating



5.6 Costs to Consider

A product will provide a direct overall economic benefit if it decreases the incidence of sharps injuries and counting or recounting delays by being easy to use and suitable for purpose. Costs to consider include:

Staff injury cost:

Sharps Boxes and Rigid Plastic Pads should protect staff against sharps injuries which can potentially result in serious illness or fatalities.

Operating time cost:

A device that clearly displays the used sharps may make sharps counting easier and help to avoid recounting delays.

Purchase cost:

Most prices are negotiable depending on volume and frequency of orders. Cost savings can therefore be achieved by (a) ordering only one or two models that meet the needs of all users, (b) placing bulk purchase orders.

Disposal cost:

All products will require incineration and the cost is normally based on weight. Devices should be manufactured from materials that give off no toxic substances during incineration.

6 Cost/Benefit Analysis – Business Planning

Ultimately decisions have to be made based on a balance of any additional costs of control measures against the potential costs to the organisation and individual i.e. the risk potential. Preparation of a robust business case which addresses the concerns of all sharps injury prevention stakeholders will be required.



Figure 11: Risk: Cost v Savings (Purple Surgical 2013)

In 2007, Grimes³² produced a generic business case template for safer systems at work which outlines the financial, legal and regulatory case for healthcare employers to invest in safer systems of work to protect staff, patients and visitors. The arguments presented can be adapted and supplemented with local data and information.

6.1 Financial (Cost) Considerations

Grimes suggests that direct cost comparisons for introducing new systems often show an adverse cost variance, which discourages hospitals from considering investment. However, such comparisons often do not take into account important elements, several of which have been highlighted previously:

- **Organisational costs resulting from payments for the Clinical Negligence Scheme, fines and penalties imposed for breaches in Health and Safety law, staff compensation payments and legal costs.**
- **Safer medical devices are generally more expensive for manufacturers to produce. However, unit costs reduce as volumes increase, benefitting from manufacturing economies of scale. Procurement processes also reduce prices, particularly as hospitals become compliant with national guidance and legislation.**
- **Possible savings due to changes in usage patterns of available devices. Calculations are inevitably based on past usage figures, which may well change with the introduction of safer systems of work.**
- **Savings from the reduction in the rate of exposure incidents. A Trust 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.**
- **Introducing new products in response to a preventable adverse incident rather than in a planned manner is more expensive.**

³² Grimes P Generic Business Case for Investment in Safer Systems of Work December 2007 Safer Needles Network <http://www.saferneedles.org.uk/?page=71&id=5>

A simple table showing return on investment based on the cost of using Sharps Safety Management devices in the Operating Theatre is shown in Figure 12 below.

Department Specific Information	Number of procedures performed per year	10,000
	Injury incidence per 1,000 procedures	150 ¹⁶
	Estimated number of predictable injuries per 1,000 procedures	50
	Estimated cost of managing a sharps injury	£5,000
	Total cost of managing sharps injuries	£250,000

Prevention category	Unit cost per Item (supplier)	Control measure	Additional cost	Average number used per procedure	Total cost per annum	Your estimate of risk reduction %
Sharps Containment	£ -	No Protection	£ -		£ -	0%
	£0.48	Cardboard Sharps Pad	£0.48	1	£4,800	2%
	£1.09	Cost of upgrade to Puncture-Proof-Pad	£0.61	1	£6,100	10%
	£1.23	Cost of upgrade to Needle Proof Sterile Sharps Count	£0.14	1	£1,400	20%
Scalpel Removal	£ -	Finger / forceps removal	£ -		£ -	0%
	£1.48	Cost of upgrade to Sharps Safety Station™ including safe Scalpel Remover	£0.25	1	£2,500	30%
Safe Transfer	£ -	Kidney Dish	£ -		£ -	0%
	£7.33	Cost of Magnetic Drape	£7.33	1	£73,300	15%
Sharps Recovery	£ -	Staff search	£ -		£ -	
	£243.60	One Off Cost of Reusable Golden Retriever - Magnetic Blade Roller	£243.60		£243.60	3%
Total					£88,344	80%

