Occupational exposure to blood borne pathogens among healthcare workers and preventative strategies

Joanna Trim

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Summary

The risk of occupational exposure to blood borne pathogens via percutaneous inoculation injuries (PIIs), has been well documented (Public Health Laboratory Service, 1999). Most recently, PIIs were the second most frequently reported injury by HCWs within hospitals in the UK (National Audit Office, 2003). In the USA, it is estimated that between 300,000 and 1 million PIIs occur annually (Occupational Safety and Health Administration, 2001), whereas in the UK, it is estimated that 100,000 PIIs are sustained each year (Godfrey, 2001). The true incidence of PIIs is, however, unclear due to under reporting (Pugliese *et al.*, 2001).

Preventative strategies, including hepatitis B vaccination, training, education and universal precautions were implemented in an attempt to reduce the risk of occupational exposure to blood borne pathogens. Although these strategies had some impact in reducing this risk, HCWs continued to be exposed to blood borne pathogens, with a number seroconverting to hepatitis C and HIV (Thomas, 2002).

The most recent preventative strategy has been needle protective devices (NPDs). With advancements in technology, NPDs have become the focus for reducing the risk of exposure to blood borne pathogens, particularly following American legislation in 2001 (Pugliese *et al.*, 2001). However, technological advancement has out paced HCWs' ability to comprehensively evaluate these products for usability, acceptability and efficacy in reducing PIIs, particularly in the UK. BD Safelon™ Pro (SLP) was a new NPD, not previously used in the clinical setting.

The study, undertaken at University Hospital Birmingham NHS Trust, initially evaluated the product as acceptable to HCWs, however during the clinical trial, blood splash during the catheterisation procedure was a potential risk of mucocutaneous inoculation injury to HCWs. Consequently, the product was modified and a non-clinical trial found improved acceptability and reduced blood splash.

The number of reported PIIs were evaluated over a two year period. HCWs utilised various methods to report incidents, frequently not complying with current Trust policy. To gain further insight into the number of PIIs sustained by HCWs, an under reporting study was undertaken for both clinical and ancillary staff. Percutaneous inoculation injuries were not always reported, most frequently due to pressure of workload and self assessment of the incident. Ancillary staff also sustained PIIs and near miss incidents due to inappropriately disposed sharp devices. Indeed, HCWs' knowledge of inoculation injuries, the risk of transmission of blood borne pathogens and the reporting procedure was inadequate. Furthermore, HCWs did not routinely wear gloves when handling sharp devices.

Key words: hepatitis B, hepatitis C, human immunodeficiency virus, needle protective devices

To Craig

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Chapter 1: Introduction

1.1 Intravenous peripheral catheters

Intravenous (IV) peripheral catheters are an essential and frequently used part of clinical practice for the administration of fluids, nutrients, blood products and medications, as well as monitoring patient's haemodynamic status (Parker, 2002; Evans *et al.*, 2001; Todd, 1999). Accurate statistics reflecting current rates of IV peripheral catheter use are limited. In a Birmingham National Health Service (NHS) Trust, 32% of all patients had an IV peripheral catheter sited (Baker *et al.*, 2002). Previous estimations ranged from 18 to 80% (Wilkinson, 1996; Springhouse Corporation, 1993; Feldstein, 1986; Nystrom *et al.*, 1983). Between 2000 and 2001 over 12.7 million ported, 2.1 million straight and 3.8 million winged IV peripheral catheters were sold to the NHS in England, (NHS Purchasing and Supply Agency, 2001).

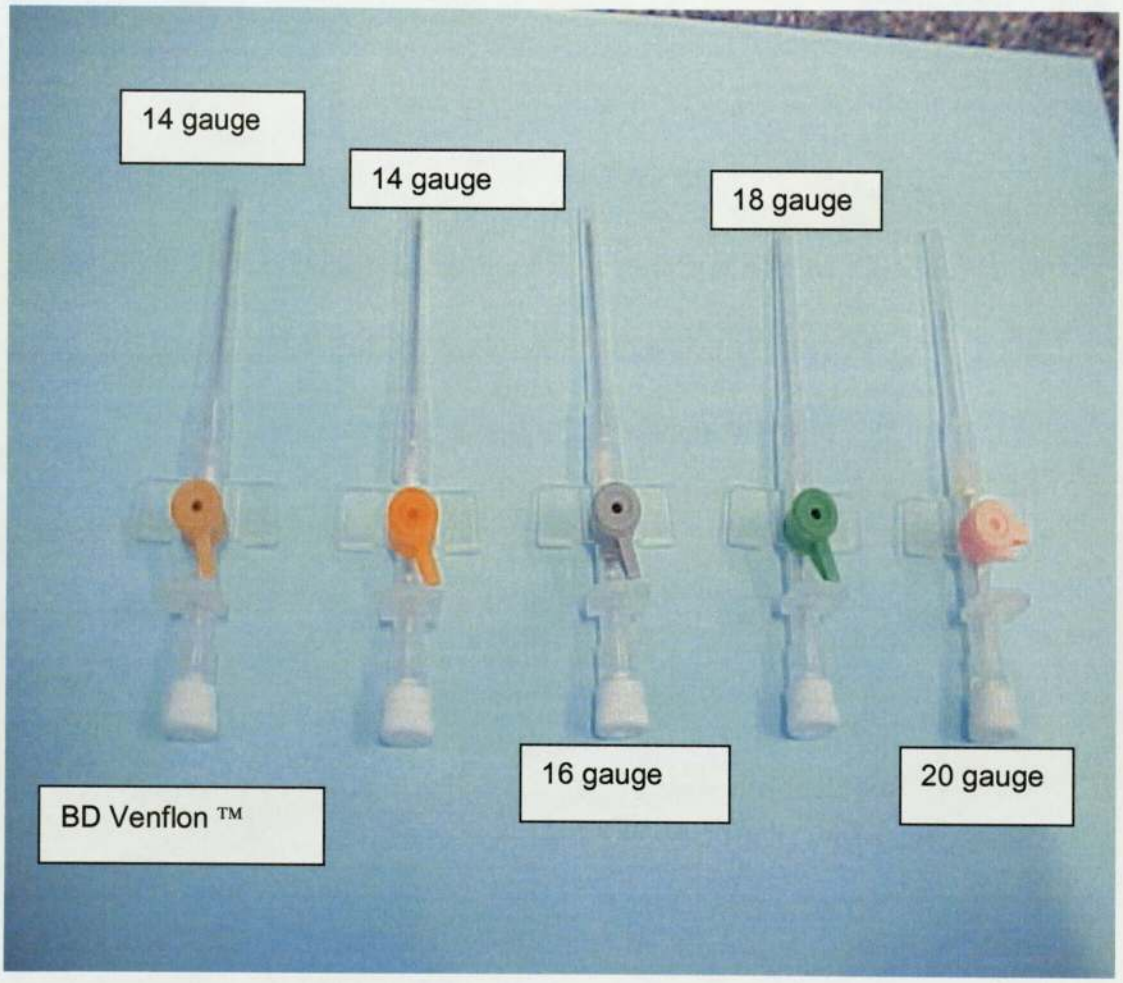
There are a wide variety of IV catheters available reflecting diverse clinical management and healthcare worker (HCW) preference (table 1.0).

Table 1.0: Type of intravenous catheter and use in the clinical setting.

Type of intravenous catheter	Use in clinical practice
Central venous catheter: Single, double, triple or quadruple lumen	Haemodynamic monitoring Drug and fluid administration Haemodialysis Chemotherapy Blood sampling
Tunnelled central venous catheter Hickman catheters Port-A-Cath	Long term vascular access
Peripherally inserted central catheters (PICCs) Inserted into the superior vena cava via the cephalic or basilar veins of the antecubital space. Easier to maintain than shorter peripheral catheters, and fewer complications than CVCs.	As above
Peripheral catheters: Venous:	Drug and fluid administration Parenteral nutrition Blood sampling Blood gas monitoring
Arterial	Haemodynamic monitoring Blood sampling Blood gas monitoring

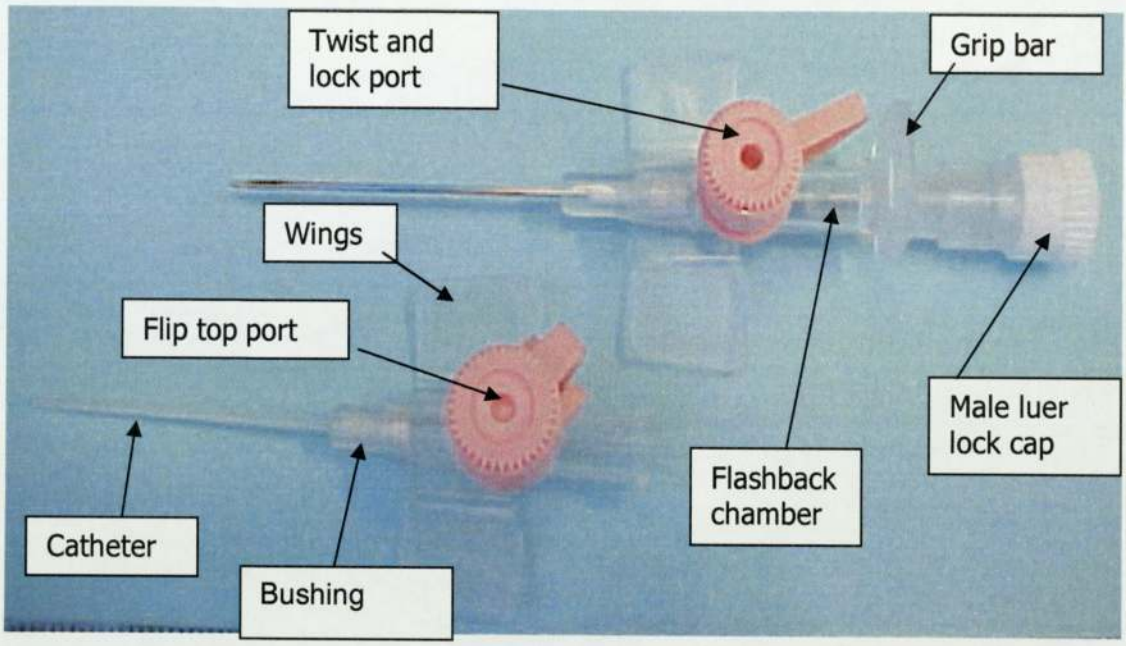
Intravenous peripheral catheters range in size, each with a colour code (figure 1.0).

Figure 1.0: Various intravenous peripheral catheter gauge sizes and colour codes.



Intravenous peripheral catheters can be inserted into various veins, for example antecubital, metacarpal, cephalic or pedal veins. Intravenous peripheral catheter features assist with insertion, for example, the HCW identifies accurate positioning of the catheter using the flashback chamber, which fills with blood when the vein is accessed. In addition, whilst *in situ*, the catheter's wings allow it to lie flush with the skin, improving comfort for the patient (figure 1.1).

Figure 1.1: An intravenous peripheral catheter and its features.



1.2 Complications of intravenous peripheral catheters

Risk factors associated with IV peripheral catheter infection include duration of catheterisation, lack of experience of the operator inserting the device, choice of insertion site, catheter material, lumen diameter, skin disinfection and post insertion catheter care (Parker, 2002; Creamer *et al.*, 2002; Hirschmann *et al.*, 2001; Curran *et al.*, 2000).

The incidence of local or bloodstream infections associated with IV peripheral catheters is low (Cornely *et al* 2002; Creamer *et al.*, 2002; Mermel *et al.*, 2001), however a multi-centred European study found an overall 10.3% incidence of thrombophlebitis (Nystrom *et al.*, 1983). Complications associated with IV peripheral catheters are most frequently extravasation and phlebitis. Extravasation develops when the catheter penetrates the catheterised vein and fluid is delivered into the interstitial space. This causes swelling, discomfort, burning, pain and may cause tissue damage (Workman, 1999; Clarke, 1997). This is known as 'tissuing' (Clarke, 1997).

Phlebitis is inflammation of the vein (Campbell, 1997) and affects the inner endothelial layer of the vein. It is caused by chemical, physical or mechanical irritation (Curran *et al.*, 2000; Monreal *et al.*, 1999; Campbell, 1998; Lamb, 1996). Symptoms include pain tenderness, erythema (redness), inflammation and increased temperature at the insertion site (Lamb, 1996). Furthermore, thrombophlebitis may develop whilst the catheter is *in situ*. This is inflammation of the vein caused by a thrombus formation, for example at the tip of the catheter within the vein (Clarke, 1997; Lamb, 1995). Erythema may develop from the catheter insertion site along the vein, known as 'tracking' (Clarke, 1997).

Intravenous peripheral catheters should be removed after 72 hours (Workman, 1999; Lamb, 1996). After this time, bacterial contamination increased significantly (Hirschmann *et al.*, 2001; Fuller and Winn, 1998; Lundgren *et al.*, 1993). However, phlebitis may occur at any time whilst the IV peripheral catheter is *in situ* (White, 2001). Interestingly, Lai (1998) reported no significant difference between IV peripheral catheters left in place for 72 and 96 hours. Indeed Bregenzer *et al.*, (1998) found no increase in phlebitis, catheter-related infections or mechanical complications for catheters left *in situ* for 1 to 28 days.

1.3 Intravenous peripheral catheterisation: the technique

If a patient requires IV peripheral catheterisation, the HCW must determine the most appropriate insertion site for the intended use of the device. Both factors influence the catheter gauge required. For example, surgical patients are frequently catheterised with 14 or 16 gauge catheters. In comparison, a patient requiring hydration may be catheterised with a smaller catheter, for example 20 or 18 gauge. The choice of catheter is also influenced by the quality of the patient's vein. Elderly patients have smaller, more mobile veins, which are often friable. These patients require a smaller gauge catheter to reduce the risk of phlebitis and other complications. It is recommended that the selected catheter size should be the smallest possible for the intended clinical management and inserted into the most prominent vein (Schmid, 2000; Workman, 1999). Hand hygiene, skin site preparation and using a sterile insertion technique are essential to minimise the risk of infection (Salemi *et al.*, 2002; CDC 2002; Hirschmann *et al.*, 2001; Schmid, 2000). If IV therapy is required for a number of weeks, the catheter should be sited at the distal end of the arm, to allow for proximal catheter re-location (Millam, 1988), or a CVC may be considered.

Intravenous peripheral catheterisation requires an introducer needle to penetrate the skin and access the vessel. Once the vein has been accessed and the catheter *in situ*, the needle is removed and a male luer lock cap attached. The IV peripheral catheter is secured to the patient's skin surface with a semi-permeable dressing. Healthcare workers are at risk of sustaining a percutaneous inoculation injury (PII) from the introducer needle.

1.4 Percutaneous inoculation injury

A PII may result from a needle, sharp-edged instrument, broken glassware, or any other item which may be contaminated during use by blood or body fluids and which may cause laceration or puncture wounds. Sharp tissue such as spicules of bone or teeth also poses a risk of injury (DH, 1998).

Percutaneous inoculation injuries are caused by any sharp device, for example IV catheter introducer needles, suture needles, scalpels, glass vials and lancets (ECRI (formerly Emergency Care Research Institute), 2001). Within the literature, PIIs are referred to as needlestick injuries and sharps injuries. Within the following text, a PII will encompass a percutaneous injury caused by a contaminated sharp device used in the clinical setting.

1.5 Incidence of percutaneous inoculation injuries

The reported incidence of PIIs varies widely. In the USA, the Occupational Safety and Health Administration (OSHA) (2001) reported 384,325 PIIs per year, increasing to 590,164 when non-healthcare workers were included. Previously, estimates in the USA have ranged from 400,000 PIIs among 4 million HCWs to 1 million PIIs per annum (Perry, 2000; Porta *et al.*, 1999; Bell, 1997). In California, an estimated 96,000 injuries occur each year (Department of Health Services, 2002), whereas in the UK, an

estimated 100,000 PIIs occur each year (Godfrey, 2001; Pearce, 2001; Martell, 2000), with the highest number in hospitals (Martell, 2000). In Germany, PIIs sustained by HCWs in 2 hospitals were used to estimate an annual incidence of 500,000 PIIs among all HCWs in Germany (Hofmann *et al.*, 2002).

Percutaneous inoculation injury data is also collected by individual hospitals, however these initiatives lack a consistent, co-ordinated and reliable nationwide surveillance approach (May and Churchill, 2001; Short Life Working Group, 2001) (table 1.1).

Table 1.1: The incidence of percutaneous inoculation injuries: a review of studies.

Author	Location and country	Rate of reported percutaneous inoculation injuries (PIIs)	Details of the study
Dobie *et al.*, (2002)	UHB NHS Trust, UK	195 per annum	
Bryce *et al.*, (1999)	Vancouver hospital, Canada	221 per year	
Short Life Working Group (2001)	Scotland, UK	6811 between 1996 and 1999	Annual PII breakdown between 2100 and 2400 PIIs per year
Williams *et al.*, (1993)	Surgical theatre department, teaching hospital, London, UK	26 during 4 weeks	Injuries sustained by 14 HCWs. Four injuries were reported.
RCN (2002)	EPINet™ sharps injury surveillance pilot study, UK	473 over 3 months	20 UK hospitals.
Beekmann *et al.*, (2001)	Iowa and Virginia, USA	5.3 PIIs per 100 HCWs	
Department of Health Services (2002)	Californian SHARPS programme, USA	1940 over 2 years	One hundred and ninety nine hospitals participated in the statewide voluntary pilot surveillance programme. Two hundred and forty three healthcare establishments did not report any PIIs and 92% of incidents occurred in hospitals.
Smedley *et al.*, (1995)	Wessex and Oxford, UK	1102 over 9 months	Fifteen participating NHS hospitals within the allocated region.
Whitby and McLaws (2002)	Eight hundred bedded teaching hospital, Australia	1836 over 10 years.	

There is no national consensus on the most appropriate denominator to calculate PIIs by, frequently dependent upon the available data. Denominators utilised included number of devices, number of full-time equivalent staff and number of occupied beds (Pugliese *et al.*, 2001). Indeed, studies have used diverse study methodologies and data collection methods (Gillen *et al.*, 2002) with which to gather data, minimising comparative analysis. Furthermore, employers appeared reluctant to disclose PII data. Indeed, in 1999, the Executive Health Department in Scotland requested all its NHS Trusts and Health Boards to provide information relating to PIIs; only 23 of the 28 Trusts and 15 of the 21 Health Boards responded (Short Life Working Group, 2001).

1.5.1 Percutaneous inoculation injury surveillance systems

Over the last 20 years, PII surveillance systems have been implemented and developed to monitor the number of occupational exposures to hepatitis B virus (HBV), hepatitis C virus (HCV) and Human immunodeficiency virus (HIV). These systems were introduced at local and national levels. In the UK, the Public Health Laboratory Service (PHLS), part of the Communicable Disease Surveillance Centre (CDSC) implemented a national strategy in 1984, following the first documented HIV seroconversion from an occupational exposure. The surveillance system was updated in 1997 (CDSC, 2000). Reports are sent voluntarily and confidentially from Occupational Health and Safety departments and genitourinary medicine (GUM) clinics. Criteria for inclusion are exposure to HIV, HCV and HBV, where the source status is unknown and when the HCW is treated with post exposure prophylaxis (PEP). Six weeks following the initial report, exposures to HIV and HCV and those on PEP (with source patient status unknown) are followed up. At 6 months, those exposed to HIV and HCV are followed up. Currently, 250 Occupational Health and Safety departments and GUM clinics report to the CDSC (Thomas, 2002). The Scottish Centre for Infection and Environmental Health (SCHIEH) also commenced an

equivalent surveillance system for HCWs in Scotland (Thomas, 2002). National surveillance systems were also developed in Canada and USA (California Department of Health, 2002; Nguyen *et al.*, 2002).

Between June 2000 and June 2001, the Royal College of Nursing (RCN) commenced a sharps injury surveillance pilot study using EPINet™ software to audit PII data. EPINet™ is the Exposure Prevention Information Network, first developed in the USA by Janine Jagger and colleagues at the International HCW Safety Center at the University of Virginia. It was first introduced in 1992, and is now used by more than 1500 hospitals in the USA, as well as Canadian, Italian, Australian, Japanese and Brazilian hospitals (May and Churchill, 2001). The Exposure Prevention Information Network™ provides healthcare facilities with a standardised method for recording percutaneous injuries and contacts with blood and body fluids. A pre-programmed form is used to collect data, providing statistical analysis, customised reporting and tracking of injuries by job, device and procedure. Injuries that may have been prevented if a needle protective device (NPD) was used, can be highlighted. Furthermore, information can be linked to a national database if required (May and Churchill, 2001).

Most recently, the UK National Audit Office (NAO) reviewed injuries sustained by HCWs in NHS Trusts. Overall, 20% of NHS Trusts reported an increase in PIIs, 33% a decrease, 42% reported no change and 5% were not able to provide information (NAO, 2003). This report highlighted that data collection strategies frequently lacked consistency, co-ordination and the time, expertise and financial resource required to collect, manage and analyse meaningful surveillance data (Doebbeling, 2003).

1.6 Under reporting of percutaneous inoculation injuries

An accurate calculation of the number of PIIs is limited by under reporting (Pugliese *et al.*, 2001). Reluctance to report injuries was first highlighted in the USA by Jackson *et al.*, (1986) and continues amongst HCWs today. Findings from various studies are shown in table 1.2.

Table 1.2: The under reporting of percutaneous inoculation injuries: a review of studies

Authors	Country	Under-reporting rate	Details of the study
Mangione *et al.*, (1991)	USA	70%	Three teaching hospitals, with a high prevalence of Human immunodeficiency virus (HIV) among patients over a 1 year period.
Haiduven *et al.*, (1999)	USA	26%	
Osborn *et al.*, (1999)	USA	55 to 35%	Reduced under reporting rate during the 7 year longitudinal study
Patterson *et al.*, (1998)	USA	82.5%	Surgeons.
Shen *et al.*, (1999)	USA	57%	Fourth year medical students.
Hamory (1983)	USA	40% 75%	Over 3 months Over 1 year
Tandberg *et al.*, (1991)	USA	65%	Five year study period
O'Neill *et al.*, (1992)	USA	91%	Five hundred and fifty medical students and junior medical staff working in 1 Californian medical centre between 1989 and 1990.
Mendelson *et al.*, (1997)	USA	46%	Anonymous questionnaire documenting PIIs not reported in the previous year.
Mercier (1994)	UK	41.7%	One teaching hospital in London.
Hettiaratchy *et al.*, (1998)	UK	82.5%	One hundred and ninety junior doctors in 3 hospitals. Surgeons were least likely to report PIIs.
Dobie *et al.*, (2002)	UK	65%	Retrospective review of unreported injuries over a 1 year period.
Williams *et al.*, (1993)	UK	85%	Four week audit in surgical theatres in 1 hospital.
Burke and Madan (1997)	UK	91% doctors 54% midwives	Six month retrospective audit of doctors and midwives.
Rosenthal *et al.*, (1999)	France	61%	Anonymous questionnaire from 200 medical students at Nice University.
Rabaud *et al.*, (2000)	France	51.5%	French nursing staff.
Shiao *et al.*, (1999)	Taiwan	81.8%	8645 medical, nursing, technical and ancillary staff employed in 16 randomly selected teaching hospitals.

The rate of under reported PIIs ranged from 26 to 91%. In 1 study, only 5% of injuries sustained by surgeons were reported because their decision to report was influenced by judgements made about the source patient's lifestyle (Nash and Goon, 2000). In Australia, the number of nurses not reporting PIIs significantly decreased to 4% in 1992, however increased to 14-25% over the latter part of the decade (Whitby and McLaws, 2002). This may have been due to nurses' increased knowledge of blood borne pathogens and associated risk of exposure. Study comparisons were limited, however, due to diverse study methodologies.

Healthcare workers perceive PIIs as an inevitable part of handling sharp devices, therefore, injuries go unreported and bad practice is tolerated (Jeanes, 1999; Connington, 2002). A number of reasons for not reporting PIIs have been identified. In the UK, HCWs were influenced by the associated stigma as well as the fear of a positive result following a PII (May and Brewer, 2001). Furthermore, HCWs may not have known how to report PIIs (Cutter and Jordan, 2003), compounded by policy changes between day and night shifts. In a recent study, 1 in 6 staff were unaware of the reporting policy following a PII and 66% of doctors completing their pre-registration year failed to recall sharps awareness training, including how to report injuries (Wilson, 2001).

Other reasons for not reporting PIIs included using subjective assessment, the injury was caused by an unused device, pressure of workload, (Metules, 2002; Short Life Working Group, 2001), reporting was time consuming, no action could be taken following the incident (Burke and Madan, 1997) and the injured HCW was vaccinated against HBV (Shiao *et al.*, 1999). In Scotland, despite only 3% of nurses not being aware of the procedure for reporting PIIs, injuries were not consistently reported because the PII was not deemed serious, the injury would be perceived as poor clinical

practice by managers, pressure of workload and PIIs were an inevitable occupational hazard (Connington, 2002).

Rabaud *et al.*, (2000) described the behaviour of 964 French nurses (qualified staff and students) after an occupational exposure to blood. The nurses' reasons for not reporting an incident included having good local antisepsis immediately after the incident (48.5%), seeking the serological status of the patient immediately after the incident (57%), and staff assessing their own serological status 3 and 6 months following the incident (40% and 31% respectively). French medical students' reasons for not reporting incidents included, like Burke and Madan (1997), being unable to influence the outcome as well as lack of knowledge of how to report the incident and being advised by colleagues not to report the injury (Rosenthal *et al.,* 1999). Physicians and medical students were reticent to report PIIs due to the potential subsequent restrictions on their clinical practice, lack of confidence in prophylactic treatment and denial of personal risk (Osborn *et al.*, 1999).

Previous studies have, however, documented an increase in PII reporting (Chiarello and Cardo, 2000). In Italy, PII reports increased throughout the 3 year study period. This may have reflected improved compliance with the policy following training and the introduction of universal precautions. Similarly, in Scotland, PII reports increased by 12.5% over 3 years, however it was not known whether this was due to an actual increase in PIIs or raised awareness causing a higher number of reports (Short Life Working Group, 2001).

1.7 The risk of percutaneous inoculation injury

All sharp devices present a hazard to HCWs and ancillary workers because they are integral to the provision of healthcare, in addition to having the potential to cause harm. The risk of PII is the probability of the hazard, namely a sharp device, causing injury (Infection Control Nurses Association, 2003; Health and Safety Executive, 1999). The risk posed by PIIs to HCWs was first described by McCormick and Maki in 1981.

1.7.1 Healthcare workers

1.7.1.1 Nursing staff

Nurses report the majority of PIIs and are most at risk (O'Connell and Hayes, 2003; Gillen *et al.*, 2003; Clarke *et al.*, 2002; Whitby and McLaws, 2002; Shiao *et al.*, 2002; Ling *et al.*, 2000; EPINet, 1999; O'Dowd, 1999; Gershon *et al.*, 1999; OSHA, 2001; Nguyen *et al.*, 2002). In the USA, it was estimated that PIIs occurred in 45 to 49% of all nurses (Department of Health Services, 2002; Porta *et al.*, 1999; English, 1992). In Scotland, nurses sustained 63% of all reported PIIs (Short Life Working Group, 2001), and in the UK, 42% of exposures to blood borne pathogens identified by the PHLS were reported by nurses (Thomas, 2002; May and Brewer, 2001). In an Australian hospital, 50% of ward nurses sustained a PII within a 2 year period (de Vries and Cossart, 1994), whereas in 1 year, 45% of nurses in a London hospital sustained a PII (Mercier 1994). These findings concurred with those of the sharps injury surveillance pilot study undertaken by the RCN between June 2000 and June 2001 (RCN, 2001). Results highlighted that nurses sustained the majority of PIIs; however, this was expected because 44% of the NHS workforce comprised nurses, who undertook many clinical procedures involving sharp devices. The second year of the pilot study commenced in January 2002. Results from January to March 2002 corresponded with

the first year's data; however, the number of PIIs sustained by junior doctors increased from 11 to 16%, with only a 1% rise in PIIs sustained by nurses (RCN, 2002).

Nurses with more years of service were more likely to have sustained a PII in their career than less experienced nurses. However, inexperience influenced the risk of incurring recent PIIs. Nurses with less than 5 years experience and who undertook venepuncture and insertion of IV peripheral catheters as part of their clinical practice were 50 to 100% more likely to report a PII than their more experienced colleagues (Clarke *et al.*, 2002).

1.7.1.2 Medical staff

1.7.1.2.1 Medical students and pre-registration house officers

Medical students and junior doctors are at risk of PIIs due to inexperience and limited expertise in medical procedures (Patterson *et al.*, 2003; Wiwanitkit, 2002; Varma and Mehta, 2000; Doig 2000; Osborn *et al.*, 1999; Calabro *et al.*, 1998; Shalom *et al.*, 1995; de Vries and Cossart, 1994; Albertoni *et al.*, 1992). Furthermore, the number of PIIs sustained by doctors was proportionately greater than their representation in the workforce, resulting in a higher injury rate when compared with nurses (Ng *et al.*, 2002; Hanrahan and Reutter, 1997, Mercier, 1994). In the most recent UK PHLS publication from the CDSC on exposure to blood borne pathogens, doctors comprised 35% of all reports received between July 1997 and June 2002 (Thomas, 2002).

More recently, medical students' occupational risk of exposure to HIV during time spent in developing countries during elective placements was highlighted. Currently, an estimated 60 to 70% of British medical students visit developing countries. This group are at high risk of exposure to HIV because of the increased prevalence of HIV

infection in these countries, in addition to their limited experience and technical skill (Tilzey and Banatvala, 2002; Gilks and Wilkinson, 1998). Furthermore, medical students who sustained PIIs abroad may not have received the appropriate PEP treatment (Gamester *et al.*, 1999).

1.7.1.2.2 Surgeons

Surgeons are regularly exposed to blood and sharp objects during their daily surgical activities. This professional group was more likely to sustain PIIs when compared with nurses, however, least likely to report PIIs, with many going unnoticed during surgical procedures (Cutter and Jordan, 2003; Nash, 2001; Tokars *et al.*, 1992). Twenty nine percent of surgeons admitted to having at least 1 potential exposure to body fluid per month, few of which were reported (Manian, 1996). In an Italian study, 55% of those who sustained a PII were surgeons (Albertoni *et al.*, 1992), whereas in a UK study, 22% of PIIs were sustained in surgical operating theatres (Mercier, 1994). More recently, Charles *et al.*, (2003) highlighted that surgeons' risk of exposure to blood borne pathogens was associated with the number and complexity of surgical procedures as well as level of experience. Indeed, out of working hours, surgical procedures may be undertaken by more junior medical staff where fatigue level of experience may place them at an increased risk of injury (Charles *et al.*, 2003).

1.7.2 Downstream percutaneous inoculation injuries

Clinical staff sustained downstream injuries, where the injured person was not the original user of the sharp device. Assisting with a clinical procedure was the most frequent cause of injury (May and Brewer, 2001; Department of Health Services, 2002), particularly for medical students (Shen *et al.*, 1999). A more recent study estimated that 40% of all PIIs were not sustained by the original user of the device (Adams and Elliott, 2002; May and Churchill, 2001).

Housekeepers and domestic staff were also at risk of downstream injuries (O'Connell and Hayes, 2003; Department of Health Services, 2002; Godfrey, 2001; May and Brewer, 2001; Cone, 2000; Jeanes, 1999; EPINet, 1999). Indeed, in a recent study, 13.5% of all reported PIIs were sustained by ancillary staff (O'Connell and Hayes, 2003). Healthcare workers did not dispose of sharp devices correctly, for example, disposing of needles in bins, instead of in a designated sharps container. Puro *et al* (2001) concurred with these findings that inadequate sharps disposal and the presence of sharp devices in the work place influenced the risk to housekeepers in Italy. Indeed, study findings from Taiwan, Singapore and India supported European and American findings that ancillary workers were at risk of PIIs (Shaio *et al.*, 2001; Richard *et al.*, 2001; Ling *et al.*, 2000). In July 2001, the Medical Devices Agency (MDA), in the UK, issued a formal safety notice highlighting that inappropriate use and disposal of sharp devices caused injury (MDA, 2001; Short Life Working Group, 2001).

1.7.3 Clinical practice

In the late 1970's, initial attempts to prevent PIIs focused on safe work practices. Puncture resistant containers for the disposal of contaminated sharp devices were introduced (Chiarello and Cardo, 2000; Hanrahan and Reutter, 1997). Furthermore, HCWs were educated not to re-sheath needles (returning the needle to its cap), a practice previously advocated. Despite prohibition of this practice, it remained one of the highest causes of injury (Porta *et al.*, 1999; Jeanes, 1999). Currently, both the Department of Health (DH) and the RCN in the UK, and the American National Institute for Occupational Safety and Health (NIOSH) currently advocate avoiding this practice (RCN, 2001; NIOSH, 1999). Despite this, PIIs continue to be sustained by re-sheathing needles (RCN, 2002; RCN, 2001; Roudot-Thoroval *et al.*, 1999; Rodero Perez *et al.*, 1994; English, 1992; Dalton *et al.*, 1992; Wooley *et al.*, 1991). Indeed, in 1 study, re-sheathing needles caused a significantly higher number of PIIs than using a

sharp device to penetrate an artery or vein (Varma and Mehta, 2000). Sullivan *et al.*, (2000), however, found no relationship between PIIs and re-sheathing needles.

Percutaneous inoculation injuries were sustained at particular stages whilst using sharp devices. Injuries occurred after use but before disposal, during disposal and due to inappropriate disposal (Do *et al.*, 2003; RCN, 2002; Whitby and McLaws, 2002; Department of Health Services, 2002; Short Life Working Group, 2001; May and Churchill, 2001; Cone, 2000; Osborn *et al.*, 1999; de Graaf *et al.*, 1998; English, 1992). Thomas (2002) identified that 59% of exposures to blood borne pathogens, reported to the PHLS, occurred during the clinical procedure and 15% during use or after disposal. Moreover, blood sampling and venepuncture accounted for 36% of all exposures reported at 6 weeks, compared with 9% suturing, 21% medical procedures and 4% insertion of IV peripheral devices.

Current sharps disposal containers enable overfilling and therefore increased risk of PIIs from protruding sharp devices (Hatcher, 2002; Gershon *et al.*, 2000). A new sharps container system was implemented with a consequent statistically significant reduction in PIIs ($p=0.002$) (Hatcher, 2002). Other clinical activities associated with PIIs included administering injections, venepuncture, handling clinical waste and soiled linen (Metules, 2002; Department of Health Services, 2002).

1.7.4 Medical devices

Any sharp device used in the clinical setting poses a risk to the HCW. However, the highest risk of transmission of a blood borne pathogen to a HCW is via a hollow bore needle device, for example an IV insertion device or venepuncture equipment (Jeanes, 1999). Hollow bore needles are used in a variety of clinical procedures, for example injections, venepuncture and inserting IV peripheral catheters. Some procedures carry

less risk of transmission, for example subcutaneous or intramuscular injections. In comparison, procedures categorised as high risk include hollow bore needles used for IV peripheral catheterisation or venepuncture (May and Churchill, 2001).

The volume of blood held by a contaminated hollow bore needle is determined by the size of the device. The volume of blood in a contaminated 20 gauge needle was 30 times greater than the amount in a 27 gauge needle (Shirazian *et al.*, 1992). The average volume of blood inoculated during a hollow bore needle injury with a 22 gauge needle was 1ul (Napoli and McGowan, 1987). Indeed, the needle size and depth of penetration of the injury were significantly associated with blood transfer thus a deep injury poses an increased risk of injury (Mast *et al.*, 1993).

Hollow bore needle devices were associated with the highest number of PIIs (Whitby and McLaws, 2002; Rabaud, 2000; NIOSH, 1999; Osborn *et al.*, 1999; Greene *et al.*, 1998; Patel and Tignor, 1997; Ippolito *et al.*, 1994). The RCN EPINet™ sharps injury surveillance pilot study identified that more than a quarter of all PIIs were caused by a hollow bore needle and an estimated 12 - 19% of devices were used for venepuncture or IV peripheral catheterisation (RCN, 2002; May and Brewer, 2001). Indeed, the PHLS in the UK found 47% of all reported exposures to blood borne pathogens were sustained whilst using a hollow bore needle (Thomas, 2002).

1.7.5 Healthcare location

The healthcare setting influenced the risk of PII (Infection Control Nurses Association, 2003; Doebbeling, 2003; Batty *et al.*, 2003; Twitchell, 2003). Nurses working in clinical areas with staff shortages and poor organisational climates were twice as likely as nurses working in well staffed, organised clinical settings, to report risk factors, PIIs and near miss incidents (Clarke *et al.*, 2002). These findings concurred with those of Aiken

et al., (1997) who also identified that reducing the number of temporary staff working in clinical areas minimised nurses' risk of exposure to blood borne pathogens. The recent NAO report (2003) found that UK NHS Trusts highlighted increased bed numbers and staff workload as factors that increased the number of PIIs sustained by HCWs (NAO, 2003). Indeed, under-staffing, noise, distractions, pressure of workload and carelessness due to fatigue may all increase the risk of mistakes, injury and potential exposure to blood borne pathogens (Stringer *et al.*, 2001; de Graaf *et al.*, 1998). Healthcare workers perceived that 'being careful' may have prevented injury whilst practising inherently dangerous techniques, such as re-sheathing needles (Gershon *et al.*, 2000).

The ward setting, for example a patient's room or the ward, were associated with the highest number of PIIs (Thomas, 2002; RCN, 2002; RCN, 2001; Short Life Working Group, 2001). Indeed, as many as 52% of all PIIs occurred in the ward setting (Short Life Working Group, 2001). This reflected clinical activity, with the majority of procedures involving sharp devices taking place in the ward setting. Surgical operating theatres were also highlighted as areas associated with higher numbers of PIIs (Short Life Working Group, 2001; RCN, 2001).

Other contributing factors associated with PIIs included patients moving or being agitated during the procedure (26%), non compliance with universal precautions (17%), no sharps disposal container to hand (12%), tiredness (5%) and distraction (6%) (Thomas, 2002).

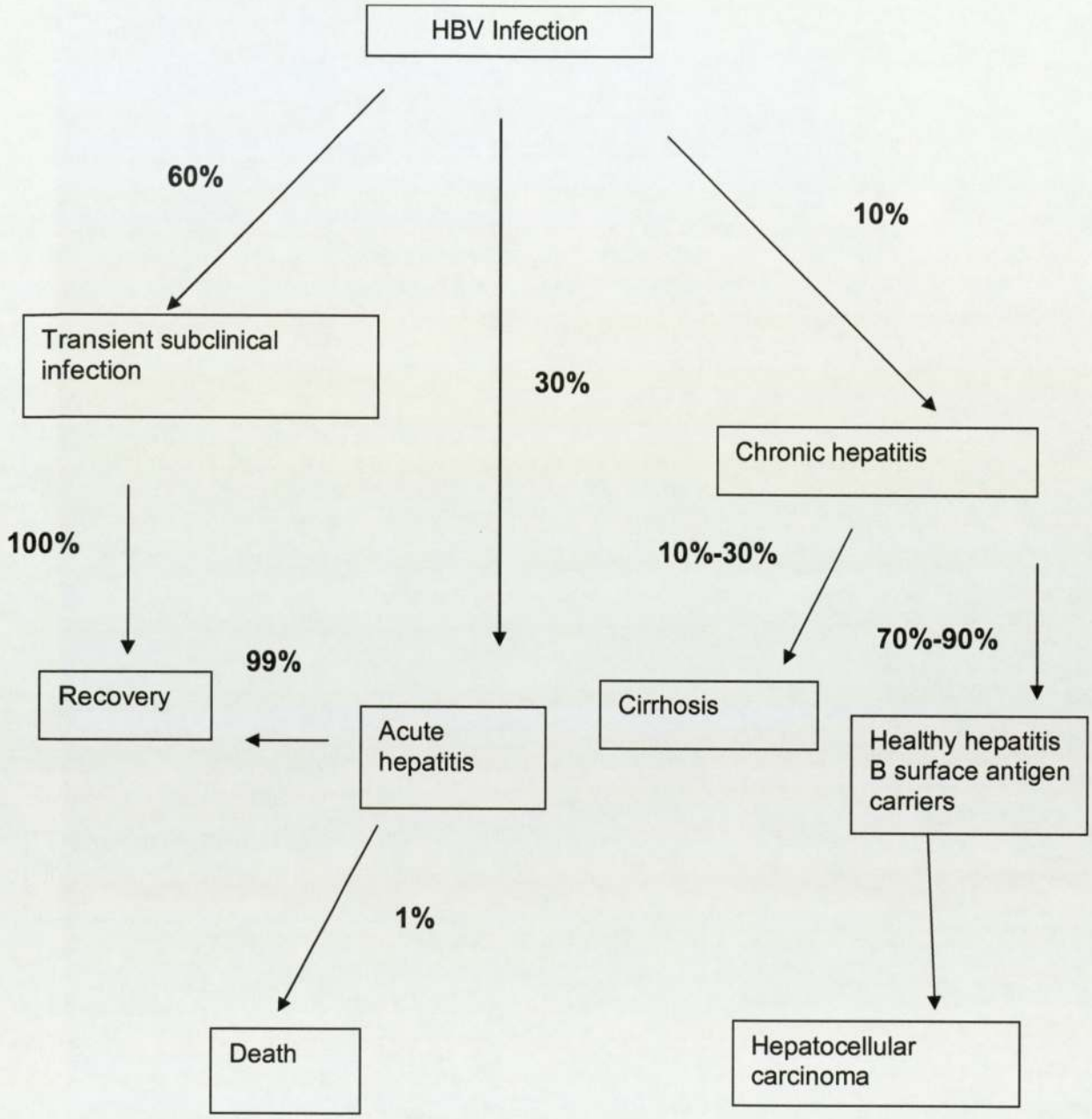
1.8 Blood borne pathogens

1.8.1 Hepatitis B

Hepatitis means inflammation of the liver, caused most commonly by viral or bacterial infection (Grahame-Smith, 2001; Dougherty and Dreher, 2001).

Hepatitis B virus is a deoxyribose nucleic acid (DNA) virus and is transmitted parenterally, with an incubation period of 6 weeks to 6 months. Symptoms include malaise, anorexia and jaundice (Elliott *et al.*, 1997). In 90% of cases, hepatic damage may be reversed (Elliott *et al.*, 1997), however in the remaining 10%, chronic liver infection develops (Grahame-Smith, 2001) (figure 1.2).

Figure 1.2: Hepatitis B disease process and outcome following transmission.



(Hepatitis Clinical Nurse Specialist, University Hospital Birmingham NHS Trust, Birmingham, UK, unpublished)

Hepatitis B virus is highly infective, with high concentrations of HBV viral DNA in serum and abundant viral particles contained within hepatocytes (Ryder and Beckingham, 2001). Diagnosis is made by immunoassays detecting hepatitis B surface antigen

(HBsAg), hepatitis B e-antigen (HBeAg), antibodies to hepatitis B core antigen (HBcAg) [immunoglobulin M (IgM) and immunoglobulin G (IgG), HBeAg (anti-HBeAg) and HBsAg (anti-HBsAg)] (table 1.3).

Table 1.3: Serological markers of hepatitis B.

Hepatitis B virus (HBV) component	**Diagnosis**
Hepatitis B surface antigen (HBsAg)	Identifies carrier status and mild infection. A positive result between 0 to 6 months demonstrates an acute infection, more than 6 months a chronic infection.
Hepatitis B antibodies (Anti-HBs)	A positive result demonstrates presence of antibodies. In vaccinated HCW's anti-HBs titre should be more than 100 miu/ml.
Hepatitis B e antigen (HBeAg)	Identifies replicating virus and an infectious status. A positive result for more than 3 months demonstrates a chronic disease status.
Antibodies to hepatitis B e antigen (Anti-HBe)	Suggests low infectivity status. Serological testing will detect HBsAg positivity.
Hepatitis B core antibodies (HBcAb)	Hepatitis B virus core antibodies demonstrate previous infection. A positive IgM test result indicates recent infection; conversely, a positive IgG test result reflects chronic infection. High levels of HBcAb may suggest acute hepatitis.
HBV DNA	A positive result demonstrates a very infectious status.
Hepatitis D (HDV)	A patient with HBV may be at risk of developing HDV, a virus exclusive to those with HBV.

Hepatitis Clinical Nurse Specialist, Queen Elizabeth Hospital, University Hospital NHS Trust (unpublished); DH (2000); Beltrami *et al.*, (2000).

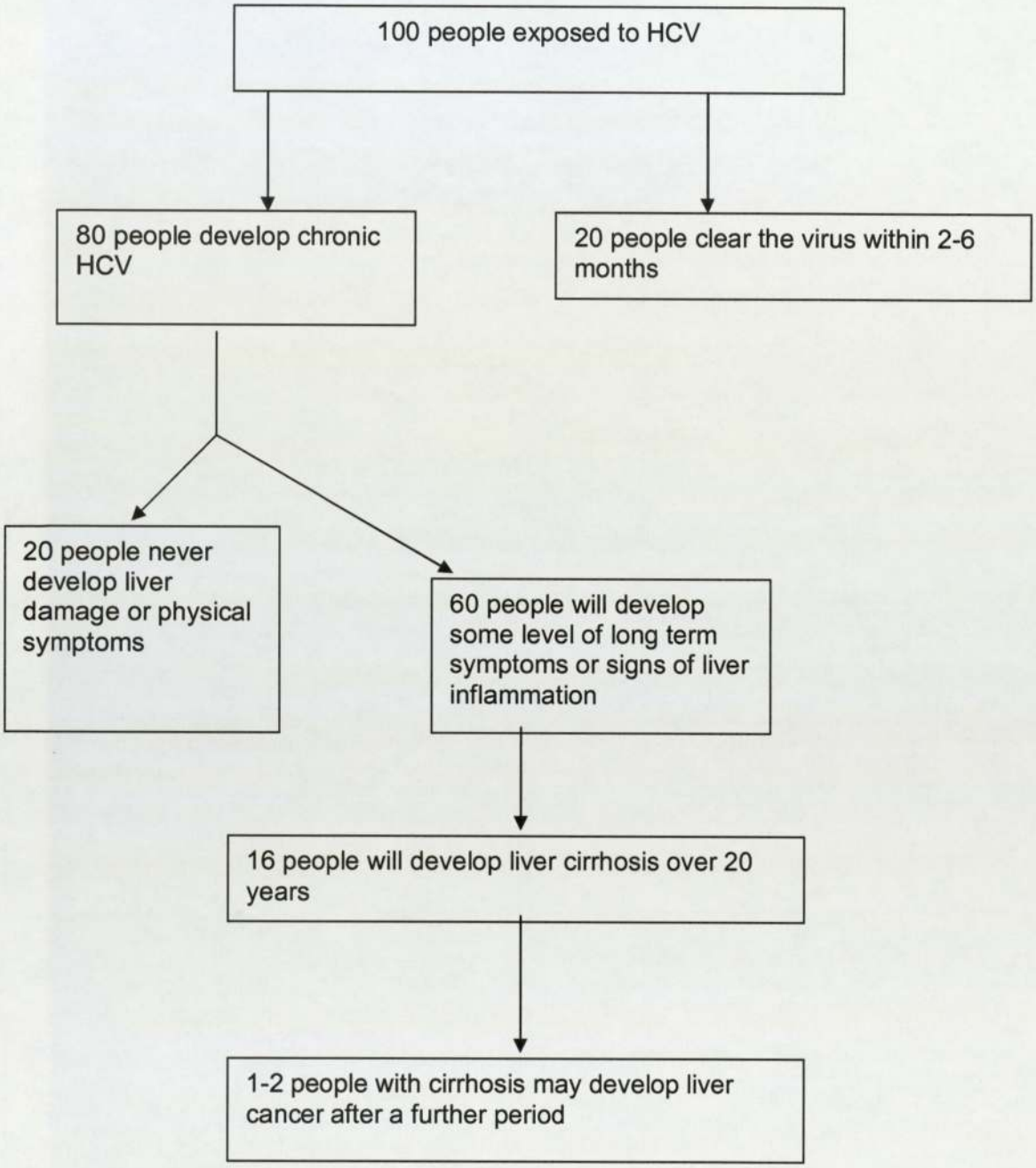
1.8.1.1 Hepatitis B treatment

In the 1980's, alpha interferon, an anti-viral drug, was first shown to effectively treat patients with HBV (Ryder and Beckingham, 2001). Alpha interferon mimics naturally occurring alpha interferon, which the body produces as part of the immune response to infection, with an estimated 40% of cases responding to treatment (Ryder and Beckingham, 2001). Side effects include nausea, fatigue, muscle aches, headaches and depression. Combination treatment may be advised incorporating interferon and lamivudine – a potent inhibitor of HBV viral DNA with reduced damage to the liver (Grahame-Smith, 2001). In long term trials using lamivudine, the majority of patients showed prompt and sustained inhibition of viral DNA replication, improved liver inflammation and reduction in the progression of liver fibrosis (Ryder and Beckingham, 2001).

1.8.2 Hepatitis C

Hepatitis C virus was first discovered in 1989, prior to which clinicians described it as 'non-A, non-B' hepatitis (DH, 2002; Rosenberg, 2001). Hepatitis C is a ribose nucleic acid (RNA) virus, which is slowly progressive with cirrhosis development over 30 years. During the acute stage, symptoms may be undetectable, however lethargy, depression, brief illness, nausea, vomiting and rarely jaundice may develop (DH, 2002). Following exposure to HCV, 15% of sero-positive patients 'clear' the virus naturally, the remaining 85% develop chronic infection (figure 1.3) (Rosenberg, 2001).

Figure 1.3: Hepatitis C disease process and outcome following transmission.



DH (2002); DH, (2001)

1.8.2.1 Hepatitis C treatment

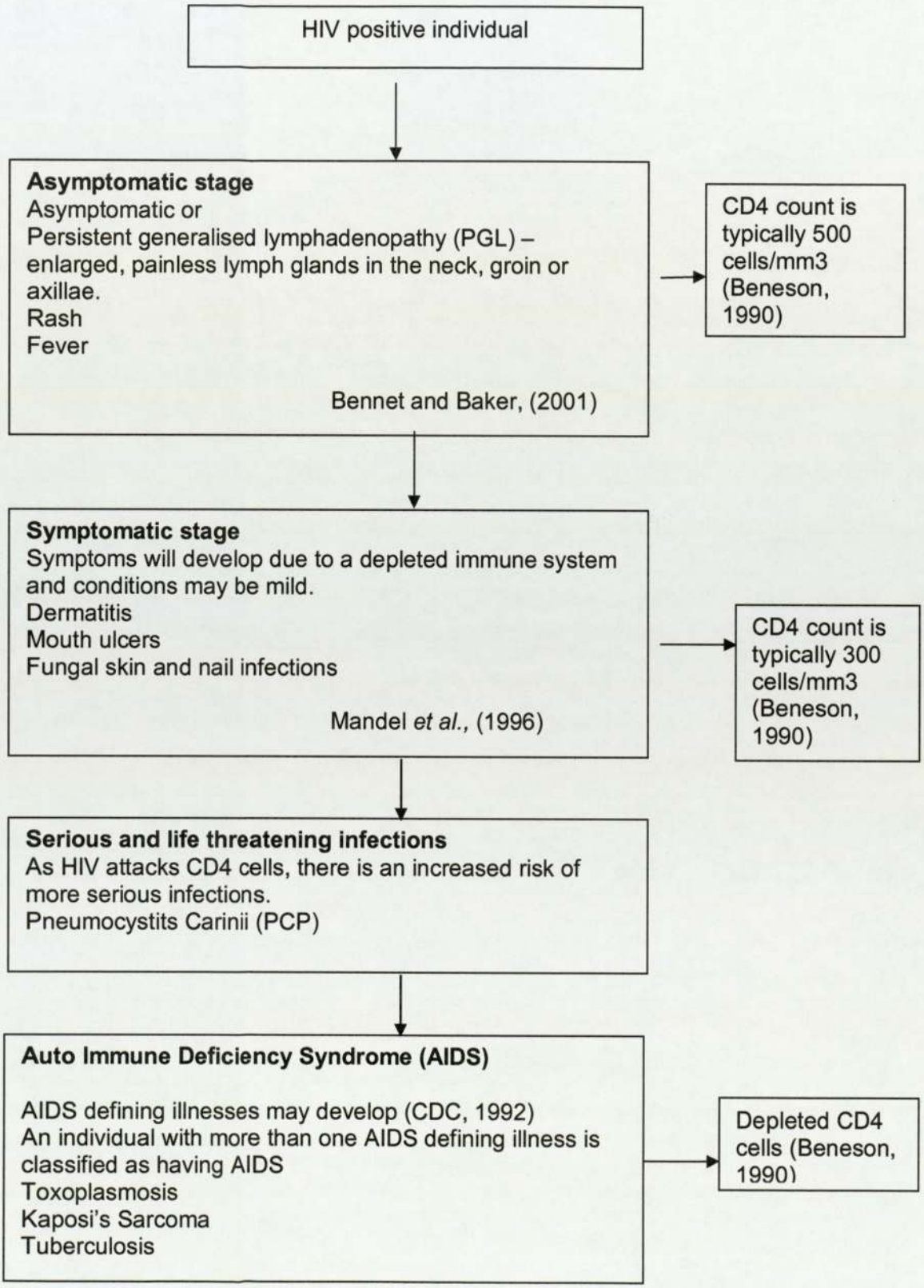
There is no vaccination or effective PEP treatment for HCV (Sulkowski *et al.*, 2002; May and Brewer, 2001; Ramsay, 1999), however trial treatments are available. The National Institute for Clinical Excellence (NICE), recommended a combination therapy of alpha interferon and ribavirin (NICE, 2000). Side effects include fatigue, nausea, headaches and depression. A newer slow-release pegylated alpha interferon is available, which maintains therapeutic drug levels over a longer period and has demonstrated an efficacy rate of 55% (Manns *et al.*, 2001), however the treatment is expensive (£10-11,000 per patient per year) (Rosenberg, 2001; Nash, 2000).