*Risk Reduction

Preventable Cost of Managing Sharps Injuries

£250,000 80% £200,000

(Excluding compensation, fines, legal costs and individual impact)

Cost of Prevention Control Measures

£88,344

Estimated annual saving when adopting Safe Sharps Management products

£111,656

Figure 12: Example Calculation of Return on Investment in using Safe Sharps Management Products (Purple Surgical 2013)

¹⁶ Al-Benna S Needlestick and sharps injuries amongst theatre care professionals. Journal of Perioperative Practice December 2010/Volume 20 Issue 12 440-445

In this calculation, the potential saving is calculated based on department specific information including the number of procedures performed per year, the incidence of sharps injuries (taken from incident reporting records, which may be adjusted for under reporting) and the cost of managing a sharps injury (see Table 3).

The cost of using devices or the additional cost (**blue values**) of using better quality is then calculated based on supplier information and experience based estimates of usage volumes (**pink values**). An estimate is then made of the relative risk reduction achieved (**green values**) by the control measure. Realistically, this is unlikely to be 100% in total although this is the target.

The total cost of managing sharps injuries is then adjusted by the anticipated risk reduction to show the preventable costs of managing sharps injuries. When the additional cost of the control measures is subtracted, the annual saving to the organisation can be seen.

Clearly, the additional cost exposure described in sections 3.3 can then be added in. (Cost calculator spread sheet templates are available on request from Purple Surgical.)

6.2 Legal and Regulatory Considerations

In this document the focus has been on the recent “Sharps Directive” legislation and related Health and Safety regulations. In addition to these there are a variety of national and international guidelines compelling healthcare employers to protect staff and patients which can be referenced as appropriate to any particular case.