1.8.3 Human immunodeficiency virus

Human immunodeficiency virus is a member of the Lentivirinae subfamily of human Retroviridae and is associated with auto immune deficiency syndrome (AIDS) (Collier and Oxford, 1996). Human immunodeficiency virus targets the CD4 lymphocyte found on T helper cells, which have a central role to immunity (Smith, 2002). An absence of T cells renders the individual highly susceptible to viral attack (Bennet and Baker, 2001).

A serological antibody test is performed for diagnosing HIV. Antibodies to HIV develop approximately 2 to 3 months post exposure. Seroconversion may take up to 12 weeks; therefore, antibody testing is repeated after 3 months. Diagnosis is usually evident within 6 months from exposure (Hanrahan and Reutter, 1997); however, Meyohas *et al.* (1995) reported a delay of 8 months between exposure and HIV seroconversion following occupational exposure in one individual. Human immunodeficiency virus disease progression is described in figure 1.4. Human immunodeficiency virus may develop over 8 to 10 years (Mandal *et al.*, 1996), however, there are exceptions with 'rapid progressors', 'non-progressors' and 'long-term survivors'.

Figure 1.4: The development of symptoms following seroconversion to human immunodeficiency virus.



1.8.3.1 Human immunodeficiency virus treatment: post exposure prophylaxis

Antiviral therapy is not curative; it interferes with replication and therefore slows the disease process. The aim of commencing antiviral therapy is to reduce the viral load to an 'undetectable' level. The first major antiviral drug to be licensed was zidovudine (AZT), which became available in 1986 (National Aids Manual, 1999/2000). Others followed, for example, lamivudine (3TC) and zalcitabine (ddC). Following advances in treatment, a triple or quadruple therapy became standard treatment for HIV due to increased resistance to AZT (DH, 2001). Side effects associated with treatment include diarrhoea, nausea and peripheral neuropathy. Presently, treatment includes anti-emetic medication to control nausea (Bennet and Baker, 2001).

The recommended PEP treatment for individuals post PII is zidovudine 200 mg three times per day (tds) or 250 mg twice per day (bd), lamivudine 150 mg bd and nelfinavir 750 mg tds or 1250 mg bd (DH, 2001). If the exposure incident poses a high risk of transmission, a protease inhibitor is added – indinavir or nelfinavir (Flaherty and Snyder, 1999). It is recommended that the majority of HIV exposures are treated with a 4 week, 2 drug regimen; however, more severe exposures may require triple therapy (Gerberding, 2003; Metules, 2002; CDC, 2001, Diprose *et al.*, 2000). PEP has not been successful in all incidents of seroconversion (Do *et al.*, 2003; Beltrami *et al.*, 2002); however, AZT was associated with a 70 to 81% reduction in the risk of HIV transmission (Gerberding, 2003; Parkin *et al.*, 2000).

Following occupational exposure to HIV, anti-viral therapy should be initiated as soon as possible, ideally within an hour of exposure (DH, 2000), or within 24 to 36 hours (Metules, 2002; National Aids Manual, 2001). Occupationally exposed HCWs are counselled to make an informed decision whether to commence PEP. This is based

on a full assessment of the risk of potential transmission and with knowledge of the potential side effects of treatment (Gerberding, 2003; Smith, 2002).

PEP administration has been monitored by the CDSC. Between July 1997 and June 2002, 509 out of 1550 HCWs, who reported an occupational exposure to blood borne pathogens, were administered PEP. The drug regimens prescribed reflected those recommended by the DH. The side effects of the drugs, particularly gastrointestinal side effects, frequently caused HCWs to discontinue treatment (Tomkins *et* al., 2003; Gerberding, 2003; Thomas, 2002). Interestingly, 81 out of 369 HCWs chose not to have PEP despite the source patient being positive to HIV. Reasons included perceived low risk and HCW decision, time delay, unknown source status and pregnancy. The time delay between occupational exposure and commencing PEP varied. Thirty seven percent received treatment within the recommended 1 hour, compared with 26% 1 to 2 hours, 18% 2 to 8 hours, 39% 8 to 24 hours, 13% 24 to 48 hours and 16% over 48 hours (Thomas, 2002). Reports up to December 2002 indicated that the number of HCWs who commenced PEP within 1 hour decreased to 35.3% (Tompkins *et al.*, 2003).

1.9 The risk of transmission of blood borne pathogens

The risk of occupational transmission of blood borne pathogens is influenced by the prevalence of infection in the patient population and the nature, frequency and severity of blood exposure (Chiarello and Cardo, 2000; PHLS, 1999; Ramsay, 1999). The risk is also increased by a number of factors. These include hollow bore needles, volume of blood, source patient's blood viral load, procedures involving placement of a needle directly in a vein or artery, a deep injury and terminal HIV related illness in the source patient (Department of Health Services, 2002; Goldmann, 2002; RCN, 2001; Culver, 1997; Cardo *et al.*, 1997; CDC, 1995). Furthermore, HCWs' knowledge deficit of the

reporting procedures may increase the risk of seroconversion following exposure to a blood borne pathogen (Metules, 2002).

Percutaneous inoculation injuries can lead to exposure to HBV, HCV and HIV, however bacterial and fungal infections may also be transmitted, for example the herpes virus (Douglas *et al.*, 2002), *Myobacterium tuberculosis, Treponem palliduma* and *Cryptococcus neoformans* (Collins and Kennedy, 1987).

The risk of percutaneous transmission of HBV is 1:3, from a HBeAg positive source to a non HBV vaccinated recipient, HCV is 1:30 and HIV is 1:300 (both from positive source patients to negative recipients) (Rosenberg, 2001; DH, 2000).

In the USA, it was estimated that 12,000 HCWs per year acquire HBV from an occupational exposure (Paton, 2002). In 1995, an estimated 800 American HCWs were infected with HBV, a 95% decline since 1983, mainly due to the introduction of HBV vaccination (CDC unpublished data, cited by NIOSH, 1999). In the UK, in the same year, there were no occupational acute cases of HBV reported to CDSC (Goldberg and McMenamin, 1998).

In the USA, an estimated 2 to 4% of the total number of HCV infections (28,000 in 1995) occurred among HCWs who were occupationally exposed (CDC, 1997). In the USA during 1997, the average incidence of anti-HCV seroconversion was estimated to be between 1.8 and 10% (Goldmann, 2002; CDC, 1997). Studies between 1992 and 1994 were integrated, reviewing more than 11,000 HCWs exposed to HCV in 6 countries and reported a transmission rate of 0.5% (Jagger *et al.*, 2002). Furthermore, transmission of HCV increased if the source patient was co-infected with HIV (Campbell *et al.*, 2000; Serra *et al.*, 1998). In the UK, the prevalence of HCV infection was estimated to be 0.23% among all HCWs and 0.28% in those at risk of occupational

exposure to blood and body fluid (Ramsay, 1999; Neal *et al.*, 1997; Zuckerman *et al.*, 1994). The CDSC identified 3 reported cases of occupational transmission of HCV to HCWs between 1997 and 2002 (Tomkins *et al.*, 2003).

In the UK, from July 1997 to December 2002, 1,684 initial reports of occupational exposure to 1 or more blood borne pathogens were reported to the CDSC (Tomkins *et al.*, 2003). Forty six percent of HCWs were exposed to HCV, 26% to HIV and 10% to HBV. At 6 weeks, 1178 reports were received decreasing to 808 reports at 6 months. Between July 1997 and December 2002, 4 HCWs seroconverted, 1 HCW to HIV, despite triple PEP and 3 HCWs to HCV. However between 1984 and June 2002, there were 5 definite cases of HCW seroconversion to HIV (table 1.4) and 12 cases of possible (no other risk factors identified other than occupational transmission) HIV seroconversion (Thomas, 2002). Of those definite cases of occupational transmission, 4 are known to have died. The 12 possible cases of HIV seroconversion occurred between 1988 and 2000. Of these, 5 were nurses, 3 doctors, 2 surgeons, 1 midwife and 1 HCW of unknown profession. In each case, the country of possible acquisition was Africa, India, USA or Italy (Thomas, 2002). Three of the HCWs are known to have died.

Table 1.4: Details of documented cases of human immunodeficiency virus seroconversions in the UK between 1984 and 2002 (Thomas, 2002).

Diagnosis date	Occupation	Post Exposure Prophylaxis	Exposure	Source status	First positive diagnosis from time of injury
1984	Nurse	No	Re-sheathing needle	AIDS	Day 49
1992-93	Nurse	Yes < 1 hr	Intravenous catheterisation	AIDS	Day 56
1992-93	Phlebotomist	No	Venepuncture	HIV +ve	Day 90
1992-1993	Healthcare worker	No	Venepuncture	AIDS	Day 81
1999	Nurse	Yes <90mins	Venepuncture	AIDS	Day 91

In the USA, to December 1999, 56 cases of occupational exposure to HIV and consequent infection were reported to the CDC and 136 possible occupational transmissions (CDC, 1999). By December 2001, 1 further documented case of HIV seroconversion and 2 possible seroconversions were recorded in the USA (Gerberding, 2003). Eighty nine percent of transmissions were associated with PIIs (Department of Health Services, 2002). In Italy, occupational exposure to blood borne pathogens over 5 years in 18 acute care hospitals was documented. Transmission of HCV occurred with 4 HCWs (95% CI) (Puro *et al.*, 1995).

Limitations were highlighted regarding these data due to the infrequency of infection following occupational exposure, variations in post exposure testing and differences over time in the sensitivity of HIV antibody testing methods (Pinto *et al.*, 1997). Furthermore, data were dependent upon adequate reporting systems. Ninety two percent of all occupationally acquired infections have been reported from countries with developed surveillance systems and low HIV prevalence (PHLS AIDS and STD, 1999). Indeed, the global surveillance data required to estimate the true frequency of occupationally acquired HIV are not currently available (Gerberding, 2003).

Transmission of HCV and HBV from HCWs to patients has been documented. In the UK, the first reported incident was in 1994, however in total there have been 5 reported incidents in which 15 patients were infected with HCV from a HCW (DH, 2002). In Scotland an estimated 3 cases of HCV transmission were reported from HCWs to patients (SCIEH, 2000) and in 1 case, the rate of transmission was 0.36% (Duckworth *et al.*, 1999). Internationally, 4 cases of HCV transmission were reported; 1 in Spain, 2 in Germany and 1 in the USA (DH, 2002). Since 1970, more than 375 patients worldwide have been reported to be infected with HBV from surgeons (Paton *et al.*, 2002).

The risk of transmission of HIV from an infected HCW to a patient is very low. Between 1984 and 1989 a dentist in the USA (Paton et al., 2002) potentially infected 6 patients with HIV. To date, no case of HIV transmission from an infected HCW to a patient has ever been recorded in the UK (DH, 2001). However, a consequence of this potential method of transmission of blood borne pathogens was the UK DH publishing a number of guidelines for testing HCWs. In August 2002, guidelines were published regarding HCV (DH, 2002). This document addressed both testing HCWs for HCV and management following seroconversion. In January 2003, a further document was published for consultation, reviewing health clearance for HCWs. This guidance addressed HIV, HCV and HBV (DH, 2003). Furthermore, in July 2002, a revised guidance on HIV infected HCWs was published for consultation, with a view to replace the 1998 document (DH, 1998, DH, 2002).

1.10 Healthcare workers' perceived occupational risk of exposure to blood borne pathogens

Healthcare workers perceived risk of transmission of blood borne pathogens was frequently inaccurate (Anderson *et al.*, 2003). In the UK, nurses' perception of the risk of transmission of blood borne pathogens following single or multiple exposure to blood or body fluid were evaluated and demonstrated limited knowledge with a subsequent need for further educational input (Leliopoulou *et al.*, 1999).

Risk awareness and behavioural methods of protection against blood borne pathogen transmission during surgery were evaluated in 768 surgeons in the USA. Most surgeons reported slight or moderate concern of contracting HIV, however 8% had extreme concern regarding HIV transmission and 4% were not concerned (Patterson *et al.*, 1998). Similarly, 26 surgeons participated in a telephone survey in the UK. No

surgeon knew the correct risk of transmission of HIV from a positive source patient. Furthermore, only 10 surgeons were aware that PEP should be commenced within 1 hour of exposure and only 2 knew how to access treatment out of working hours (Duff *et al.*, 1999).

Awareness of the occupational risk of exposure to blood borne pathogens was assessed in 108 employees at a large teaching hospital in Scotland (Scoular *et al.*, 2000). Respondents demonstrated a poor level of awareness of blood borne pathogens and associated risk factors. In particular, 60% of HCWs agreed that all gay men and IV drug users should be screened for blood borne pathogens perioperatively and 70% of respondents, located in clinical and laboratory areas, described themselves as having sufficient knowledge, however, uncertainty and inaccurate information regarding blood borne pathogens was frequently demonstrated. More recently, nurses from 71 hospitals in Scotland participated in a survey. Although 68% of nurses agreed that reducing PIIs in clinical practice was important, 32% did not perceive this to be a priority because their clinical areas were perceived as low risk and personal clinical practice was sufficient to ensure safety (Connington, 2002).

In an audit of anaesthetists in a UK teaching hospital, only 34% were aware of the true risk of transmission of HIV, with 22% overestimating and 43% underestimating the risk. Less than half of all consultants knew which body fluids presented the highest risk for transmission of HIV. Moreover, non consultant and trainee anaesthetists demonstrated a significantly higher level of knowledge than consultants. Nearly all participants were aware of whom to contact following exposure, however only 68% knew which 2 first aid actions should be undertaken. Only 15% were aware that HIV PEP treatment should be commenced within 1 hour of injury and 40% believed HIV PEP could be started within 24 hours of injury (Diprose *et al.*, 2000). Similarly, when questioned about the risk of occupational transmission of blood borne pathogens, 77% of doctors and 69% of

midwives underestimated the risk of HBV and 52% of doctors and 36% of midwives underestimated the risk of HIV (Burke and Madan, 1997).

1.11 Impact of percutaneous inoculation injuries

The consequences of a PII can affect both the employer and employee. The impact on the employer is, in the main, financial. Indeed, UNISON negotiated a deal with NHS Trusts whereby claims for certain PIIs are settled by a Trust for £2,000 (NAO, 2003). However, in 2002, £58,000 was awarded to a HCW following a PII sustained in 1997 (NAO, 2003). The impact of a PII on an employee is both financial and psychological (Twitchell, 2003; RCN, 2001). There have been emotive accounts of HCWs who, through occupational exposure, seroconverted to HIV, HBV or HCV (Black, 2001; Algie *et al.*, 1999).

The cost, both financial and psychological, is substantial for HCWs whose career may be prematurely ended due to occupational exposure and consequent seroconversion to blood borne pathogens (Richards, 2001). However, if a HCW does return to work following exposure and subsequent seroconversion to a blood borne pathogen, the disease may guide their clinical practice. The DH (2000) published guidelines for HBV positive HCWs in the clinical setting (table 1.5). An exposure prone procedure (EPP) is where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times (DH, 2002).

Table 1.5: Summary of guidelines for hepatitis B positive healthcare workers practising in the clinical setting (DH, 2002).

Disease status of the healthcare worker (HCW)	Guideline
Hepatitis B virus (HBV) viral load less than 10^3 genome equivalents per ml	May perform exposure prone procedures (EPP).
Hepatitis B virus viral load less than 10^3 genome equivalents per ml and HBV e antigen negative	No restrictions on practice. Annual serological testing.
Hepatitis B virus viral load more than 10^3 genome equivalents per ml or suspected transmission from HCW to patient	EPP prohibited.
HCW undergoing treatment	EPP prohibited until viral load less than recommended level 1 year following cessation of treatment.

In the UK, prior to 2002, HCWs with HCV infection were not restricted from performing exposure prone procedures unless they were known to have transmitted HCV to a patient (CDSC, 1995), because the risk of transmission from a HCW to patient was found to be minimal (Duckworth *et al.*, 1999). However, in August 2002, the DH published revised their guidelines. Healthcare workers who are HCV RNA positive are excluded from EPP and any person intending to undertake training for a career that relies on performing EPP should be tested for HCV. If infected, restrictions on training will be implemented. In addition, HCWs who may have been exposed to HCV should seek and follow confidential advice on serological testing. Indeed infected HCWs (who have antibodies to HCV) and who undertake EPP should be tested for HCV RNA. Healthcare workers who respond to treatment (HCV RNA negative 6 months after cessation of treatment) may recommence EPP and should undergo further testing 1 year post treatment (DH, 2002).

A HCW with HIV working in the clinical setting is excluded from all EPP. Other clinical activities are assessed on an individual basis (DH, 2002). Returning to work, may

however, cause psychological distress and anxiety. The individual's confidentiality should be preserved (DH, 2002), however the fear of disclosure may be high.

1.12 Prevention

Ways of preventing occupational transmission of blood borne pathogens are varied, however, to date, the most effective strategies included training and education, universal precautions and HBV immunisation (Twitchell, 2003; Gerberding, 2003; PHLS AIDS and STD Centre, 1998). Other strategies have included policy and procedure, awareness campaigns and NPDs.

1.12.1 Training and education

The DH recommended training and education to prevent PIIs, improve adherence to good clinical practice and use of safer equipment because it was perceived as integral to developing awareness among HCWs (Wang *et al.*, 2003; DH, 2002; Heinrich, 2000; Jeanes, 1999; DH, 1998; Mercier, 1994), including ancillary staff (RCN, 2001). However, adherence to guidelines and safe work practices are complex, relating to both behavioural and organisational factors. The NAO's recent review of injuries sustained in NHS Trusts highlighted that a number of UK hospitals had focused on training medical staff in an attempt to reduce the incidence of PIIs (NAO, 2003).

Implementing universal precautions and sharps management training and education programmes reduced the risk of PIIs, encouraged safer work practices, increased compliance with policy and procedure and altered the behaviour of HCWs previously resistant to change (Gerberding, 2003; Department of Health Services, 2002; Connington, 2002; Huang *et al.*, 2002; Richard *et al.*, 2001; Kim *et al.*, 2001; Short Life Working Group, 2001; Calabro *et al.*, 1998; Seto *et al.*, 1989). Indeed, education and

training is a requirement of the Control of Substances Hazardous to Health (COSHH) regulations (DH, 1994).

Induction programmes were highlighted as an appropriate forum to initiate such education (Short Life Working Group, 2001). However, the volume of information provided during orientation overwhelmed students and the importance of information provided regarding sharps awareness was not always realised (Doig, 2000). Furthermore, there was limited evidence of pre-registration training for doctors (Goodfellow and Claydon, 2001), despite findings which suggested that basic infection control procedures and blood borne pathogen awareness training reduced primary catheter related bloodstream infections and proved to be cost efficient (Sherertz *et al.*, 2000).

However, despite studies demonstrating the efficacy of training programmes (Eggimann *et al.*, 2000; Moongtui *et al.*, 2000; Puntis *et al.*, 1990), the degree to which HCWs retain the information is unclear. One study demonstrated increased compliance with hand washing and glove use immediately post training; however, there was no sustained compliance (Moongtui *et al.*, 2000). Indeed, with the introduction of NPDs, the importance of effective training and education has been further emphasised, requiring both theoretical and practical elements (Metules, 2002; OSHA, 1999; Osborn *et al.*, 1999), to ensure competency with new technology (Adams and Elliott, 2002; Godfrey, 2001; Eck *et al.*, 2000).

1.12.2 Universal precautions

With the first report of occupational HIV transmission in 1984, came the introduction of universal precautions to prevent patients with HIV being stigmatised during clinical management and to protect HCWs against potential exposure to blood and body fluid

(McCreaddie, 2001). Simultaneously sharps management emerged (Gershon *et al.*, 2000).

Universal precautions involves wearing clean, non sterile gloves when dealing with blood, body fluids, secretions, excretions and contaminated items; hand washing after glove removal and wearing eye protection and gowns (aprons) if splashing of blood and body fluid is likely. Care is required when handling soiled equipment, linen and waste, as well as during the safe disposal of needles (Ayliffe *et al.*, 2000). Under universal precautions, HCWs should presume that all patients are infectious, and therefore adhere to infection control procedures at all times (Godin *et al.*, 2000).

Despite rigorous training however, HCWs demonstrated inadequate knowledge of blood borne pathogen infection risk, under-reported exposures, did not use personal protective equipment or comply with guidelines ensuring safer use and disposal of sharp devices (Stein *et* al., 2003; Twitchell, 2003; Lynn *et al.*, 1999; Roy and Robillard, 1994; Hershey and Martin, 1994; Dalton *et al.*, 1992). Previous studies repetitively reported non adherence to universal precautions due to a lack of investment in staff training, limited understanding in HCWs' safe behaviour in the workplace and HCWs' complacency (Twitchell, 2003; Henderson, 2001; Godin *et al.*, 2000; Cone, 2000; Akduman *et al.*, 1999; Nelsing *et al.*, 1997). Indeed, Cutter and Jordan (2003) commented that HCWs perceived adherence to universal precautions as an unwarranted increase in their administrative burden or impossible to accommodate with current clinical pressures. Other reasons for non compliance included reduced dexterity, forgetting to comply, wearing prescription glasses was protection enough, protective equipment was not available, HCWs did not bother to wear protective clothing and gloves did not fit properly (Stein *et al.*, 2003; Nelsing *et al.*, 1997).

In a Canadian study, nurses were more likely to adhere to universal precautions if it was perceived as the social norm within their clinical area in addition to working conditions and workload influencing the degree to which they adhered (Stein *et* al., 2003; Godin *et al.*, 2000). In California, engineering, administrative and other work practice controls, personal behaviour, improved sharps disposal container placement, not re-sheathing needles, improved injury and illness protocols, correct use of sharp devices and improved staff training were highlighted as factors that may prevent PIIs (Cone, 2000). Interestingly, although universal precautions contributed to decreased PIIs (Wiwanitkit, 2002), it did not influence the reporting of injuries (Weltman *et al.*, 1995; Beekmann *et al.*, 1994; Linnemann *et al.*, 1991).

An anonymous national survey of HCWs highlighted that perception of risk of occupational blood borne infection and knowledge of routes of transmission influenced compliance with universal precautions. Despite training and education, only 55% of HCWs routinely adhered to universal precautions (Willy *et al.*, 1990).

In accordance with universal precautions, gloves must be worn when there is a risk of exposure to blood or body fluid (Ayliffe *et al.*, 2000). Gloves were recognised as one of the most effective means of barrier protection, reducing the risk of PII and exposure to blood borne pathogens (Godfrey, 2001; Hirschmann *et al.*, 2001; May, 1999; Ben-David and Gaitini, 1996). Despite this, doctors infrequently wore gloves when inserting IV peripheral catheters or performing venepuncture (Stein *et al.*, 2003; Nobile *et al.*, 2002; Hettiaratchy *et al.*, 1998; Bermingham and Kippax, 1998; Wooley *et al.*, 1991). Indeed, in one study, 22% of those who sustained PIIs were not wearing gloves at the time of injury (O'Connell and Hayes, 2003).

Glove material reduced the volume of blood transferred following injury with a hollow bore needle by 46 to 86% (Mast *et al.*, 1993). More recently, this was supported by the

DH and other authors, advising HCWs to wear gloves because blood was 'wiped off' the needle as it penetrated a gloved finger, if a PII occurred (Infection Control Nurses Association, 2003; DH, 1998). Interestingly, however, a study involving medical students at Birmingham University, UK, reported that PIIs were associated with wearing gloves (Sullivan *et al.*, 2000).

Glove use during surgical procedures is mandatory; however, glove perforation has been documented (Alrawi *et al.*, 2001; Laine and Aarnio, 2001; Kralji *et al.*, 1999; DH, 1998; Rice *et al.*, 1996). Subsequently, double gloving (wearing 2 pairs of gloves) was advised by the DH for all high risk procedures where glove puncture may occur (DH, 2002; DH, 1998). Reasons for not complying with double gloving included reduced dexterity and discomfort (Nash, 2001; Kim *et al.*, 1999).

Puncture resistant sharps containers reduced the number of PIIs and UK NHS Trusts improved the type and location of the containers in a further attempt to reduce PIIs. However, permanently locating sharps containers in close proximity with the patient has presented some concern (NAO, 2003). Rotherham General Hospital NHS Trust attempted to address this issue by implementing plastic trays incorporating a sharps container, which was taken to the patient for a procedure. All sharps containers were removed from patient's rooms and the trays with the integrated sharps container were located in a central area in the clinical area. This strategy reduced reported PIIs by 42% (NAO, 2003).

1.12.3 Vaccination

Prior to 1982, HCWs were not vaccinated against HBV (McCreaddie, 2001). The DH first published guidelines for HBV vaccination for HCWs in 1993, which was subsequently amended in 1996 (DH, 1996). Vaccination provides protection in an

estimated 90% of recipients (DH, 1998, DH, 1996), with a minority group not responding to vaccination (Ramos *et al.*, 2000; Boxall and Dennis, 1998; CDC, 1990).

Healthcare workers are complacent with regard to their HBV immunity, frequently unaware of their immunity status or failing to be vaccinated (Brotherton *et al.*, 2003; McGrane and Staines, 2003). Consequently, HCWs are at increased risk of transmission of HBV following a PII (St Germaine *et al.*, 2003; Whitby and McLaws, 2002; Radon *et al.*, 2001; Alzahrani *et al.*, 2000; Thompson and Norris, 1999; Patterson *et al.*, 1998; Haire and Sharma, 1996; Smith *et al.*, 1996; Prendergast *et al.*, 1995). Indeed, Gyawali *et al.*, (1998) reported that HBV vaccine uptake was 78%, reducing to 70% in paramedics and 45% in domestic staff. More recently in Australia, 96% of hospitals offered HBV vaccination, however 28% of nurses reported incomplete vaccination and provision for physicians was poor (54%) (Brotherton *et al.*, 2003).

1.12.4 Percutaneous inoculation injury policy and procedure

It is essential that hospitals implement a PII policy and HCWs are aware of this procedure should such an injury occur (Metules and Ventura, 2001). The procedural policy at UHB NHS Trust concurs with guidance from the UK DH (table 1.6).

Table 1.6: Procedure following a percutaneous inoculation injury and associated issues.

Procedure	Associated issues
Remove the needle and encourage the wound to bleed by squeezing under warm running water (Infection Control Nurses Association, 2003; McCreaddie, 2001).	In the USA, it is not recommended to bleed the wound due to a paucity of supporting evidence (Metules, 2002; CDC, 2001).
Wash the wound with soap and water without scrubbing and apply a waterproof dressing (Infection Control Nurses Association, 2003; DH, 1998; Campbell, 1997).	Antiseptics, disinfectants and caustic substances should not be used (CDC, 2001).
Contact Occupational Health and Safety or the out of hours equivalent (Metules, 2002; Smith, 2002; DH, 1998). Blood will be obtained from the recipient.	In the UK and USA, some hospitals implemented 24 hour 'hotline' strategies to provide advice and counselling following injury (Short Life Working Group, 2001; Osborn *et al.*, 1999; DH, 1998).
With consent, blood should be obtained from the source patient (DH, 1998). If the source patient refuses or is unknown, the incident should be managed as a high risk incident (Ramsay, 1999).	Chiarello and Cardo (2000) highlighted the importance of testing source patients for HBV, HCV and HIV. Dimond (2003) reviewed the issues surrounding source patient consent.
Complete a Risk Management incident form (RCN, 2001).	If the employee is absent for more than 3 days following injury or seroconverts to HBV, HCB or HIV, the incident is reported to the Health and Safety Executive according to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) (Health and Safety Executive, 1995).

Despite extensive education and training, HCWs remain unaware of policy and procedures (Connington, 2002; May and Brewer, 2001). In Scotland, only 10% of nurses were aware of their employer's PII policy (Connington, 2002). Furthermore, it is essential for employers to provide the facility to manage such injuries. Studies in the UK and USA demonstrated that, despite recommendations, not all hospitals provided the appropriate facilities or management structure to treat PIIs (Beekmann *et al.*, 2001; Wareham and Breuer, 2000; Sidwell *et al.*, 1999). Indeed, in 1 study, medical students were discouraged from reporting their PIIs by senior staff (Osborn *et al.*, 1999).

1.12.5 Awareness campaigns

The profile of PIIs and the consequence of exposure to blood borne pathogens has been raised by campaigns and legislation. In the USA, the Needlestick Safety and Prevention Act was passed into law in November 2000, requiring NPDs to be introduced into the clinical setting, as well as improve PII data collection and audit. OSHA revised its Bloodborne Pathogen Standard to mandate the use of safety engineered devices and implement a PII log for recording exposure incidents (Pugliese *et al.*, 2001).

In the UK, the RCN and UNISON raised awareness of PIIs and occupational transmission of blood borne pathogens via campaigns (RCN, 2001; Godfrey; 2001). A safer needles network was subsequently organised and comprised healthcare professionals with an interest in sharps awareness (May and Churchill, 2001). In Scotland, the Short Life Working Group (2001) involved staff, management, trade unions, professional organisations and the Scottish Executive to review PIIs within Scottish healthcare institutions. Interestingly, however, 1 year following its publication, 21% of nurses from 71 hospitals in Scotland were not aware of the publication or any other literature regarding PII prevention (Connington, 2002). Currently, UNISON is in discussion with the DH and Health and Safety Executive regarding the requirement for specific legal guidance for NPDs (Mummery, 2002).

1.12.6 Needle protective devices

The most recent strategy to prevent PIIs and occupational exposure to blood borne pathogens was NPDs. A protective device can be defined as any product that can be used to protect HCWs from accidental PII and other sharps injuries (ECRI, 2001).

NPDs may be passive, where the safety feature is an integral part of the device. Users take no action to activate the device and the safety mechanism should work effectively, reliably, be acceptable to the HCW and should not adversely affect patient care (NIOSH, 1999). There are, however, devices available that require the user to activate the safety mechanism for example BD Insyte™ Autoguard™ and Tyco Monoject®. Recommendations are available to assist HCWs in their evaluation of such devices (table 1.7).

Table 1.7: Compilation of recommendations for evaluating needle protective devices.

Recommendation
- Needle protective devices (NPDs) should minimise the risk of infection to patients and should not create infection control issues beyond those of conventional products (ECRI, 2001).
The NPD should: - provide a barrier between the user's hand and the needle. The user's hand should remain behind the needle at all times; - have an integral safety feature; - be simple to use, requiring little or no training to operate effectively; - have a safety feature that remains in situ after disposal to protect other HCWs. (Food and Drug Administration (FDA), 1992; Jeanes, 1999)
The NPD should: - reduce or minimise the risk of PIIs to users and other HCWs both during use and after disposal; - be reliable and automatic; - minimise risk of infection to the patient; - should be easy to use with minimal or no assembly; - ensure the user technique is similar to that of conventional products; - not cause any additional discomfort to the patient; - be compatible with conventional products; - only have a minimal increase in volume of disposal; - be available in a size range similar to conventional products; - be easy to use under all circumstances. Appropriate training should be available prior to produce implementation ECRI (2001)

In addition, the Training for Development of Innovative Control Technology Project (TDICT) produced evaluation tools for a number of NPDs (appendix 1a).

The development of NPDs has outpaced HCWs' ability to determine their efficacy, safety and cost benefit, however initial evaluations highlighted variable efficacy in reducing PIIs (Alvarado-Ramy *et al.*, 2003; Heinrich, 2000). Despite this, some healthcare establishments have purchased expensive NPDs regardless of the lack of rigorous evaluation (Duffin, 2002; Orenstein *et al.*, 1995).

1.12.6.1 Evaluation of needle protective devices

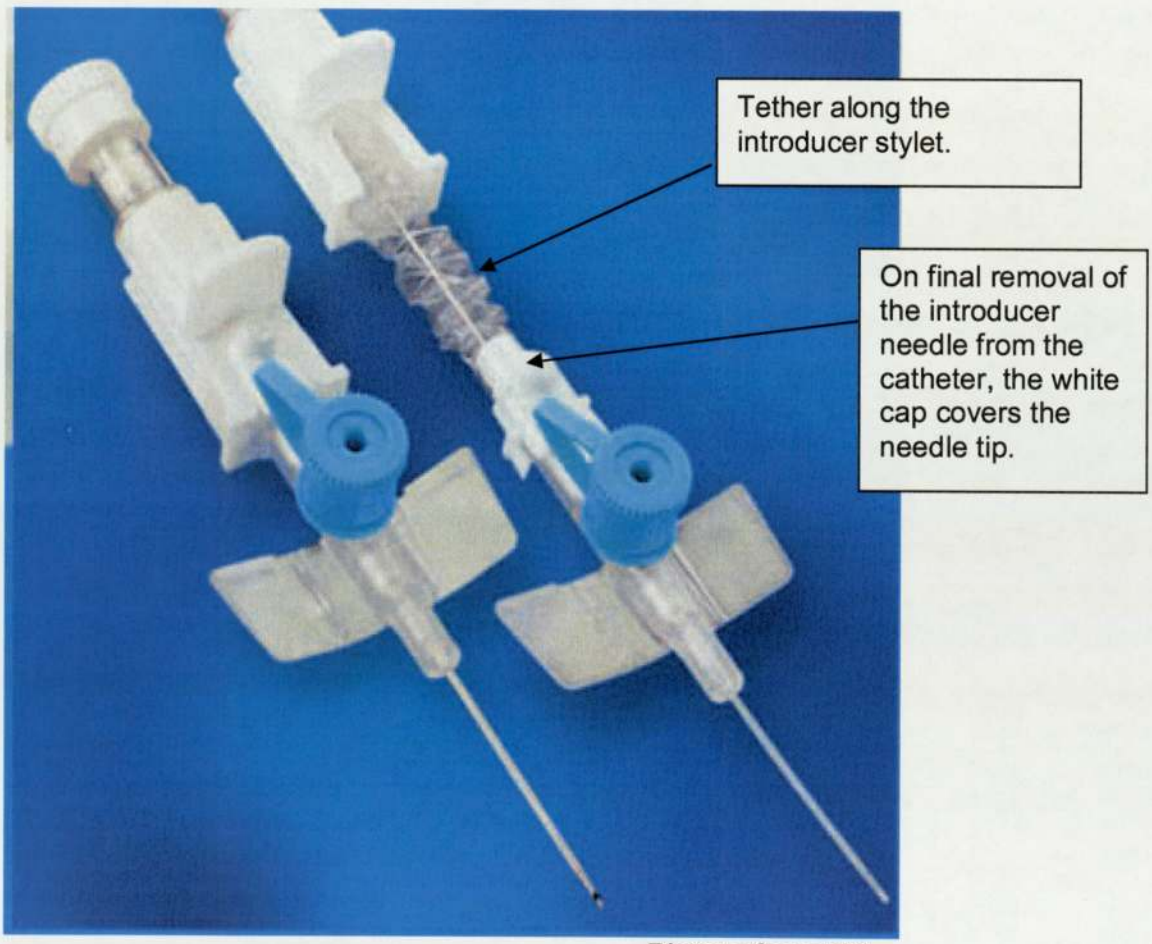
The first reaction to a new device designed to prevent PIIs may be one of enthusiasm, followed by a more practical and critical assessment. Trials require a minimum of 100,000 devices to achieve statistical significance, dependent upon the device being compared and the statistical parameters set (Jagger, 1996). Sample sizes large enough to demonstrate efficacy of NPDs based on associated injury rates are rarely feasible in a single facility (Pugliese *et al.*, 2001).

The majority of studies to evaluate NPDs have been undertaken in the USA, with a paucity of evidence from the UK when compared with the number of devices currently available. Informal evaluations were most frequently adopted, involving clinical observation of a small number of devices producing information about user preference and product characteristics, however did not provide objective conclusions about PII reduction rates or safety performance of the device (Pugliese *et al.*, 2001). Subsequently, statistical significance has not always been achieved (Eck *et al.*, 2000).

To date, only 6 studies have been undertaken to assess the efficacy of IV peripheral catheter NPDs. In 1995, Becton Dickinson (BD) Safelon™ (figure 1.5) was evaluated to assess its usability by 4 medical staff in an Accident and Emergency department in the UK. Ninety five percent of insertions were successful on first attempt and 93% of insertions were easier or comparable with conventional devices. Patients who moved

during the catheter insertion procedure or those who presented with hypovolaemia were deemed difficult to catheterise using the NPD. Blood leaked from the distal end of the IV peripheral catheter prior to connection or during attachment of the luer-lock cap (10%). In 98% of insertions, the safety feature activated, with failures due to incorrect operator technique (Watters *et al.*, 1995).

Figure 1.5: BD Safelon™ intravenous peripheral catheter.



Picture from BD

In Japan, Asai *et al.*, (1999) evaluated the usability and acceptability of BD Insyte™ Autoguard™ (figure 1.6) compared with its conventional counterpart BD Insyte™. Catheterisation was successful at the first attempt in 36 out of 50 patients in the study group compared with 35 out of 50 in the control group (conventional catheter). No

significant difference with ease of insertion was noted and the handling of the withdrawn needle was perceived as significantly safer in the study group when compared with the conventional catheter (p=0.001). Blood leak was experienced between removing the introducer needle and connecting the infusion for 7 out of 50 patients in the control group and 5 out of 50 patients in the study group. However, a significant reduction in blood contamination was found with the study catheter (p=<0.0001).

Mendelson *et al.*, (2000) undertook a clinical trial in the USA to evaluate BD Insyte™ Autoguard™ (figure 1.6) and Protectiv™ Plus (Johnson and Johnson) (figure 1.7). The study has not, to date, been published, however was presented at the Society for Healthcare Epidemiology of America in 2001. BD Insyte™ Autoguard™ significantly reduced associated PIIs by 89%, however no findings were documented for Protectiv™ Plus.

Figure 1.6: BD Insyte™ Autoguard™.

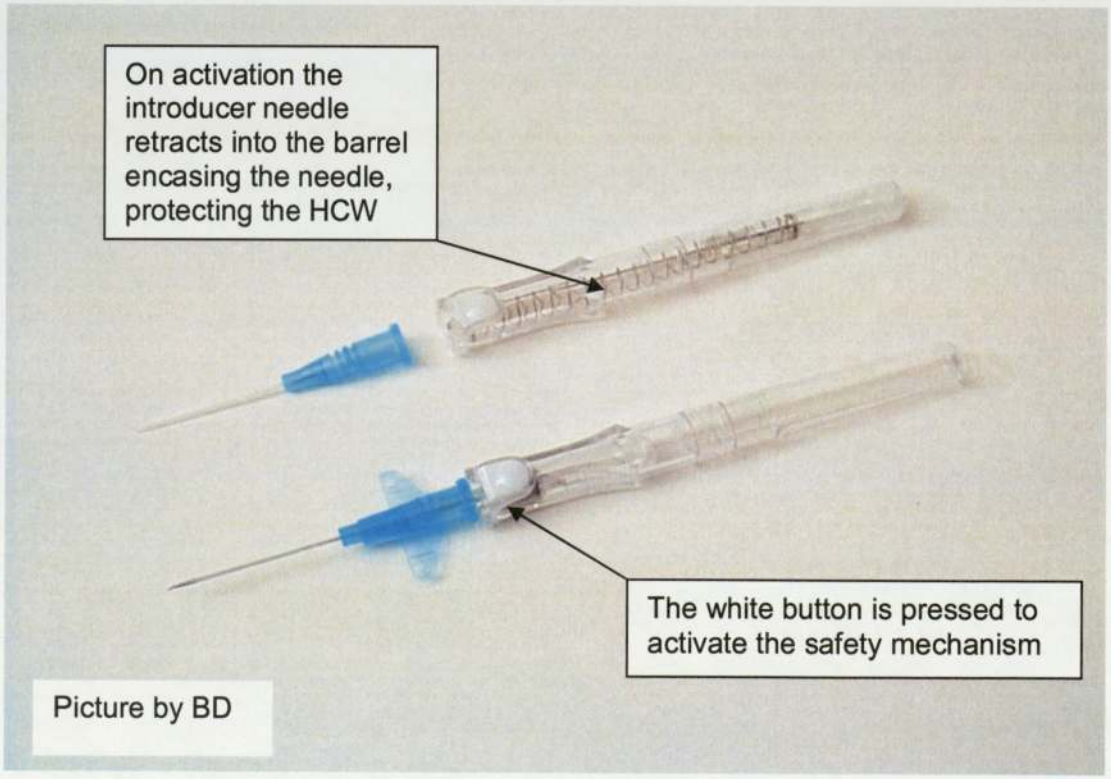
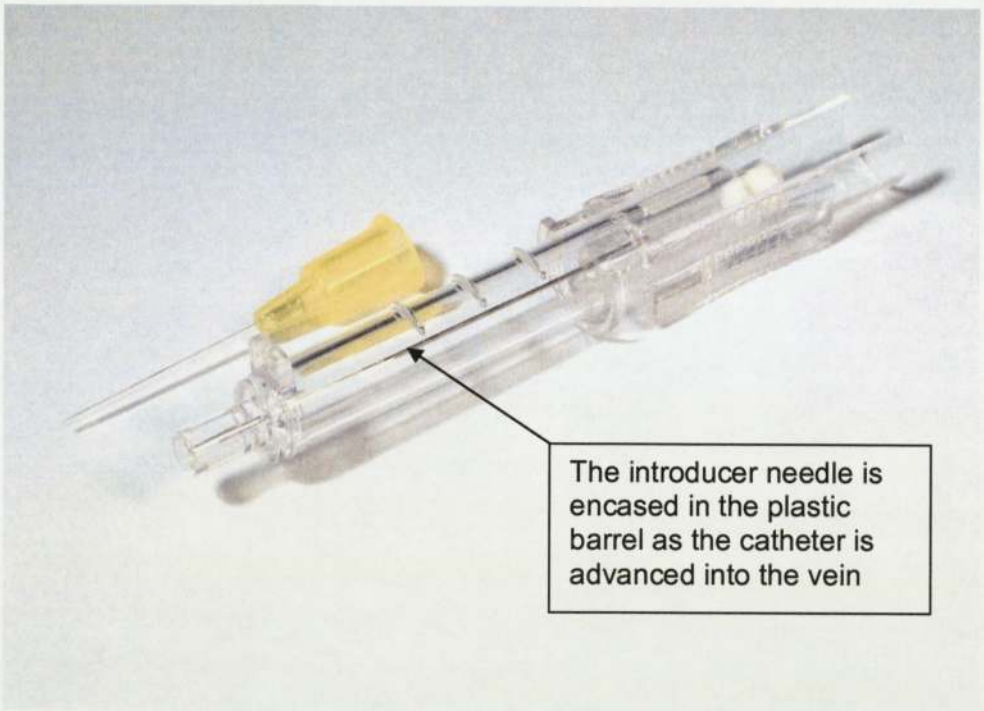


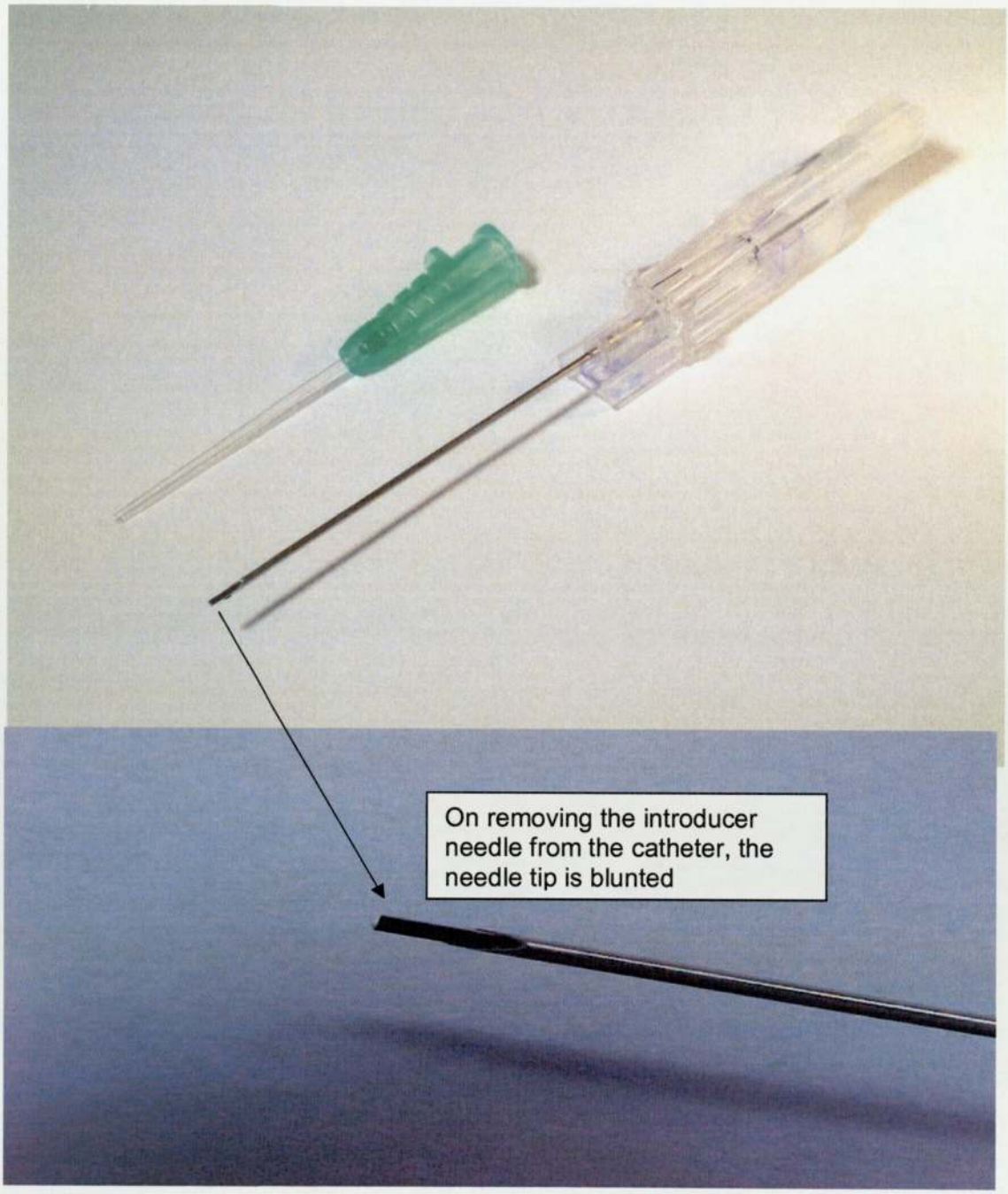
Figure 1.7: Johnson and Johnson Protectiv™ Plus.



Picture by BD

BD Insyte™ Autoguard™ (figure 1.6) and Johnson and Johnson Protectiv Acuvance™ (figure 1.8) were evaluated in Japan, to assess usability and acceptability by HCWs in the clinical setting for IV and intra-arterial catheterisation (Asai *et al.*, 2002). Results demonstrated that both NPDs were more difficult to use than conventional products, however Insyte™ Autoguard™ was safer when handling the used needle, with a lower incidence of blood contamination compared with conventional products. Protectiv Acuvance™ was evaluated as having an adequate flashback chamber, however back flow of blood was too slow. For IV peripheral catheterisation, Insyte™ Autoguard™ was preferable, however for intra-arterial catheterisation, conventional catheters were perceived to be the easiest to insert. Blood contamination occurred whilst removing the needle and connecting an infusion line more frequently with Insyte™ Autoguard™. In 5 incidents, blood splashed on the palm or trunk of the operator during retraction of the needle because blood had penetrated the plug at the rear of the chamber.

Figure 1.8: Johnson and Johnson Protectiv Acuvance™.

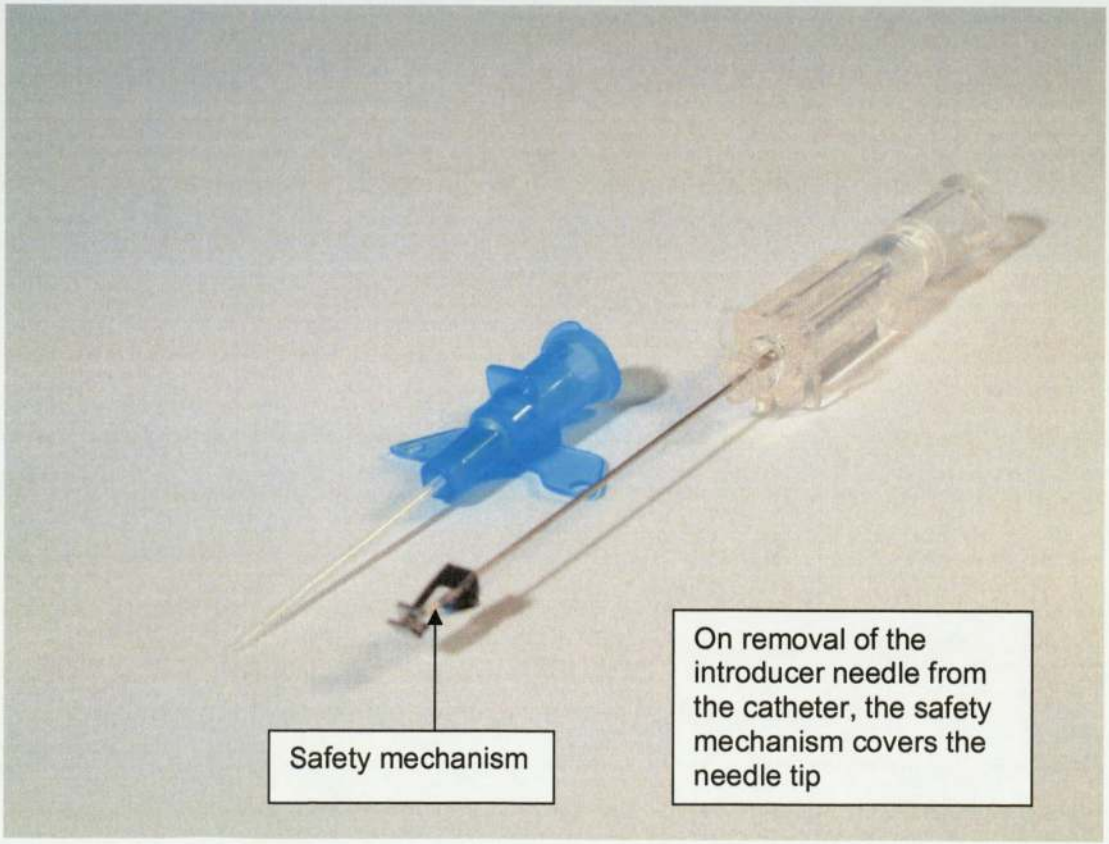


In the most recent UK study, Mummery (2002) evaluated 4 NPDs, 2 of which were IV peripheral catheters, for usability and acceptability by HCWs. Each product was rated between 1 and 5, 1 being the most favourable score, inferring the HCW liked the product. Sixty Johnson and Johnson's Protectiv Acuvance™ (figure 1.8) NPDs were

used giving an average score of 2.4. In comparison 42 BD Safelon™ (figure 1.5) were used with an average score of 2.9. Ten hospitals participated in the study however, the number of HCWs participating in the study was not documented. Due to the size of the study, statistical significance was not reached.

Most recently in the USA, B Braun Introcan Safety IV catheter (figure 1.9) was evaluated at Mount Sinai Medical Centre. The NPD was implemented in surgical theatres including recovery areas and neonatal and paediatric intensive care units. During the 6 month study period no PIIs were sustained (0 injuries per 87,000 uses) compared with the 36 month baseline period where HCWs in the study clinical areas reported sustaining 13 PIIs (5.08 per 100,000 uses) (B Braun, 2003). This study has not to date been published in a journal, however was presented at the Society of Healthcare Epidemiology of America in April 2003.