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8 References

1. European Directive: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF>
2. UK legislation: http://www.legislation.gov.uk/ukxi/2013/645/pdfs/ukxi_20130645_en.pdf
3. Explanatory Memorandum to The Health & Safety (Sharps Instruments in Healthcare) Regulations prepared by the Health and Safety Executive on behalf of the Department for Work and Pensions: http://www.legislation.gov.uk/ukxi/2013/645/pdfs/ukxiem_20130645_en.pdf
4. National Audit Office: A Safer Place to Work - Improving the management of health and safety risks to staff in NHS trusts. Report by Comptroller and Auditor General, HC 623 Session 2002-2003: 30 April 2003
5. Health Protection Agency: Eye of the Needle 2012 United Kingdom surveillance of significant occupational exposures to bloodborne viruses in healthcare workers: December 2012
6. NHS Confederation Briefing: Protecting Healthcare workers from sharps injuries – what employers and employees need to do from May 2013 to implement new health and safety requirements – May 2013 Issue 13
7. Elder A, Patterson C (2006) "Sharps Injuries in UK Health Care: a review of injury rates, viral transmission and potential efficacy of safety devices" *Occupational Medicine* 56:566-74
8. RCN: Sharps Safety – RCN guidance to support implementation of the EU Directive 2010/32/EU the prevention of sharps injuries in the healthcare sector – Royal College of Nursing, 2011
9. Adams D (2012) Needlestick and sharps injuries: implications for practice. *Nursing Standard*. 26, 37, 49-57
10. Health Protection Agency: Eye of the Needle 2008
11. Thomas WJC Murray JRD The incidence and reporting rates of needle-stick injury amongst UK surgeons. *Ann R Coll Surg Eng* 2009; 91: 12-17
12. Trim JC Elliot TSJ A review of sharps injuries and preventative strategies. *Journal of Hospital Infection* Volume 53, Issue 4, Pages 237-242, April 2003
13. CDC workbook: http://www.cdc.gov/sharpsafety/pdf/sharpsworkbook_2008.pdf - Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program
14. Vose J G, McAdara-Berkowitz J Reducing Scalpel Injuries in the Operating Room. *AORN JOURNAL* December 2009, Vol90, No 6
15. Perry J, Parker G, Jagger J. EPINET report: 2003 percutaneous injury rates. *Adv Expos Prevent* 2005;7:42-5
16. Al-Benna S Needlestick and sharps injuries amongst theatre care professionals. *Journal of Perioperative Practice* December 2010/Volume 20 Issue 12 440-445
17. Watt AM et al: Scalpel injuries in the operating theatre – Editorial *BMJ* 2008;336:1031
18. Au E, Gossage JA, Bailey SR. The reporting of needlestick injuries sustained in theatre by surgeons: are we underreporting? *J Hosp Infect* 2008; 70: 66-70
19. H. C. Eisenstein and D.A. Smith Epidemiology of reported sharps injuries in a tertiary care hospital *Journal of Hospital Infection* (1992) 20, 271-280
20. Myers DJ, Epling C, Dement J, Hunt D. Risk of sharp device-related blood and body fluid exposure in operating rooms. *Infect Control Hospital Epidemiol.* 2008;29 (12):1139-1148
21. Jagger J, Bentley M, Tereskerz P A study of patterns and prevention of blood exposures in OR personnel. *AORN J.* 1998 May;67(5):979-81, 983-4, 986-7 passim.
22. Kerr HL, Stewart N, Pace A, Elsayed S. Sharps injury reporting amongst surgeons. *Ann R Coll Engl* 2009; 91: 430-432
23. McCann P Needlestick injury management – what's the solution? *Ann Coll Surg Engl* 2009; 91: 627
24. NICE: National Costing Statement: Infection Prevention and control (March 2012)
25. Adams, D, Elliot TS Financial costs associated with the initial treatment of a healthcare worker who has seroconverted to Hepatitis B, B or HIV following needle stick injury. *J of Hospital Infection.* 64, Suppl 1, S31 (quoted in Adams 2012)
26. Health & Safety Executive Press Release: Hospital fined after health worker infected with Hepatitis C, 6 October 2010 Release No: WM177/10. <http://www.hse.gov.uk/press/2010/coi-wm-17710.htm>
27. <http://www.thompsons.law.co.uk/ntext/compensation-needlestick-injury.htm>
28. Thompsons Solicitors Health & Safety News Spring 2010 Issue No 9 <http://www.thompsons.law.co.uk/lttext/dload/health-safety-news-009.pdf>
29. Foley M, Leyden AT (2002) American Nurses Association: independent Study Module Needlestick Safety and Prevention www.who.int/occupational_health/activities/Ianaism.pdf quoted in Adams (2012)
30. <http://www.hse.gov.uk/pubns/indg163.pdf> Five steps to risk assessment – HSE – June 2011
31. European Biosafety Network: Toolkit for Implementation of European Directive on Prevention of Sharps Injuries (Council Directive 2010/32/EU) in Member States – January 2013
32. Grimes P Generic Business Case for Investment in Safer Systems of Work December 2007 Safer Needles Network <http://www.saferneedles.org.uk/?page=71&id=5>

9 Websites

AfPP – Association for Perioperative Practice www.afpp.org.uk
AORN Association of periOperative Registered Nurses www.aorn.org
British Medical Journal www.bmj.com
CDC - Centers for Disease Control and Prevention www.cdc.gov
ECRI - independent, evidence-based healthcare research www.ecri.org.uk
European Agency for Safety and Health at Work www.osha.europa.eu/en
European Biosafety Network www.europeanbiosafetynetwork.eu
Health and Safety Executive www.hse.gov.uk/index.htm
Health Protection Agency (now part of Public Health England) www.hpa.org.uk
Hospital Infection Society www.his.org.uk
Infection Prevention Society www.ips.uk.net
International Sharps Injury Prevention Society (ISIPS) www.isips.org
National Audit Office www.nao.org.uk
NHS Confederation www.nhsconfed.org/Pages/home.aspx
NHS Employers www.nhsemployers.org/Pages/home.aspx
Public Health England www.gov.uk/government/organisations/public-health-england
Safer Needles Network www.saferneedles.org.uk
Thompsons Solicitors www.thompsons.law.co.uk