Figure 1.9: B Braun Introcan Safety IV catheter.



Despite only 6 published studies evaluating IV peripheral catheter NPDs, with only 2 assessing associated PII reduction, there are numerous other studies, which evaluated other NPDs (table 1.8).

Table 1.8: Studies evaluating needle protective devices.

Key: PII = percutaneous inoculation injury, IV = intravenous

Author/Country	Type of product	Name of product	Study findings
Chen *et al.*, (2000): USA	Winged steel needle (butterfly needle)	BD Safety-Lok™ (figure 1.10)	50% reduction in associated PIIs.
Orenstein *et al.*, (1995): USA	3 ml syringe Needleless IV system	BD Safety-Lok™ Baxter Interlink™ (figure 1.11)	61% reduction in associated PIIs. 50% reduction in PIIs associated with IV line manipulation.
Mendelson *et al.*, (1997): USA	Blunt suture needle	Ethicon Ethiguard™	Technical difficulties with penetrating tissue, tearing tissue, needle slippage and bleeding.
Younger *et al.*, (1992): USA	Shielded safety syringe	Tyco Monoject® (figure 1.12)	PII reduced from 14 per 100,000 to 2 per 100,000.
Mendelson *et al.*, (1997): USA	Winged steel needle Bluntable vacuum-tube blood collection needle Vacuum-tube blood collection needle	BD Safety-Lok™ (figure 1.10) Bio-Plexus Punctur-Guard™ (figure 1.13) Portex Venipuncture Needle-Pro™ (figure 1.14)	PIIs were reduced from 302 to 41. All Injuries were associated with BD Safety-Lok™ before the safety feature was activated (61%), by not activating the safety feature (20%), whilst activating the safety feature (15%).
Yassi *et al.*, (1995): USA	Needleless IV system	Baxter Interlink™ (figure 1.11)	79% reduction in associated PIIs.
Mummery (2002): UK	Hypodermic needle Venepuncture needle	Portex Hypodermic needle-pro™ (1.15) BD Eclipse™ (figure 1.16)	Rated 2.5 Rated 2.3 (Rated between 1 and 5, 1 being most favourable).
Adams and Elliott (2003) UK	Hypodermic needles	BD Eclipse™ (figure 1.16) BD Safetyglide™ (figure 1.17) BD Safetyglide™ insulin unit (figure 1.18)	Rated 17.26 Rated 16.09 Rated 16.46 50 nurses evaluated each device and scored the device, 10 being most favourable.

Figure 1.10: BD Safety-Lok™.

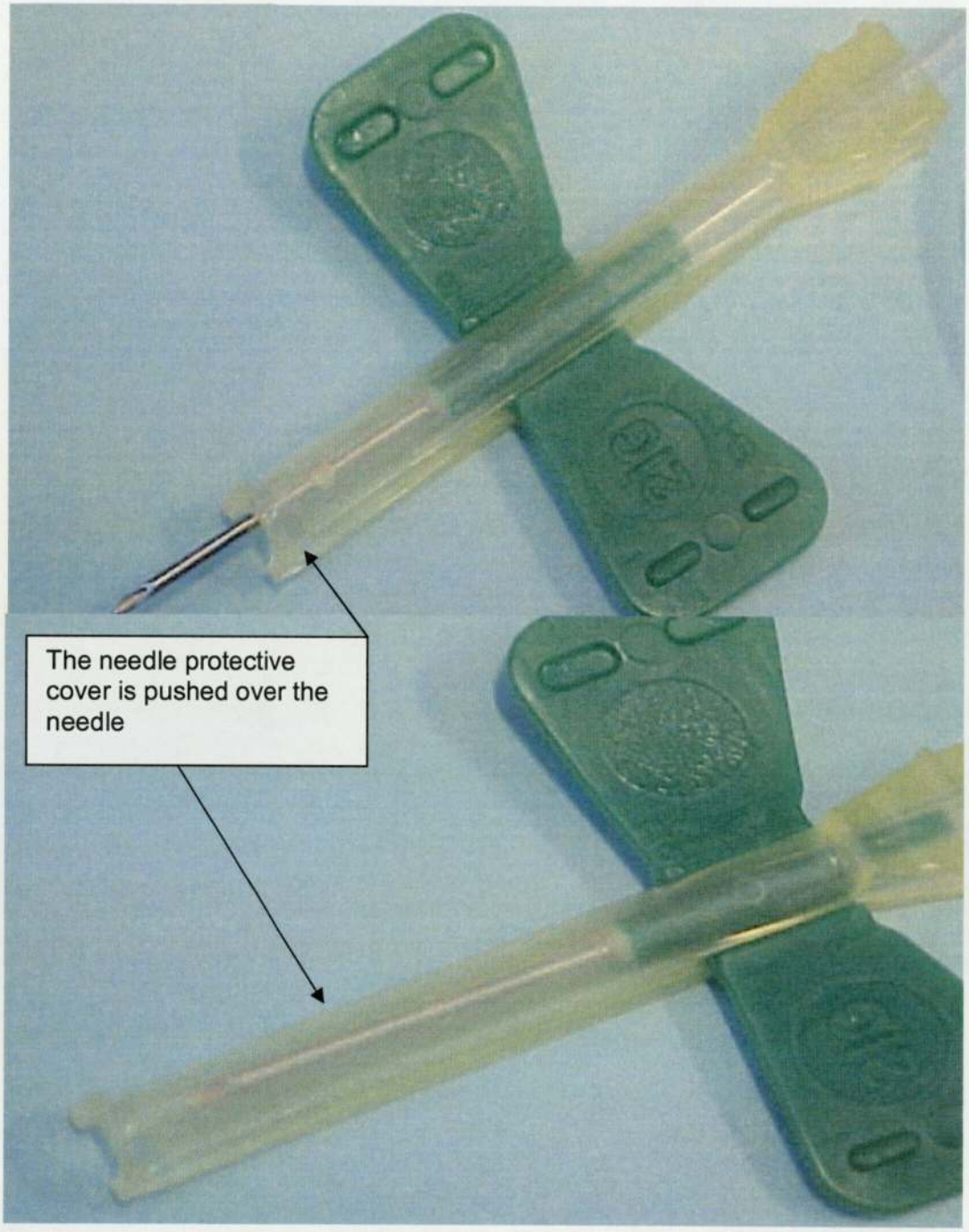
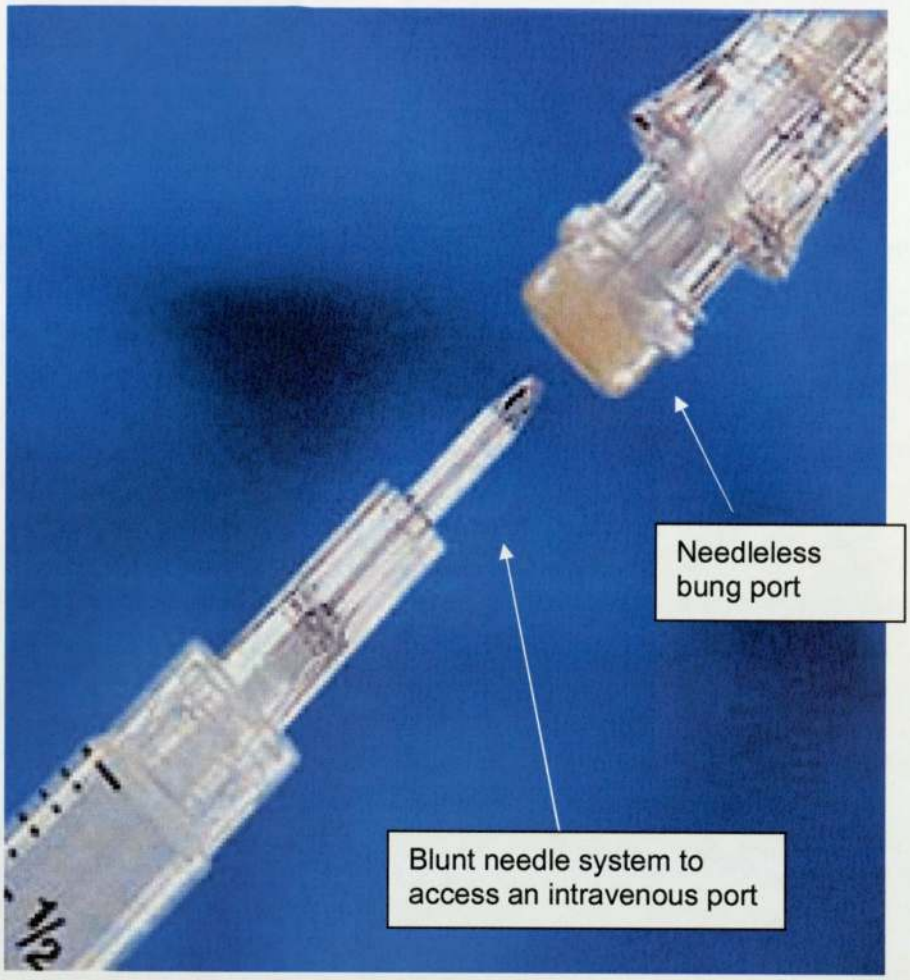
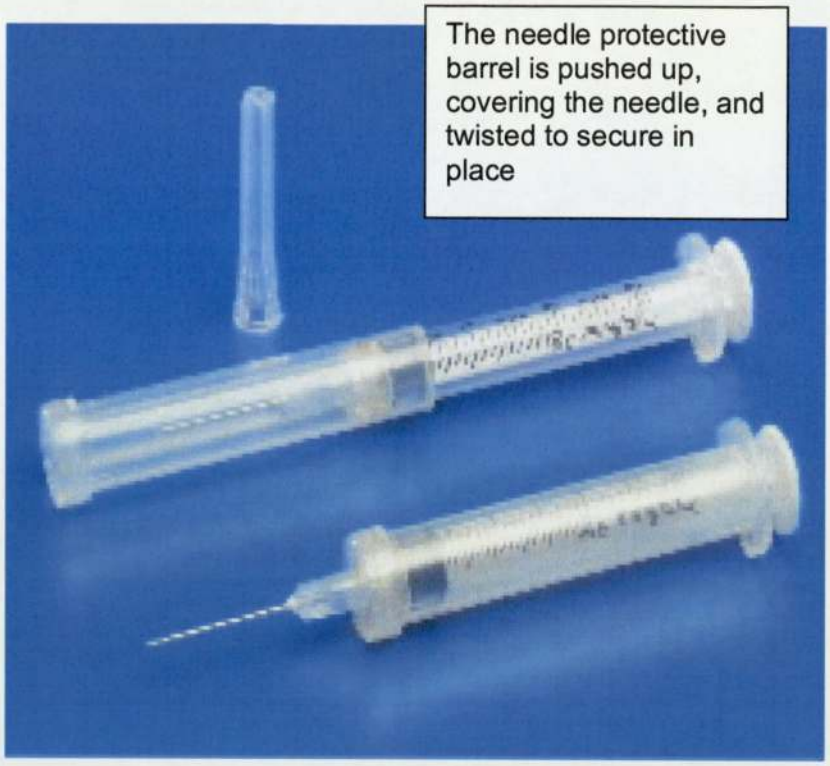


Figure 1.11: Baxter Interlink™ needleless connector system.



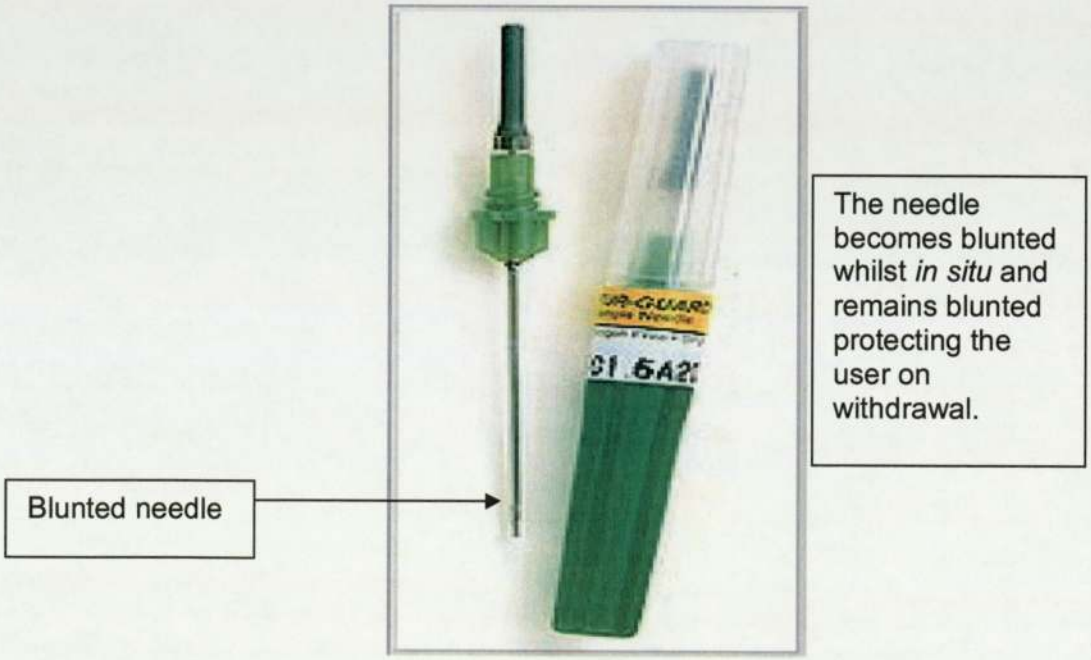
Picture by Baxter

Table 1.12: Tyco Monoject® safety syringe.



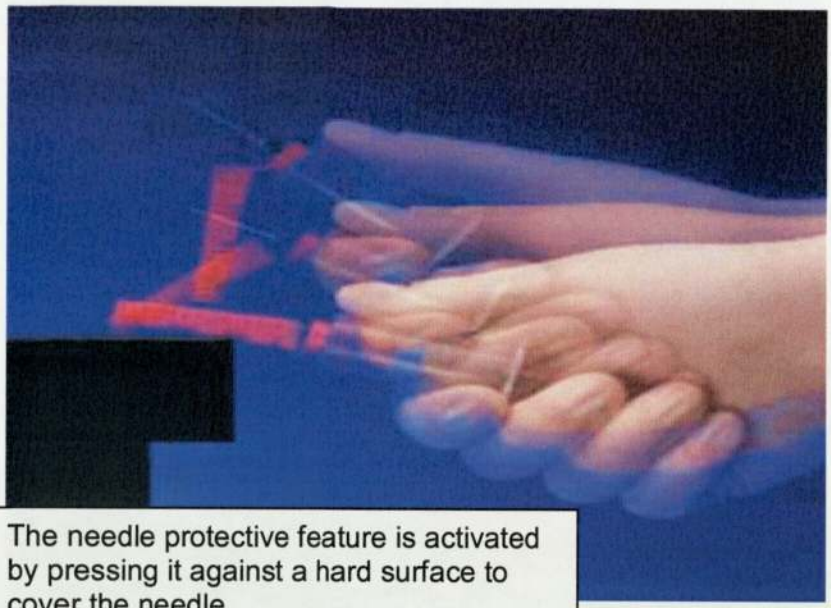
Picture by Tyco

Figure 1.13: Bio-Plexus Punctur-Guard™.



Picture by Bio-plexus

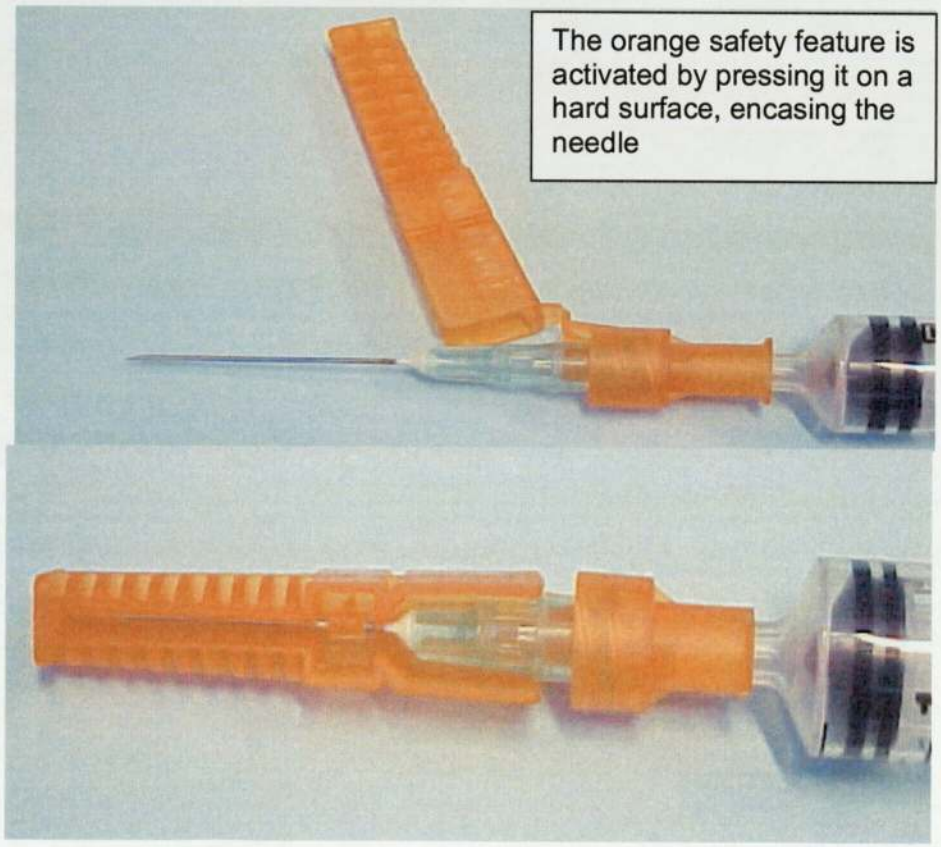
Figure 1.14: Portex Venipuncture Needle-Pro™.



The needle protective feature is activated by pressing it against a hard surface to cover the needle.

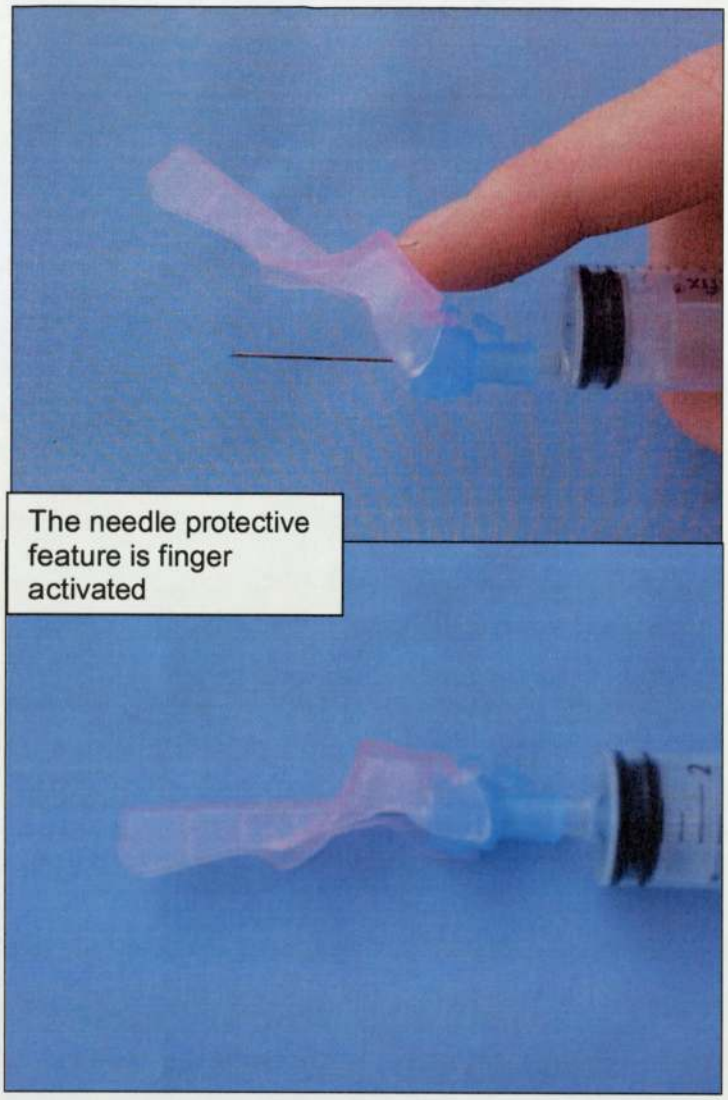
Picture by Portex

Figure 1.15: Portex Hypodermic Needle-Pro™.

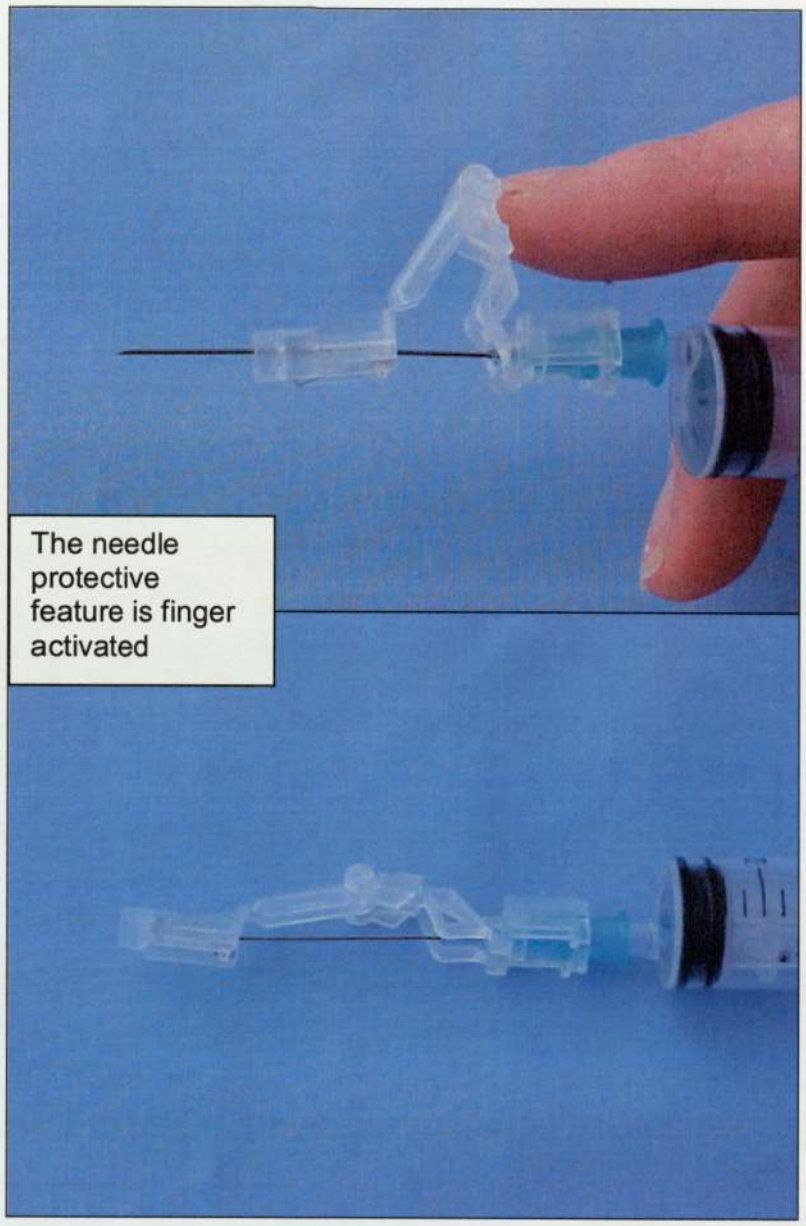


The orange safety feature is activated by pressing it on a hard surface, encasing the needle

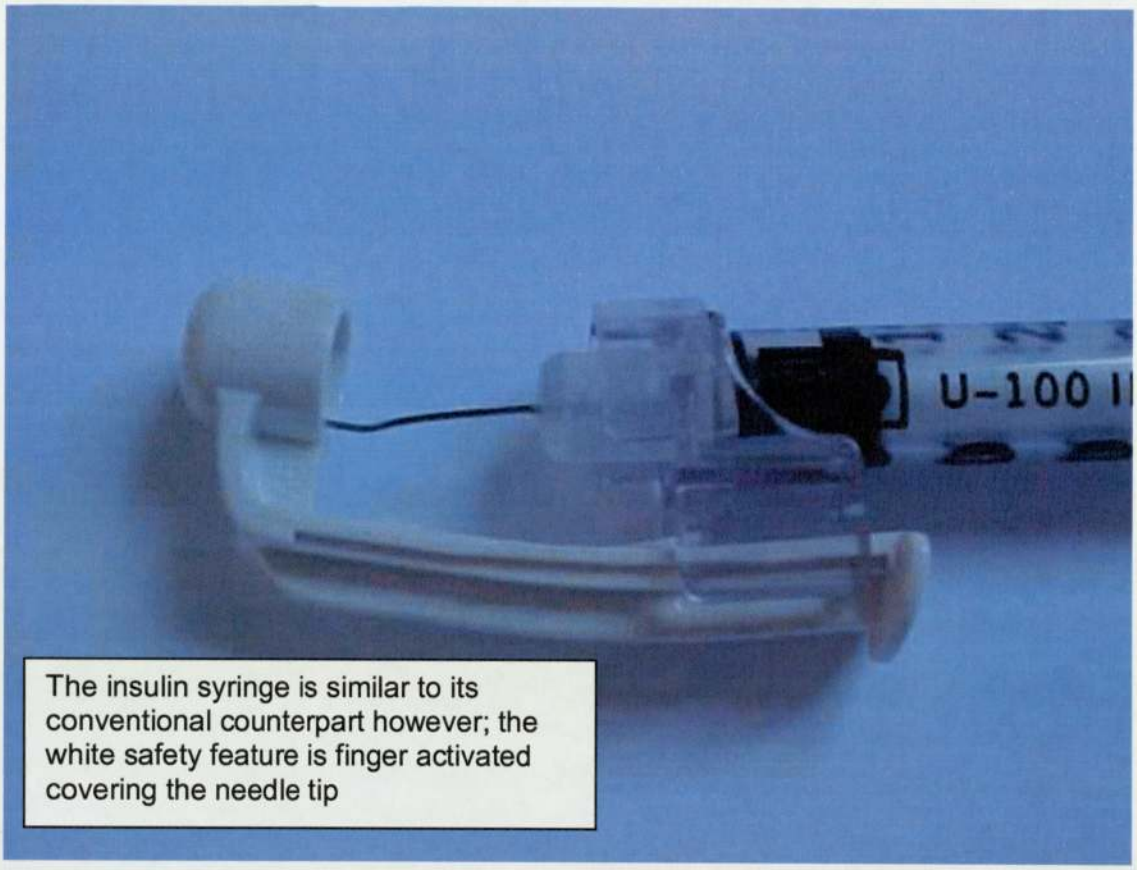
Figure 1.16: BD Eclipse™ hypodermic needle.



1.17: BD Safetyglide™.



1.18: BD Safetyglide™ insulin unit.



The insulin syringe is similar to its conventional counterpart however; the white safety feature is finger activated covering the needle tip

1.12.7 Implementing needle protective devices and cost benefit analysis

There is no one absolute approach to PII prevention. Prevention may include leadership, support from senior management, device evaluation and selection, training and education, policy and procedure, universal precautions and knowledge of behaviour change. Prevention strategies are supported by the UK DH (1998), and should be considered as part of Clinical Governance, the Health and Safety at Work Act (1974), Management of Health and Safety at Work Regulations (1999) and Control of Substances Hazardous to Health (1994) (Adams and Elliott, 2002). Indeed, prior to implementing NPDs, a user acceptability study should be undertaken (Adams and Elliott, 2003).

Factors influencing the implementation of NPDs included HCW resistance to change, improper use, changes to operator technique, compatibility with conventional products, cost of the device and inadequate training (Doebbeling, 2003; Sinclair *et al.*, 2002; Mummery, 2002; OSHA, 1999; Nixon *et al.*, 1986). Indeed, NPDs may not be entirely reliable in preventing PIIs (Department of Health Services, 2002; Short Life Working Group, 2001; CDC, 2000; Osborn *et al.*, 1999). More recently, Rivers *et al.*, (2003) identified that nurses who had adequate training, a positive institutional safety climate, who had worked in the hospital for a short period and who had used a NPD for more than 6 months were more likely to use NPDs. The study concluded that to ensure maximum implementation of NPDs, efficacious training and a supportive and safety conscious clinical environment was essential (Rivers *et al.*, 2003).

A cost-benefit analysis of NPDs should be undertaken before purchasing decisions are made (May and Brewer, 2001). The analysis should include all factors associated with the PII, including time completing incident forms, investigating the incident, statutory sick pay, staff turnover, replacement staff, training and management costs (Mummery, 2002; RCN, 2001), in addition to the cost of the NPD.

Attempts have been made at cost-benefit analysis; however, a lack of comprehensive data resulted in incomplete or estimated findings (Short Life Working Group, 2001; Heinrich, 2000). Indications to date are that the use of NPDs would be cost effective in the longer term (Whitby and McLaws, 2002; Tan *et al.*, 2001; Jagger *et al.*, 1990). However, the financial implications of these new devices, in addition to that of education and training, may be primary obstacles in preventing their implementation (OSHA, 1999).

Chelsea and Westminster NHS Trust, in London, reviewed the cost implications of NPDs. They reported that the purchase price of NPDs was approximately £136,000,

greater than the predicted financial saving. However, they also incorporated the unquantifiable impact of PIIs, including anxiety, performance, fines for breaches of health and safety legislation, in addition to the potential higher risk of injuries sustained via IV peripheral catheters. The Trust concluded that implementation of NPDs should be undertaken (NAO, 2003).

The cost of NPDs has been highlighted as preventative to their implementation in the UK (Jagger, 2002; Connnington, 2002; Munro, 2001; Godfrey, 2001), however in the USA, due to legislative action, economies of scale reduced the cost of NPDs due to competition between product companies, attempting to gain a market share in this new product area (Jagger, 2002).

The majority of studies estimating the cost of PIIs were conducted in the USA; however, such data may be limited due to a lack of standardised costing methods (Jagger *et al.*, 1998). Furthermore, cost evaluations from other countries are of limited use in the UK, because local currency was used. In 2001, the Infection Control team at the UHB NHS Trust evaluated the financial implication of a single PII to be £912.82, which included blood screening, counselling and treatment, but did not consider employee absence, the cost of agency staff and other hidden costs (unpublished). Furthermore, the estimated cost of the PEP treatment pack, which provided 3 days treatment, was £298.35 (unpublished). The Short Life Working Group (2001) estimated that a PII may cost £10 to £620,000 depending on the severity of the injury (table 1.9).

Table 1.9: Estimated financial cost of percutaneous inoculation injuries (Short Life Working Group, 2001).

Severity of percutaneous inoculation injury (PII)	Financial cost
PIIs that result in the transmission of blood borne pathogens.	£10,000 - £620,000
PIIs from source patients known to be high risk or positive for a blood borne pathogen.	£3,000 - £5,000
Downstream injuries where the source patient cannot be traced.	£1,000 - £2,000
Low risk PIIs reported to Occupational Health and Safety or the out of hours alternative.	£50 - £100
Rarely reported or non reported PIIs.	£10

Currently in the UK, it is estimated that a low-risk PII may cost £450 to manage. However, a high-risk injury may cost £4,000, including PEP and referral to a specialist practitioner (Mummery, 2002). Moreover, if a HCW did contract HIV or hepatitis following occupational exposure, the compensation awarded may outweigh the increase in device cost. Previously, individual litigation cases emphasised the potential financial implication of PIIs, for example 1 doctor received £460,000 compensation following a PII (Hayes, 1999).

The number of reported PIIs and their consequent impact were reviewed within 1 teaching hospital in London. The estimated total time spent managing the 208 PIIs was 1507 hours, the equivalent of 188 working days. In addition, the direct and indirect financial cost to the Trust was estimated at £75,000 (Williams, 2003).

1.13 Aims of the current study

1.13.1 Audit of percutaneous inoculation injuries

The aims of this study were to identify:

- the number of reported PIIs within UHB NHS Trust prior to and throughout the study period.
- the cause of injury associated with device.
- the methods utilised by HCWs to report PIIs.

1.13.2 Under reporting of percutaneous inoculation injuries

The aims of this study were to:

- evaluate the rate of unreported PIIs within UHB NHS Trust among clinical and ancillary staff.
- identify the number of near miss incidents experienced by ancillary staff within the Trust.
- identify reasons for not reporting PIIs.

1.13.3 Evaluation of staff knowledge regarding inoculation injuries and associated issues

The aims of this study were to identify:

- knowledge of inoculation injuries among HCWs within UHB NHS Trust.
- healthcare workers' level of knowledge of the Trust policy on reporting and managing PIIs.
- use of gloves among HCWs within the Trust.
- reasons for not reporting PIIs.
- knowledge of NPDs among HCWs within the Trust.
- the efficacy of training and education within the Trust associated with PIIs.

1.13.4 Evaluation of a needle protective intravenous peripheral catheter

The aims of this study were to:

- implement a new NPD, BD Safelon™ Pro (SLP) needle protective IV peripheral catheter, into UHB NHS Trust.
- evaluate HCWs' usability and acceptability of SLP.
- evaluate the efficacy of SLP in reducing associated PIIs.

Chapter 2: Education, training and reported percutaneous inoculation injuries

2.1 Introduction

The importance of education and training in raising awareness of the risks associated with PIIs has been emphasised (Twitchell, 2003; Short Life Working Group, 2001; RCN, 2001; DH, 2001) and is a requirement of the Control of Substances Hazardous to Health (COSHH) regulations (1994) (Adams and Elliott, 2002). It was suggested that Occupational Health and Safety departments were integral to educating HCWs in safe work practices in the clinical setting and that hospital induction programmes could be utilised to introduce sharps management training (Twitchell, 2003; Short Life Working Group, 2001). However, there have been inequalities in the provision of formal training for professional groups within healthcare (Stein *et al.*, 2003).

Within UHB NHS Trust, education and training in sharps management and inoculation injuries was initiated at the Trust's induction day, mandatory for all new Trust employees. During this day, the Infection Control team provided information regarding basic universal precautions and sharps management. The Occupational Health and Safety department highlighted the role of the team, management of inoculation injuries and associated issues. In addition, Risk Management provided an overview of the incident reporting policy. Following induction, professional groups were offered a continuing educational programme illustrated in table 2.0. However, there was no robust process by which attendance was monitored for either induction or continuing education programmes. Furthermore, the level of input offered to professional groups varied. For example, all clinical staff except doctors and phlebotomists had annual update sessions provided by both Infection Control and Occupational Health and Safety departments. Conversely, doctors' educational input regarding PIIs and

associated risks was delivered during their induction programme and subsequently 'on the job', with senior colleagues emphasising the potential impact of sustaining a high risk PII on their career. Phlebotomists received intermittent update sessions.

Table 2.0: Current teaching and education on universal precautions, inoculation injuries and associated issues at University Hospital Birmingham NHS Trust.

Profession	Teaching and Education
All staff (clinical and non clinical)	
Trust induction	All staff starting at the Trust attend the Trust's induction day.
Infection Control	Role of the team, universal precautions, safe disposal of sharp devices.
Occupational Health and Safety	Role of the team, management of inoculation injuries, and all aspects associated with staff health.
Risk Management	Reporting inoculation injuries and other incidents.
Nursing staff/surgical theatre staff	
Annual mandatory update	
Infection Control	Universal precautions including safe disposal of sharp devices.
Occupational Health and Safety	Inoculation injuries and associated issues.
Medical staff	
Induction for medical staff	
Infection Control	Hand washing and protocol for treating specific infections.
Occupational Health and Safety	Occupational health overview including reporting inoculation injuries.
Annual update	
Infection Control	No annual update sessions provided.
Microbiology	Ad hoc teaching sessions by Consultant Microbiologists.
Phlebotomy staff	Ad hoc annual update sessions provided.

The Trust's 'inoculation review group' was established in 2000, comprising representatives from Infection Control, Occupational Health and Safety, Risk Management and Clinical Microbiology departments. The Clinical Research Nurse (J Trim) joined the group in October 2001. During 2000, the group raised awareness of

inoculation injuries, safe disposal and use of sharp devices in the clinical setting and NPDs. Twitchell (2003) commented that Occupational Health advisors should be active members of committees, which raise awareness of the risks associated with blood borne pathogens and strategies to reduce this risk. In July 2001, a roadshow was held across the Trust, to launch the revised inoculation injury policy. Posters and leaflets on the management of inoculation injuries were distributed to all Trust employees via their monthly payslips and during the roadshow, to update knowledge and raise awareness. In addition, the use of trays incorporating both a sharps disposal container and an area for equipment were encouraged. Due to the success of this strategy, the roadshow became an annual event.

In August 2001, the department of Clinical Microbiology undertook an audit of unreported PIIs. Eighty four HCWs working at Queen Elizabeth Hospital, UHB NHS Trust, including junior doctors, nurses and phlebotomy staff, completed an anonymous standardised questionnaire. Sixty five percent of PIIs were not reported (Dobie *et al.*, 2002).

In October 2001, an open day was held at Queen Elizabeth Hospital, UHB NHS Trust. Eight product companies displayed and demonstrated a variety of NPDs. All HCWs and managers were invited to the day and were encouraged to evaluate the devices.

The need to collect PII data has been emphasised both in the UK and USA, to identify hazards in the workplace (Bourn, 1996) and provide information upon which evidence-based decisions on safer working practices can be made (May and Churchill, 2001). In the USA, following legislation in 2001, all employers were mandated to collect PII data (Clarke *et al.*, 2002; May and Churchill, 2001). However in the UK, there is currently no co-ordinated national surveillance of PIIs, although many hospitals collect and analyse their own data, which frequently lacks consistency (May and Churchill, 2001; Short Life

Working Group, 2001). At UHB NHS Trust, PII data were held within Occupational Health and Safety, the serology laboratory and Risk Management departments. The serology laboratory held written documentation of the samples sent for serological analysis following PII. Occupational Health and Safety documented PIIs sustained by staff on their individual files in addition to written data sheets detailing the injury. On receipt of Risk Management incident forms, the department entered the information onto a centralised database.

The aims of this study were to evaluate the number of reported PIIs within UHB NHS Trust one year prior to and during the study period, the device involved with the incident, cause of injury and methods of reporting.

2.2 Methods and materials

Commencing January 2001, reported PII data were collected every 6 months from the serology laboratory, Occupational Health and Safety and Risk Management departments. The information was 'matched' from each data source using a combination of date and staff name to identify the reporting method. Where possible, the type of device was documented for each injury, frequently determined by the degree of detail documented by the Occupational Health and Safety department or the person completing the Risk Management incident form.

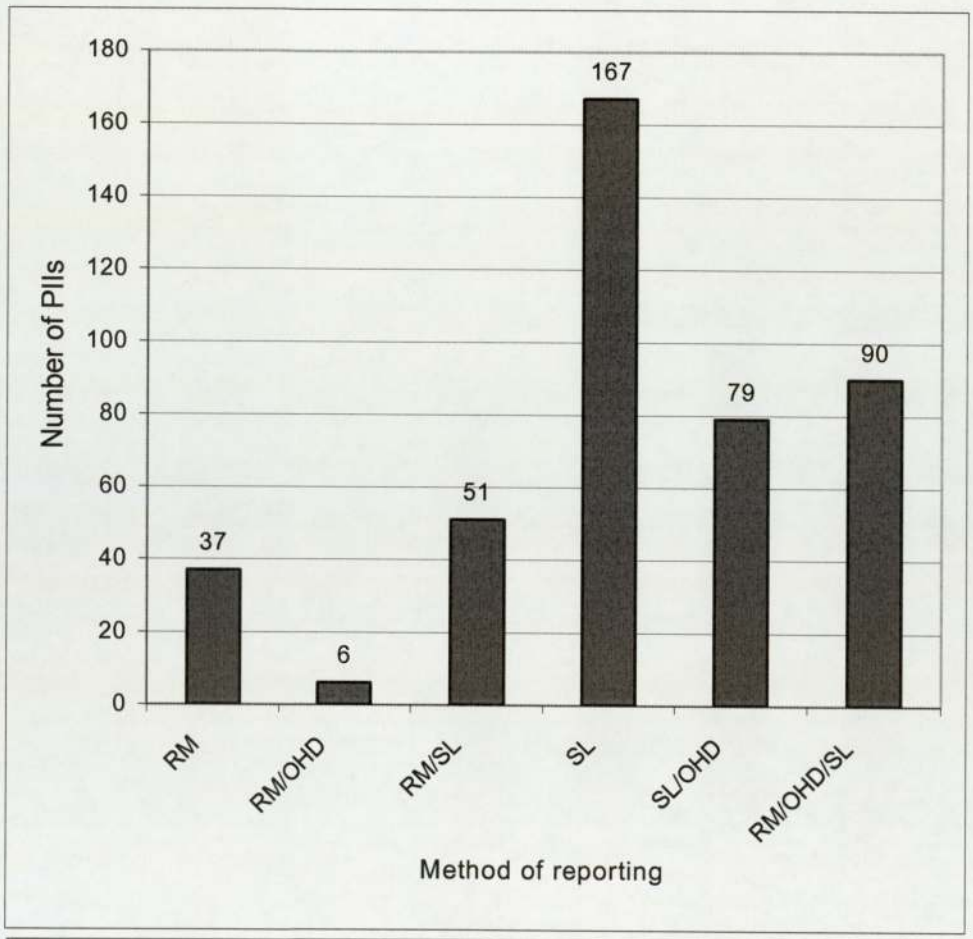
From July 2002, in an attempt to improve data analysis, data were entered into a Microsoft™ Access97 database. In addition, where available, information to the cause of injury was documented. Non parametric statistical analysis, including Binomial Confidence Interval (CI) Test and Fisher's Exact Test were applied, where appropriate, utilising commercially available software (http://www.statpages.net).

2.3 Results

2.3.1 January to December 2001

Between January and December 2001, 430 PIIs were reported to the Trust. Methods of reporting these injuries are illustrated in figure 2.0.

Figure 2.0: Methods of reporting percutaneous inoculation injuries at University Hospital Birmingham NHS Trust from January to December 2001 (n=430).



Key:
RM = Risk Management SL = serology laboratory
OHD = Occupational Health and Safety
PIIs = percutaneous inoculation injuries

Ninety out of four hundred and thirty PIIs (21%, 95% CI 17-25%) were reported to Risk Management, Occupational Health and Safety and serology laboratory departments,

adhering to Trust policy. Most frequently, however, PIIs were identified from blood samples sent for serological analysis (167 out of 430, 39%, 95% CI 34-44%). Comparatively, 79 out of 430 (18%, 95% CI 14-22%) PIIs were reported to Occupational Health and Safety and the serology laboratory, 51 out of 430 (12%, 95% CI 9-15%) to Risk Management and the serology laboratory, 6 out of 430 (1%, 95% CI 0.5-3%) to Risk Management and Occupational Health and Safety and 37 out of 430 (9%, 95% CI 6-12%) to Risk Management alone. Significantly more HCWs reported PIIs to the serology laboratory by requesting blood tests, than reporting the incident according to Trust policy (p=0.0001, Fisher's Exact Test). A potential 37 out of 430 (9%) HCWs did not have blood samples taken for serological testing because they only completed a Risk Management incident form. The number of PIIs sustained per month was similar, ranging from 26 to 55 per month, with a mean of 36 (table 2.1).

Table 2.1: The number of reported percutaneous inoculation injuries between January and December 2001 associated with month and method of reporting.

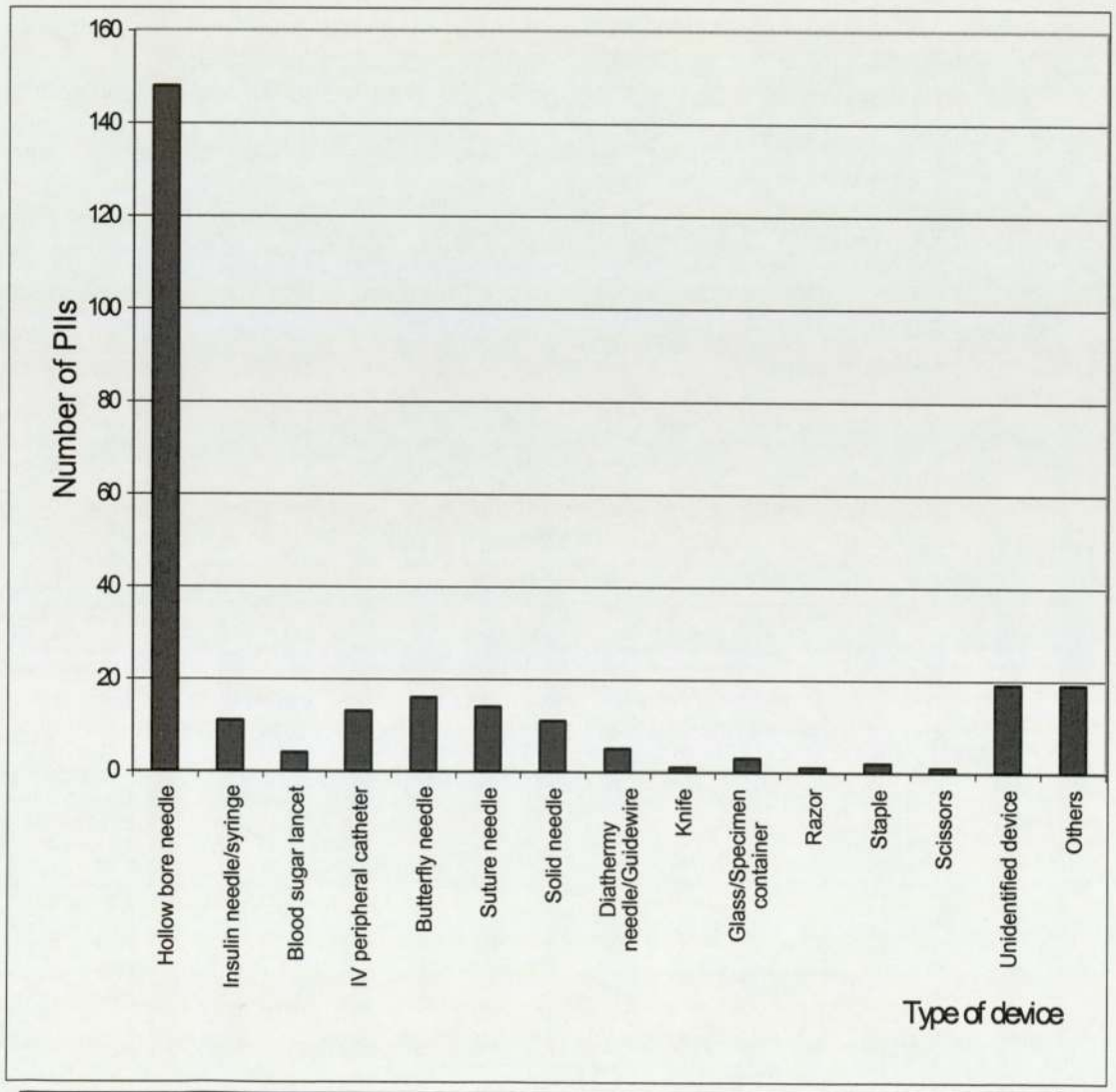
	J	F	M	A	M	J	J	A	S	O	N	D	Total
RM	4	3	4	1	2	4	3	2	6	4	1	3	**37**
RM/OHD	0	0	0	0	1	0	2	0	0	1	2	0	**6**
RM/SL	2	9	2	5	4	3	2	2	9	3	4	6	**51**
SL	15	9	15	14	12	18	11	13	18	16	11	15	**167**
SL/OHD	9	4	3	6	3	6	9	7	14	7	4	7	**79**
RM/OHD/ SL	12	13	8	6	11	5	3	5	8	9	4	6	**90**

Key:
RM = Risk Management OHD = Occupational Health and Safety
SL = serology laboratory

Letters denote month of the year

The device causing injury was documented for 268 out of 430 (62%) reported incidents. Data were not available for the remaining injuries. PIIs were most frequently caused by hollow bore needles (148 out of 268, 55% 95% CI 49-61%), compared with butterfly needles (16 out of 268, 6% 95% CI 3-9%), suture needles (14 out of 268, 5% 95% CI 3-9%) and IV peripheral catheters (13 out of 268, 5% 95% CI 3-8%). Healthcare workers were injured by hollow bore needles significantly more frequently than IV peripheral catheters (p=0.0001, Fisher's Exact Test). Other sharp devices causing PIIs are illustrated in figure 2.1.

Figure 2.1: Device associated with percutaneous inoculation injuries reported between January and December 2001 (n=268).

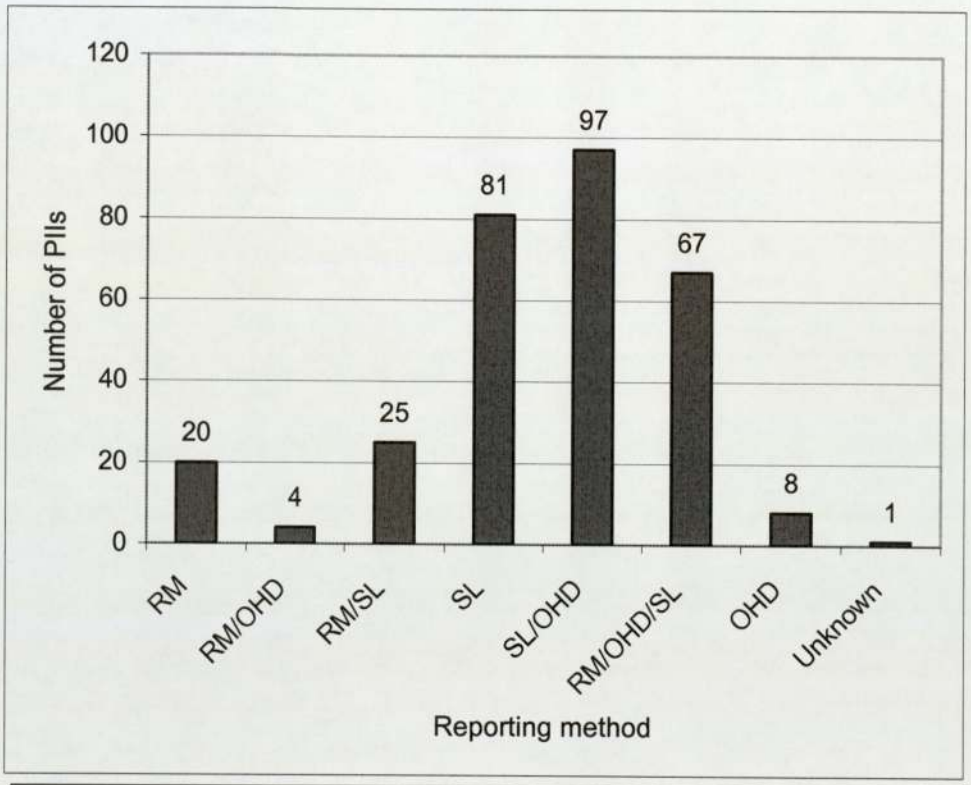


Key: PIIs = percutaneous inoculation injuries IV = intravenous

2.3.2 January to December 2002

Between January and December 2002, 303 PIIs were reported to the Trust. The method of reporting is illustrated in figure 2.2.

Figure 2.2: Methods of reporting percutaneous inoculation injuries sustained between January and December 2002.



Key:
RM = Risk Management
SL = serology laboratory
OHD = Occupational Health and Safety
PIIs = percutaneous inoculation injuries

Eighty one out of three hundred and three PIIs (27%, 95% CI 22-32%) were identified by the serology laboratory due to HCWs requesting post PII blood analysis. Ninety seven out of three hundred and three (32%, 95% CI 27-38%) PIIs were reported to Occupational Health and Safety and the serology laboratory. In comparison, 67 out of 303 (22%, 95% CI 18-27%) HCWs adhered to Trust policy and reported the PII to Risk Management, Occupational Health and Safety and had blood samples taken for

serological testing. The number of PIIs reported according to Trust policy and those received by the serology laboratory were not significantly different (p= 0.1874, Fisher's Exact Test). Twenty out of three hundred and three (7%) HCWs did not have blood taken for testing following the PII because they did not follow the correct procedure and only completed a Risk Management incident form.

The number of PIIs sustained per month and method of reporting is shown in table 2.2. The mean number of PIIs per month was 25, with a range between 13 and 48.

Table 2.2: Number of reported percutaneous inoculation injuries between January and December 2002 associated with month and method of reporting.

	J	F	M	A	M	J	J	A	S	O	N	D	Total
RM	1	2	3	1	4	1	1	1	2	1	2	1	**20**
RM/OHD	1	0	1	1	0	0	0	1	0	0	0	0	**4**
RM/SL	5	3	5	1	4	1	0	2	2	0	2	1	**26**
SL	9	8	13	11	23	9	1	2	0	2	0	3	**81**
SL/OHD	4	4	4	8	8	9	9	14	7	10	12	8	**97**
RM/OHD/ SL	6	3	3	4	8	5	10	7	1	6	5	9	**67**

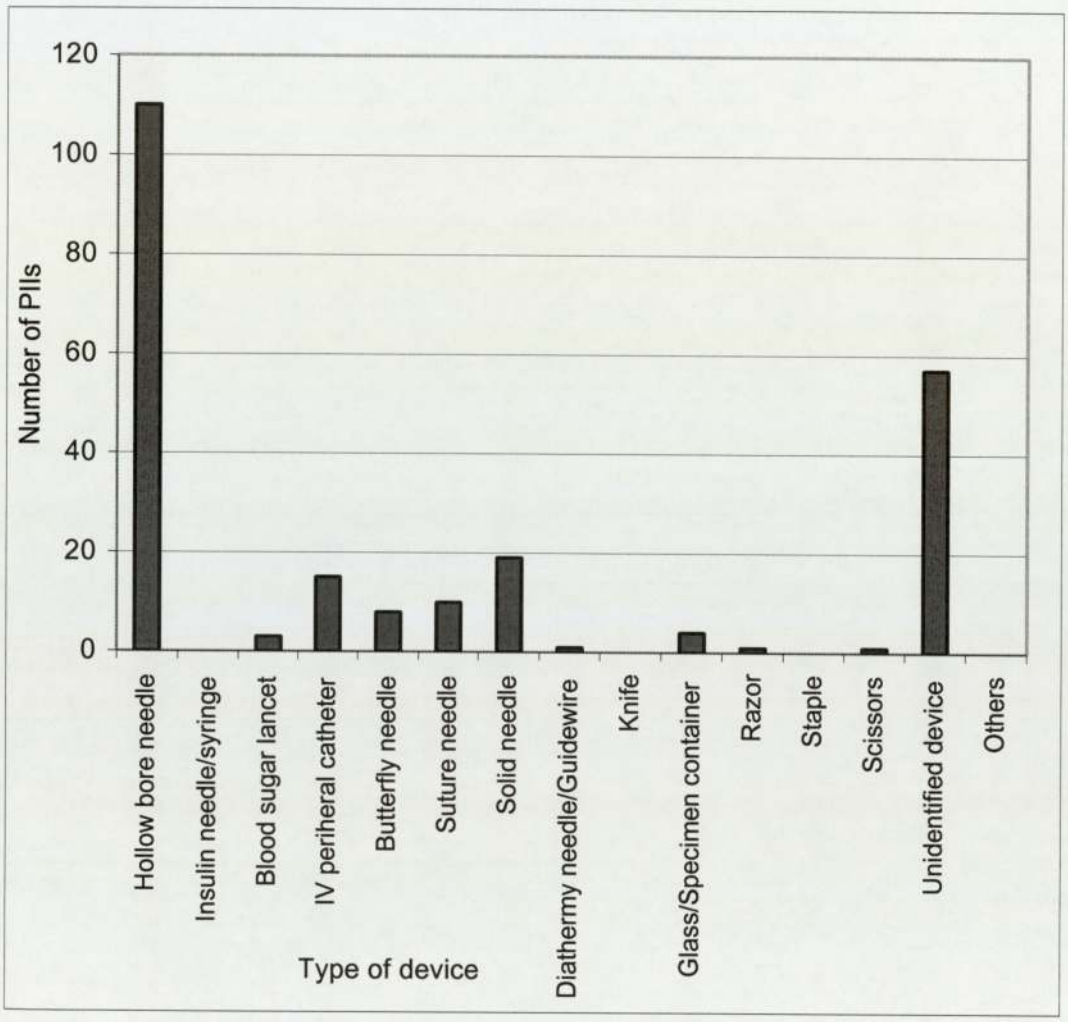
Key:
RM = Risk Management OHD = Occupational Health and Safety
SL = Serology Laboratory

Letters denote the month of the year

Information pertaining to the type of device involved in the PII was documented for 246 out of 303 (81%) reported PIIs (figure 2.3). One hundred and ten out of two hundred and forty six (45%) injuries involved a hollow bore needle. Fifteen out of two hundred and forty six (6%) PIIs were sustained via an IV peripheral catheter. A significantly

higher number of reported PIIs were sustained via a hollow bore needle when compared with IV peripheral catheters (p= 0.0001, Fisher's Exact Test). Other sharp devices causing PIIs are illustrated in figure 2.3.

Figure 2.3: Type of device associated with reported percutaneous inoculation injuries between January and December 2002 (n=229).



Key: IV = intravenous PIIs = percutaneous inoculation injuries

In July 2002, a Microsoft™ Access97 database was developed to collate the information and improve PII data analysis. Consequently, from July to December 2002, the cause of injury was documented, where possible from the available data. Of

the 129 PIIs reported between July and December 2002, 47 (36%) incident reports gave some information as to the cause of injury (table 2.3). Nine out of forty seven (19%) incidents occurred whilst attempting to dispose of the sharp device. Ten out of forty seven (21%) were downstream injuries (the injured HCW was not the original user of the device). Of these, 5 out of 10 (50%) incidents occurred during a surgical procedure.

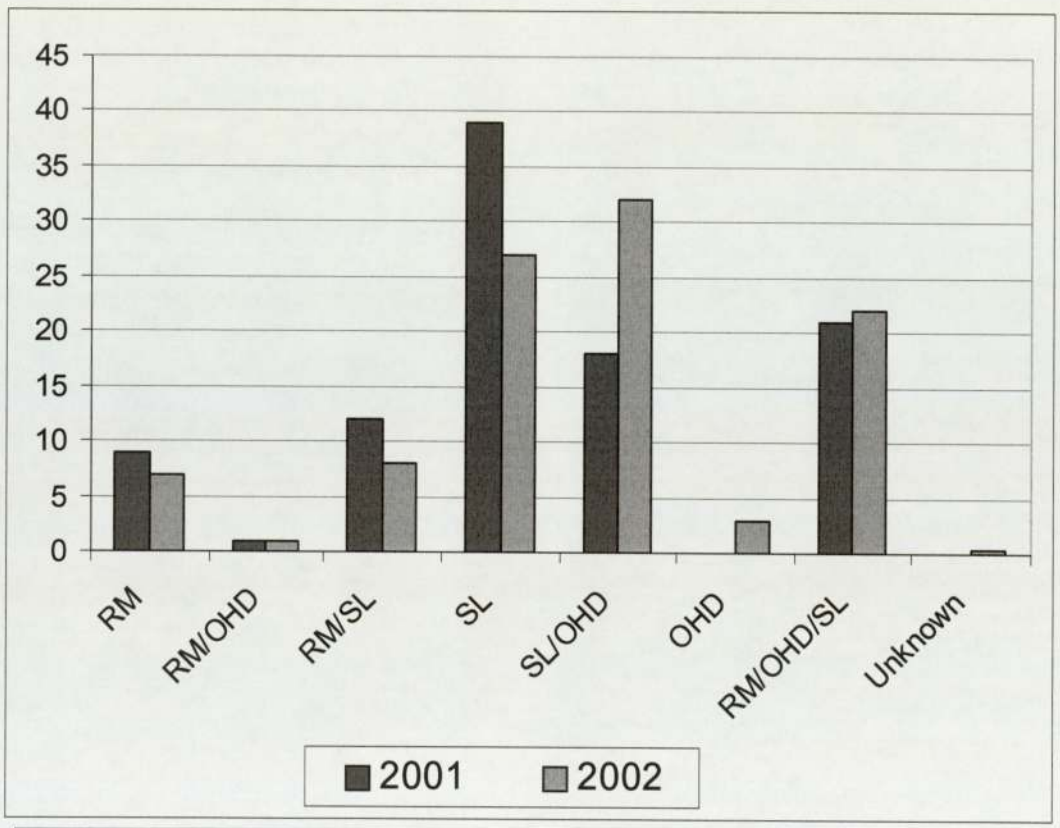
Table 2.3: Cause of reported percutaneous inoculation injuries between July and December 2002 (n=47).

Cause of injury	Number of percutaneous inoculation injuries sustained
Injections:	
Unknown type	4
Subcutaneous	2
Butterfly needle	1
Inserting intravenous peripheral catheters	2
After a procedure:	
Unknown procedure	4
Measuring a patient's blood sugar	2
Venepuncture	1
Re-sheathing the used needle	1
Downstream injury:	
Needle in mop	1
Needle in bin	1
Placing needles on a disposal pad in theatres	2
Disposing needles used by other healthcare workers	6
During disposal of the device:	
Intravenous peripheral catheter	1
Unknown device	6
Butterfly needle	2
During a procedure:	3
Whilst obtaining a sterile urine sample	1
Other causes:	
Broken glass/specimen containers	3
Clean needle	1
Scratch from a needle	2
Returning needle to its packaging	1

2.3.3 Comparison of percutaneous inoculation injury data from 2001 and 2002

The total number of PIIs fell by 127 (30%) from 2001 to 2002 and the number of PIIs reported according to Trust policy fell from 90 in 2001 to 67 in 2002. When these figures were illustrated as a percent of the total number of PIIs reported each year, the number of HCWs who reported according to Trust policy rose by 1% (figure 2.4).

Figure 2.4: Comparison of the method of reporting percutaneous inoculation injuries as a percentage of the total number during 2001 and 2002.



Key:
RM = Risk Management
SL = serology laboratory
OHD = Occupational Health and Safety

The number of PIIs identified via the serology laboratory alone fell by 12% (167 in 2001 to 81 in 2002). Furthermore, the number of completed Risk Management incident forms decreased by 2% (37 in 2001 to 20 in 2002). In 2002, 8 PIIs were reported to the Occupational Health and Safety department alone, which was not documented in 2001.

In 2001, a significantly higher number of HCWs only sent blood samples for serological testing when compared with those who adhered to the Trust policy ($p=0.0001$, Fisher's Exact Test). However when the same comparisons were made in 2002, there was no significant difference. Indeed, the reduced overall number of PIIs reported in 2002 was reflected in the decreased mean number of injuries reported each month (25 in 2002 compared with 36 in 2001).

The type of device involved in the incident was compared (table 2.4). The number of reported incidents that detailed the cause of injury rose from 62% in 2001 to 81% in 2002. Hollow bore needles were associated with the highest number of PIIs, however in 2002 the total number decreased by 7%. The number of PIIs sustained via IV peripheral catheters increased by 1% between 2001 and 2002. In 2002, PIIs sustained via butterfly needles decreased by half, however those sustained whilst using solid needles doubled. The number of incidents where the device was not disclosed increased by 18% in 2002.

Table 2.4: Comparison of the type of device documented with reported percutaneous inoculation injuries in 2001 and 2002.

Key: IV = intravenous % = percentage

Type of device	2001	% 2001	2002	% 2002
Hollow bore needle	148	**55**	110	**48**
Insulin needle/syringe	11	**4**	0	**0**
Blood sugar lancet	4	**1**	3	**1**
IV peripheral catheter	13	**5**	15	**6**
Butterfly needle	16	**6**	8	**3**
Suture needle	14	**5**	10	**4**
Solid needle	11	**4**	19	**8**
Diathermy needle/Guidewire	5	**2**	1	**1**
Knife	1	**1**	0	**0**
Glass/Specimen container	3	**1**	4	**2**
Razor	1	**1**	1	**1**
Staple	2	**1**	0	**0**
Scissors	1	**1**	1	**1**
Unknown device	19	**7**	57	**25**
Others	19	**7**	0	**0**

2.4 Discussion

2.4.1 Method of reporting percutaneous inoculation injuries

Seven hundred and thirty three PIIs were reported over the 2 year period. These figures could not be directly compared with previous studies because varying study methodologies and denominators were utilised (Gillen *et al.*, 2002). Dobie *et al.*, (2002) reported 195 PIIs in one year within UHB NHS Trust; however, it was not clear which data were utilised to determine this rate.

The number of reported PIIs decreased over the two year period, however there was minimal increase in HCWs reporting their injuries according to Trust policy (Risk Management, Occupational Health and Safety and the serology laboratory) in addition to fewer PIIs being identified via the serology laboratory alone. There was an increase in HCWs seeking advice from the Occupational Health and Safety department and subsequently having blood taken for serological analysis. Indeed, the total number of HCWs who had blood samples taken for analysis increased by 17%. A proportion of HCWs continued to report their injuries to the Risk Management department alone, inferring that no blood samples were taken and consequently no documentation in their personal file in the Occupational Health and Safety department. The majority of previous studies did not focus on whether PIIs were reported according to Trust policy and therefore comparisons could not be made.

The time taken to report injuries according to Trust policy may have discouraged notification. Anecdotally, the policy and necessary documentation was frequently perceived as laborious, therefore some HCWs sent their own blood for serological analysis, without contacting Occupational Health and Safety or completing a Risk Management incident form. In addition, the Trust was situated on two sites, Queen Elizabeth Hospital and Selly Oak Hospital. Occupational Health and Safety and

Accident and Emergency departments were both situated at Selly Oak Hospital. Thus, HCWs at Queen Elizabeth Hospital had to journey to the other site following PIIs, which may at times have been difficult due to pressure of workload or staff shortages.

Healthcare workers may also have been influenced by their colleagues. Previous studies documented senior staff discouraging HCWs from reporting injuries (Osborn *et al.*, 1999) and that staff were more likely to adhere to practice if it was perceived as the 'norm' within their clinical area (Godin *et al.*, 2000). In an attempt to encourage reporting, the Risk Management incident form was reviewed and modified in 2002. However, despite these modifications, initial results indicated that minimal impact was made on the number of HCWs completing Risk Management incident forms following PIIs. Indeed, this figure decreased from 43% in 2001 to 38% in 2002. To comprehensively review the impact of the modified form, further information would be required during 2003.

2.4.2 The main risk associated with percutaneous inoculation injuries

The main risk of PIIs was via hollow bore needles. The number of injuries sustained whilst using hollow bore needles were significantly higher when compared with IV peripheral catheters (p=0.0001, Fisher's Exact Test). This may reflect the large number of needles and diversity with which they were used within the Trust by all HCWs, in particular nurses. At UHB NHS Trust in one year, 1,119,680 hollow bore needles were used compared with 124,806 IV peripheral catheters (unpublished). This finding concurred with previous literature evidence highlighting that PIIs were most frequently sustained via hollow bore needles (Tomkins *et* al., 2003; RCN, 2002; Whitby and McLaws, 2002; Rabaud, 2000; Greene *et al.*, 1998). Furthermore, previous evidence found that nurses reported the majority of PIIs (Clarke *et al.*, 2002; Gershon *et al.*, 1999), which may be associated with hollow bore needles being the main risk.

The nurse role includes administering the majority of injections, IV medication and increasingly venepuncture and IV catheterisation, all utilising hollow bore needles.

2.4.3 Raising awareness, training and education

The combination of training, education and raising awareness of the risks associated with PIIs may have resulted in safer work practices and reduced PIIs over the two year study period. The introduction and encouragement to use trays, that included a sharps container as well as an area for equipment, may have reduced injuries by increasing the number of sharp devices disposed at the point of use. Previous studies identified that PIIs were sustained after use but before disposal (Do *et* al., 2003; RCN, 2002; Department of Health Services, 2002). In the recent NAO (2003) report, Rotherham General Hospital reduced their reported PIIs by 42% by introducing these trays and removing all other sharps disposal containers.

Alternatively, the reduction in reported PIIs may have been that increasing numbers of HCWs did not report their injuries, subsequently giving a false reduction in the incidence of reported injuries. Healthcare workers may have been concerned with the potential consequences of a positive result and therefore failed to formally report the incident for fear of the result. Moreover, increased awareness of the DH guidelines on HCV testing (DH, 2002) may have prevented HCWs from reporting their injuries.

Despite efforts to educate HCWs in the importance of reporting PIIs, current educational programmes had minimal impact on improving practice. As such, it would be necessary to gain a formal understanding of why HCWs did not adhere to Trust policy, investigate strategies that would improve compliance in addition to reviewing current educational programmes to ensure their efficacy. With reference to medical students and doctors, structured mandatory education on the risks associated with PIIs

and the importance of reporting these injuries should be considered. Other strategies to encourage reporting could include telephone stickers with contact numbers and a brief outline of the reporting procedure (Holodnick, 2000). In addition, varying poster displays ensuring annual updates may prevent posters losing their impact and continually reiterate good practice.

2.4.4 Limitations

The reporting system may have influenced the number of identified incidents. Injuries were collated utilising two software systems in addition to written documentation regarding each incident. 'Matching' incidents may have resulted in inaccuracies; however, this was the only available method to collate the information. Risk Management's software system included a comprehensive description of the incident; however, the degree of detail relied on the HCW completing a detailed and accurate account of the incident. The software system used by Occupational Health and Safety did not include incident details and was not conducive to accurate analysis. May and Churchill (2001) and Short Life Working Group (2001) suggested that these methods of data collection lacked a co-ordinated approach.

Data collection may be improved by implementing a single system, utilised by Risk Management, Occupational Health and Safety departments and the serology laboratory. One solution may be to pilot the EPINet™ software (1.5.1) to improve the data collection process and improve data accuracy. Indeed, with its facility of data analysis, it may be possible to identify injuries that may have been prevented if NPDs were introduced.

It was not possible to determine whether the revised Risk Management incident form encouraged HCWs to report PIIs because it was introduced part way through 2002. Further data collection may identify whether the new incident form increased utilisation.

2.4.5 Recommendations

As discussed above, a single confidential data collection system may improve quality of data. By implementing a centralised system, data obtained from the three departments; namely Risk Management, Occupational Health and Safety and the serology laboratory could be integrated, allowing for improved data analysis, audit and consequent review. If this system were available in the clinical setting with departmental links, it may enable reporting to be undertaken immediately, including information which may be required by other departments to determine treatment, for example patient risk factors.

Data collection should incorporate HCWs' profession in relation to PIIs to establish if there is an association between profession and method of reporting or device causing injury. This information may then assist with identifying focus issues that, if addressed, may reduce the risk of PIIs and encourage reporting if HCWs witness evidence of action and change following formal reports.

A centralised database for monitoring attendance of the induction and education programmes should be implemented to ensure all HCWs are updated on an annual basis and to highlight reasons for non-attendance. Furthermore, the introduction of annual mandatory days, including all aspects of training which requires a yearly update, for example fire, manual handling, basic life support and infection control should be considered, to reduce the number of days each HCW is absent from the clinical setting. This may also enable the implementation of multidisciplinary training,

with doctors accessing this training as well as nurses and other healthcare professionals. Indeed, ensuring doctors complete annual training is imperative.

2.5 Summary

HCWs utilised a variety of methods with which to report PIIs, most frequently via the serology laboratory or Occupational Health and Safety. Furthermore, Risk Management incident forms were not routinely completed. Despite education, training and strategies to raise HCWs' awareness of the importance of reporting PIIs according to Trust policy, minimal impact was made on practice. Non compliance may reflect that HCWs perceived reporting incidents as arduous and unnecessary and the time required to visit Occupational Health and Safety or Accident and Emergency departments might have prevented their attendance. Alternatively, HCWs sending their own blood for serological analysis may have been deemed acceptable practice in a pressurised workplace. The main risk of PII was via hollow bore needles, which may have reflected the large number of needles used within the Trust or the profession of the injured HCW. However, the reporting system was inadequate to gain detailed information on each incident. By improving software systems, it would be possible to evaluate the association between type of device involved in the incident and the profession of the HCW, in addition to further information on cause of injury. Education and training programmes should be reviewed for their efficacy in addition to identifying why HCWs did not report PIIs according to Trust policy. Indeed, it may be necessary to implement structured training for medical students and doctors to ensure awareness of Trust policy. In addition, implementing a system to monitor attendance would highlight HCWs who require updates.

Chapter 3: The under reporting of percutaneous inoculation injuries

3.1 Introduction

Many attempts have been made to accurately determine the number of PIIs sustained in the healthcare setting. The rate, unfortunately, remains unclear due to under reporting (OSHA, 1999). Healthcare workers perceive PIIs to be an inherent part of handling sharp devices and therefore tolerate injuries without reporting (Jeanes, 1999). Indeed, the reluctance to report such incidents has been well documented over the last 20 years (Pugliese *et al.*, 2001; Jackson *et al.*, 1986; Hamory, 1983), with previous studies demonstrating an under reporting rate of between 26 and 91% (Dobie *et al.*, 2002; Haiduven *et al.*, 1999; Mercier, 1994).

Reasons for not reporting PIIs included pressure of workload, lack of awareness of the reporting procedure and risks associated with injury and self assessment of the incident (Short Life Working Group; 2001; Rabaud *et al.*, 2000; Burke and Madan, 1997). In addition, doctors have been reticent to report PIIs due to the potential subsequent restrictions on their clinical practice (Hanrahan and Reutter, 1997).

The aims of this study were to evaluate the number of PIIs not formally reported to UHB NHS Trust by ancillary and clinical staff, to evaluate the number of near miss incidents that ancillary staff experienced whilst working in the clinical area and reasons for not reporting both PIIs and near miss incidents. A near miss incident is a situation in which an event or omission or a sequence of events or omissions arising during clinical care fails to develop further whether or not as a result of compensating action, thus preventing harm or injury (DH, 2000).

3.2 Methods and materials

The rate of unreported PIIs was studied over 1 year at UHB NHS Trust between November 2001 and December 2002. In November 2001, participants documented any PII sustained over the previous year (November 2000 to November 2001), cause of injury and subsequent reporting behaviour. For each month, December 2001 to November 2002, participants recorded PIIs sustained in the previous month, to reduce recall bias. The Local Research Ethics Committee and the Trust's Clinical Governance and Research and Development departments granted approval of the study.

3.2.1 Clinical staff

Each month, the Clinical Research Nurse (J Trim) visited wards and units across the hospital at varying times during the day. A convenient sample of at least 20 HCWs were asked to participate in the study and verbal consent obtained. The sample were recruited from clinical staff working in clinical areas at the time of the visit and who were available to complete the questionnaire. The aims of the study were explained to all participants and anonymity was affirmed before the questionnaire (appendix 3A) was completed. This method of data collection was chosen because it enabled access to staff, of varying grades, who worked in the clinical arena and therefore at potential risk of PIIs.

3.2.2 Ancillary staff

On a monthly basis, the Assistant Site Hotel Services Manager distributed 20 questionnaires (appendix 3B) to a convenient sample of ancillary staff to evaluate the number of PIIs and near miss incidents. The sample were recruited from ancillary staff that were available to complete the questionnaire. Verbal consent was obtained prior to participation. The aims of the study and confirmation of anonymity were assured

when the Clinical Research Nurse met with all ancillary staff prior to commencing the study.

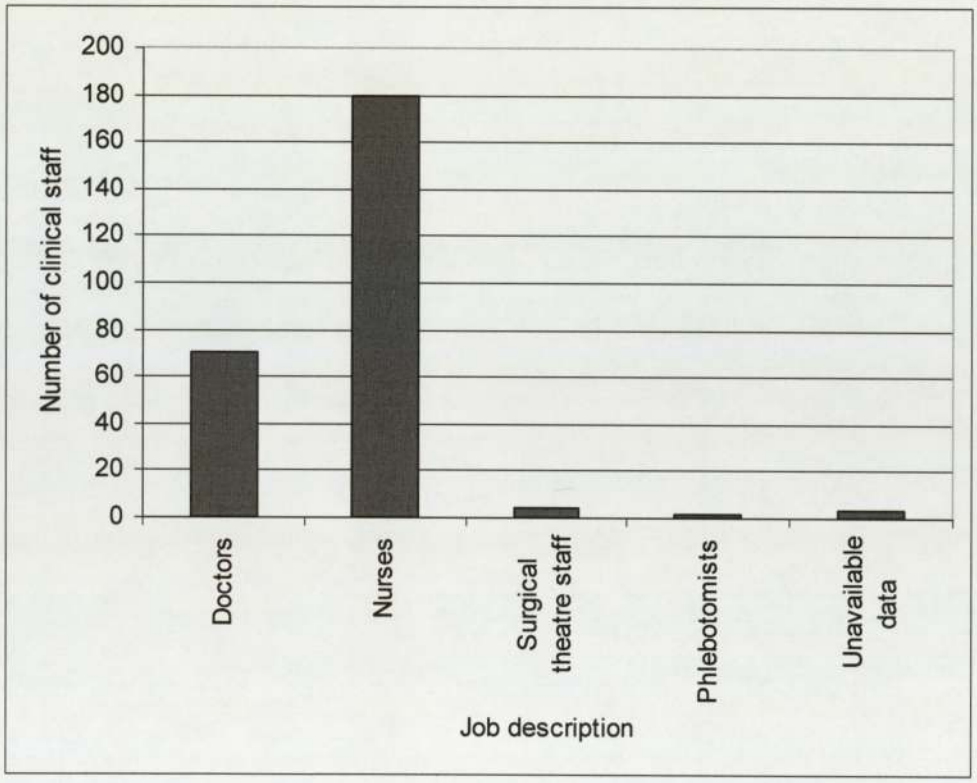
Data were collated utilising a Microsoft™ Access97 database. Where appropriate non parametric statistical analysis, including Binomial Confidence Interval and Fisher's Exact Test were applied using commercially available software (http://www.statpages.net). During data analysis, it was identified that a number of ancillary staff documented experiencing 'too many' and 'a few' near miss incidents. For the purpose of this study, these were recorded as 1 near miss incident.

3.3 Results

3.3.1 Clinical staff

Between December 2001 and November 2002, a total of 259 questionnaires were completed. Of these, 180 out of 259 (69%) were completed by nursing staff, 70 out of 259 (27%) by doctors, 4 out of 259 (2%) by surgical theatre staff, 2 out of 259 (1%) by phlebotomists and 3 out of 259 (1%) did not declare their professional status (figure 3.0).

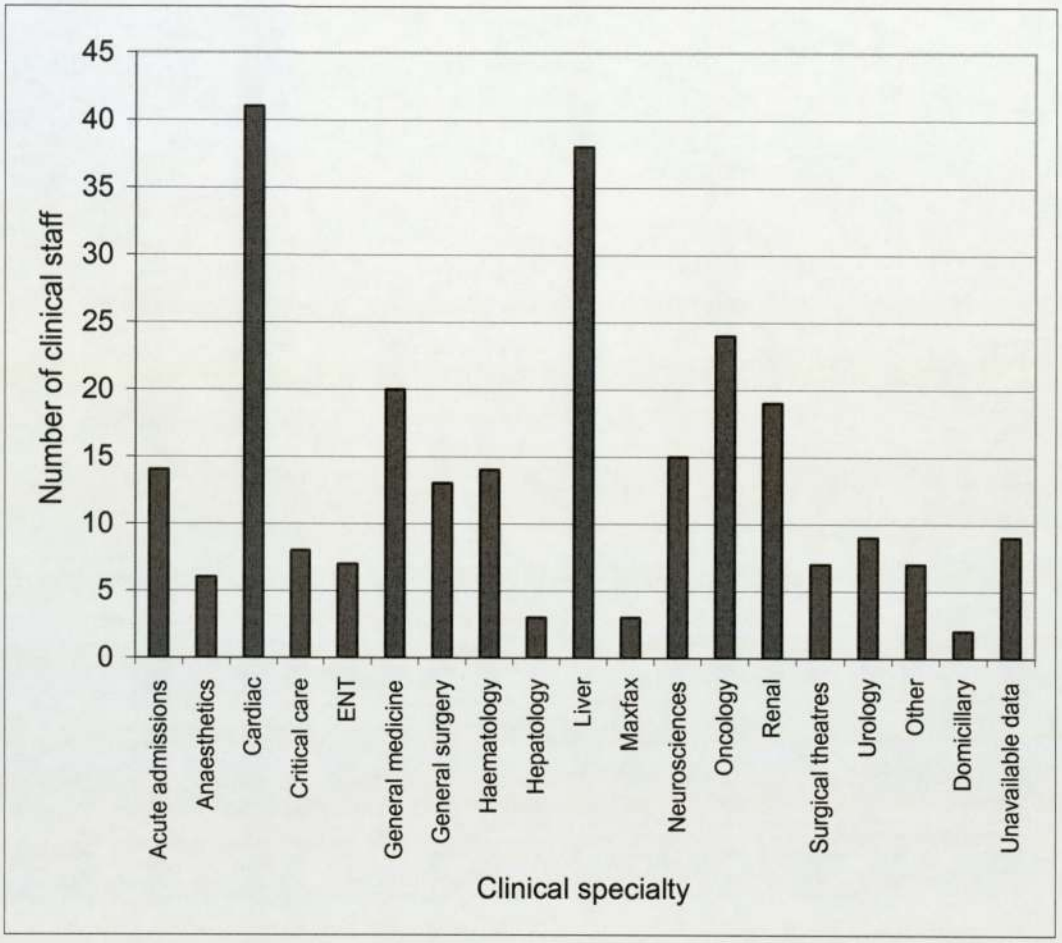
Figure 3.0: Job description of clinical staff.



Clinical staff worked within a variety of clinical specialities (figure 3.1). Thirty eight out of two hundred and fifty nine (15%) worked on the Liver Unit, compared with 41 out of 259 (16%) on the Cardiac Unit, 24 out of 259 (9%) in Oncology and 19 out of 259 (7%) in Renal services.

259 (16%) on the Cardiac Unit, 24 out of 259 (9%) in Oncology and 19 out of 259 (7%) in Renal services.

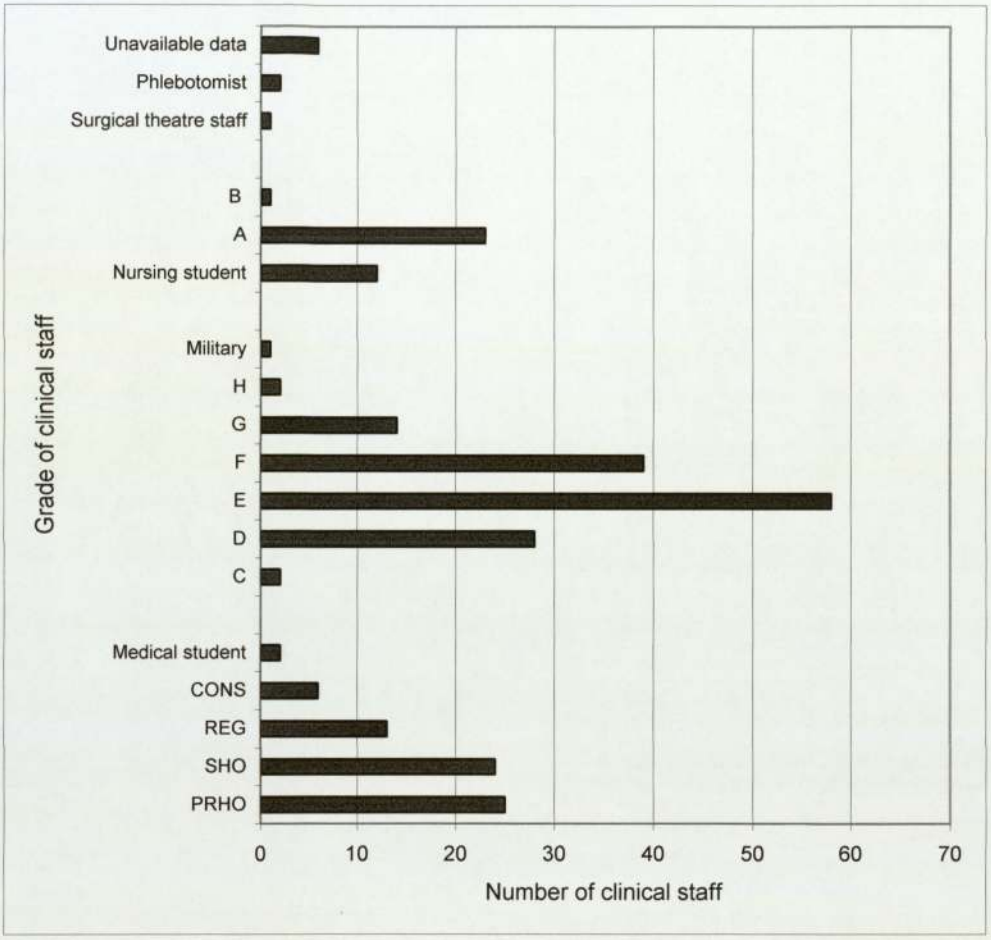
Figure 3.1: Clinical specialty of clinical staff.



Clinical staffs' grades varied within each profession (figure 3.2). Nineteen out of two hundred and fifty nine (7%, 95% CI 4-11%) were senior doctors (consultant and registrar), compared with 51 out of 259 (20%, 95% CI 15-25%) junior doctors (pre registration house officer, senior house officer and medical student). Fifty six out of two hundred and fifty nine (22%, 95% CI 17-27%) comprised senior nurses (F grade, G grade, I grade and military), compared with 94 out of 259 (36%, 95% CI 30-42%) junior nurses (C grade, D grade and E grade). Thirty six out of two hundred and fifty nine

(14%, 95% CI 10-19%) clinical staff were unqualified and the remaining staff were surgical theatre staff and phlebotomists.

Figure 3.2: Professional grade of clinical staff.



Key:

PRHO = pre registration house officer
SHO = senior house officer
REG = registrar
CONS = consultant
Letters denote grade of nurses (A and B = auxillary staff)
Student = student nurse
Military = military nurse

The length of time clinical staff were qualified is illustrated in table 3.0. Most frequently, clinical staff were qualified for less than 1 year (41 out of 259, 16%, 95% CI 12-21%). Thirty nine out of two hundred and fifty nine (15%, 95% CI 11-20%) had been qualified for more than 181 months (15 years) and between 13 and 36 months (1 to 3 years). Of

those qualified for over 181 months, 31 out of 39 (79%) were nurses, compared with 5 out of 39 (2%) doctors. In comparison, of those qualified for 13 to 36 months, 24 out of 38 (63%) were nurses, 12 out of 38 (32%) were doctors and the remaining 2, a phlebotomist and HCW who did not declare their professional status.

Table 3.0: Length of time clinical staff had been qualified.

Length of time qualified (months)	Profession	Number	Percentage (%)
0-12	Nurse	18	7
	Doctor	22	8
	Phlebotomist	1	1
	Total	**41**	**16**
13-36	Nurse	24	10
	Doctor	12	7
	Phlebotomist	1	1
	Unavailable data	1	1
	Total	**38**	**15**
37-72	Nurse	20	8
	Doctor	12	5
	Total	**32**	**12**
73-108	Nurse	21	8
	Doctor	8	3
	Total	**29**	**11**
109-144	Nurse	24	9
	Doctor	6	10
	Surgical theatre staff	2	1
	Total	**32**	**12**
145-180	Nurse	9	3
	Doctor	3	1
	Total	**12**	**5**
181+	Nurse	31	12
	Doctor	5	2
	Surgical theatre staff	2	1
	Unavailable data	1	1
	Total	**39**	**15**

In total, 112 out of 259 (43%, 95% CI 37-50%) clinical staff inserted IV peripheral catheters. Of these, 68 out of 112 (61%, 95% CI 51-70%) were doctors and 41 out of 112 (36%, 95% CI 28-46%) were nurses. Two out of one hundred and twelve were surgical theatre staff and 1 participant did not make their profession known. There was

a statistically significant higher number of doctors to nurses who inserted IV peripheral catheters as part of their clinical practice (p=0.003, Fisher's Exact Test).

The number of IV peripheral catheters inserted per week varied (table 3.1). Forty one out of one hundred and twelve (36%) clinical staff inserted less than 5 IV peripheral catheters per week, compared with 23 out of 112 (21%) who inserted 6 to 10 per week. Only 4 out of 112 (4%) clinical staff inserted more than 21 IV peripheral catheters per week.

Table 3.1: The number of intravenous peripheral catheters inserted per week by clinical staff (n=112).

Number of intravenous peripheral catheters	Number of clinical staff
0-5	46
6-10	23
11-15	9
16-20	10
21-25	2
26-30	2
Unavailable data	19

One hundred and thirty eight out of two hundred and fifty nine (53%, 95% CI 47-59%) clinical staff performed venepuncture as part of their clinical practice. Of these, 65 out of 138 (47%, 95% CI 39-56%) were doctors, 69 out of 138 (50%, 95% CI 41-59%) were nurses, 1 out of 138 were surgical theatre staff and 2 were phlebotomists. Only 33 out of 259 (13%) clinical staff inserted CVCs, 32 were doctors (97%) and 1 was from surgical theatres (3%). None of the nurses inserted CVCs.

Twenty out of two hundred and fifty nine (8%, 95% CI 4-12%) clinical staff sustained PIIs; however, a total of 27 injuries occurred between December 2001 and November 2002. Two clinical staff sustained 3 PIIs and 3 sustained 2 PIIs (table 3.2).

Table 3.2: Percutaneous inoculation injuries sustained by clinical staff, illustrated by profession.

Number of percutaneous inoculation injuries	Number of percutaneous inoculation injuries per clinical staff member	Profession of clinical staff
15	1	9 Nurses 2 Surgical theatre staff 4 Doctors
6	2	1 Nurse 1 Doctor 1 Phlebotomist
6	3	1 Doctor 1 Nurse

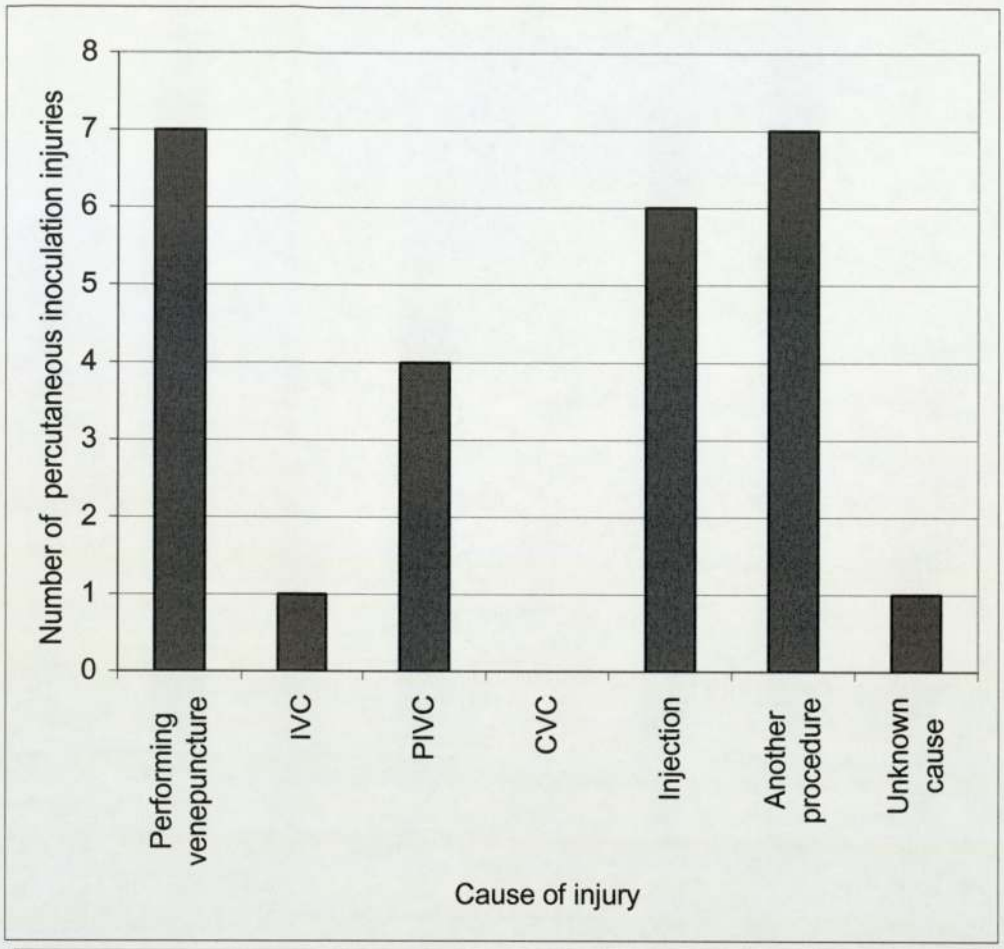
Nine out of twenty seven PIIs were sustained by doctors (33%, 95% CI 17-54%). Of these, 3 were registrars, 2 were pre registration house officers and 1 a senior house officer. In comparison, 14 out of 27 PIIs were sustained by nurses (52%, 95% CI 32-71%). Of these, 5 were E grade nurses, 3 were D grade, 2 were F grade and 1 a G grade. In addition, 1 phlebotomist and 2 surgical theatre staff sustained 4 PIIs. Statistical significance was not reached when the number of PIIs sustained by nurses and doctors were compared (p=0.1843, Fisher's Exact Test).

Of the HCWs that sustained PIIs (20), 3 were qualified less than 12 months, 5 between 13 and 36 months, 2 between 37 and 72 months, 5 between 73 and 108 months, 3 between 109 and 144 months, 1 between 145 and 180 months and 1 more than 181 months. Indeed, 8 (40%, 95% CI 19-64%) HCWs had been qualified less than 36 months.

The cause of injury is illustrated in figure 3.3. One HCW did not disclose the cause of injury or other related information. Most frequently, PIIs were sustained whilst performing venepuncture (7 out of 26, 27%, 95% CI 12-48%), administering an

injection (6 out of 26, 23%, 95% CI 9-44%) or another procedure (7 out of 26, 27%, 95% CI 12-48%). No clinical staff sustained a PII whilst inserting a CVC. Four out of twenty six PIIs (15%, 95% CI 4-35%) were sustained via an IV peripheral catheter. No statistical significance was reached when the number of clinical staff who inserted IV peripheral catheters and who sustained a PII were compared with the number who did not insert IV peripheral catheters and who sustained a PII ($p=1.000$, Fisher's Exact Test). Similarly, no statistical significance was reached when PIIs and performing venepuncture were compared ($p=1.000$, Fisher's Exact Test).

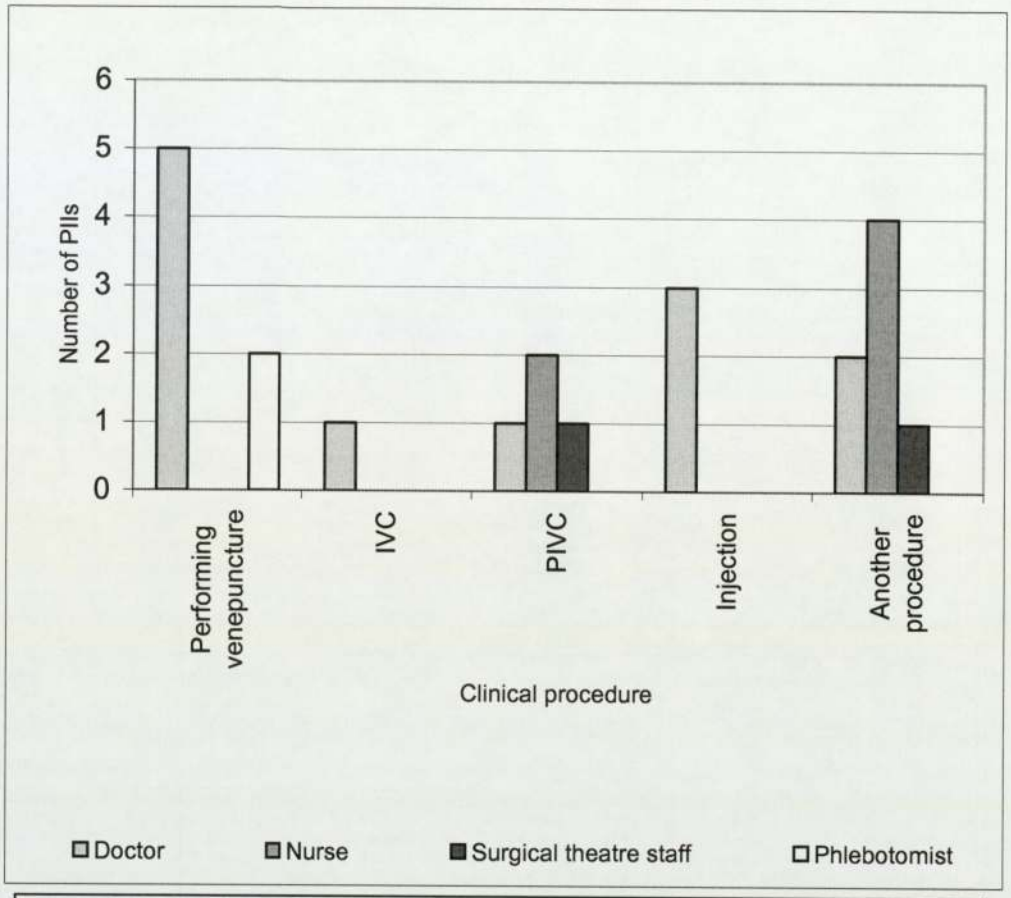
Figure 3.3: Cause of percutaneous inoculation injuries sustained by clinical staff.



Key:
IVC = intravenous catheter CVC = central venous catheter
PIVC = peripheral intravenous catheter

Doctors most frequently sustained a PII whilst performing venepuncture (5 out of 7, 71%), whereas another procedure or administering injections were the cause of nurses' PIIs (figure 3.4).

Figure 3.4: Cause of percutaneous inoculation injuries associated with profession.



Key:
IVC = intravenous catheter PIVC = peripheral intravenous catheter
PIIs = percutaneous inoculation injuries

The details of the injury enabled further insight into clinical staffs' behaviour whilst handling sharp devices (table 3.3). Only 14 out of 20 injured staff gave details of their injuries. Two clinical staff sustained PIIs from placing their hands in trays containing used needles and 3 whilst disposing of needles in a sharps bin. All injuries were caused either during use or before disposal. One downstream PII occurred where the injured HCW was not the original user of the device.

Table 3.3: Details of percutaneous inoculation injuries sustained by clinical staff.

Cause of injury	Details of injury	Total number
Performing venepuncture	- Accident (no other details given)	2
	- PII injury sustained from used needle left in a tray	1
	- Sterile needle caused injury	2
	- Unavailable data	2
Intravascular catheter	- Accident	1
Peripheral intravascular catheter	- Passing used introducer needle to another colleague	1
	- Placing hand in tray containing used needles	1
	- Prior to catheterisation (no other details given)	1
Injection	- Resheathing needle	2
	- Following injection administration	1
Other procedures involved in percutaneous inoculation injury	- Subcutaneous injection	1
	- Unblocking patient's abdominal drain with a green needle	1
	- Biopsy needle	1
	- Sterile needle	1
	- Disposing of needles and placing hand too far in sharps bin causing injury	3

Five out of twenty six (23%, 95% CI 7-39%) PIIs were not reported. These included injuries sustained by 1 doctor, 1 nurse, 1 surgical theatre staff and 2 phlebotomists. Reasons for not reporting the incident included injury via sterile sharp devices and being unaware of the reporting procedure.

During November 2001, clinical staff documented the number of PIIs sustained between November 2000 and November 2001. A total of 46 clinical staff participated. Of these, 25 out of 46 (54%) were nurses, 19 out of 46 (41%) were doctors and 2 out of

46 (4%) were phlebotomists. Thirteen out of forty six (28%) clinical staff recalled sustaining a PII over the previous year. In total, 20 PIIs were sustained by 13 clinical staff (table 3.4).

Table 3.4: Percutaneous inoculation injuries recalled by clinical staff between November 2000 and November 2001.

Number of percutaneous inoculation injuries per person	Total number of percutaneous inoculation injuries	Profession
One injury	5	1 senior house officer 3 pre registration house officers 1 phlebotomist
Two injuries	12	5 senior house officers 1 D grade nurse
Three injuries	3	3 registrars

Doctors sustained 10 out of 13 (77%, 95% CI 46-95%) PIIs compared with nurses who sustained 2 out of 13 (15%, 95% CI 2-45%) injuries and 1 out of 13 (8%) incidents was an injury sustained by a phlebotomist. Doctors sustained a significantly higher number of PIIs than nurses (p=0.0017, Fisher's Exact Test). Of those who sustained a PII, 12 out of 13 (92%) performed venepuncture as part of their clinical practice and 11 out of 13 (85%) inserted IV peripheral catheters. Statistical significance was reached when the number of clinical staff who performed venepuncture and who sustained a PII were compared to the number of who did not perform venepuncture and who sustained a PII (p=0.0353, Fisher's Exact Test). Similarly statistical significance was reached when the number of clinical staff who inserted IV peripheral catheters and who sustained a PII were compared with those who did not undertake the clinical procedure but sustained a PII (p=0.0217, Fisher's Exact Test).

Cause of injury included performing venepuncture (7 out of 13, 54%), inserting IV peripheral catheters (4 out of 13, 31%) and other procedures involving sharp devices (9

out of 13, 69%) (table 3.5). Healthcare workers sustained more than 1 injury with relation to each cause of injury.

Table 3.5: Cause of percutaneous inoculation injuries recalled by clinical staff between November 2000 and November 2001.

Number and cause of injury	Profession
Performing venepuncture (7)	1 senior house officer 1 pre registration house officer 1 phlebotomist
Inserting intravenous peripheral catheters (4)	1 senior house officer 1 pre registration house officer 1 registrar
Another procedure (9)	2 D grade nurses 3 senior house officers 1 registrar

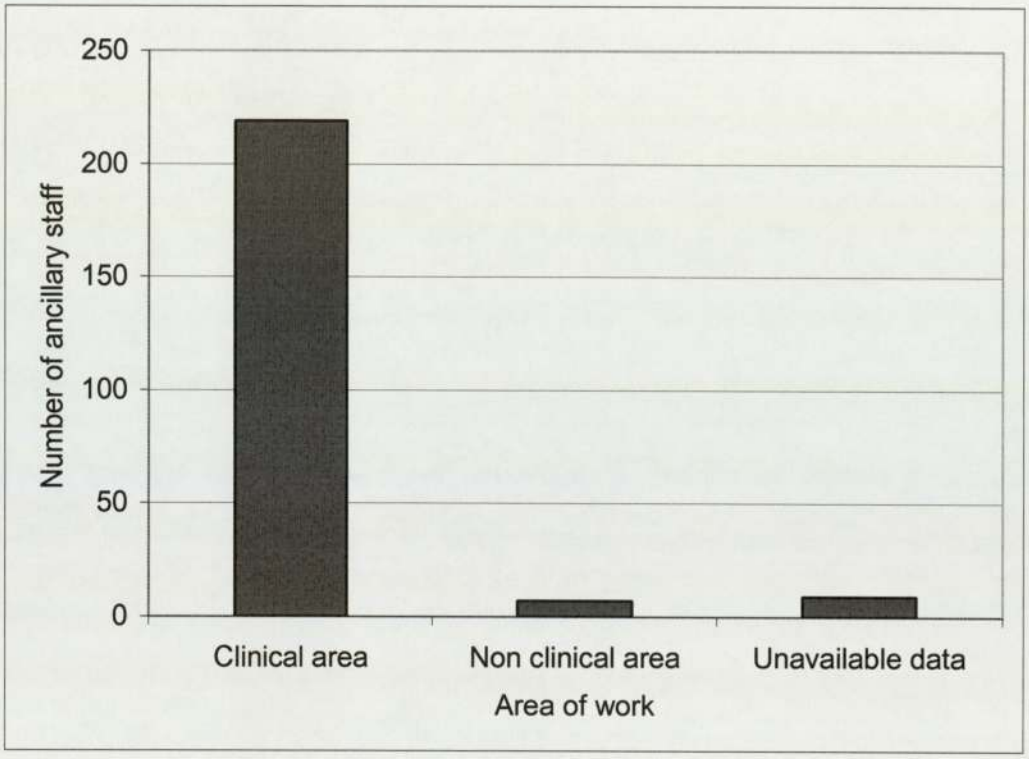
The details of the PIIs allowed further understanding of the cause of injury. Six out of 20 injuries (30%) were caused intra-operatively, although no further details were given. Three out of twenty (15%) were caused by disposing of the sharp device in the appropriate container, 2 out of 20 (10%) after use but before disposal, 1 out of 20 (5%) due to a suture needle (no further details given), 1 out of 20 (5%) from a sharp device which pierced the HCW's skin through a glove, 1 out of 20 (5%) due to the HCW placing their hand into a retainer tray that contained used sharp devices and 6 out of 20 (30%) respondents did not document any injury details.

Twelve out of twenty (60%, 95% CI 36-81%) clinical staff reported their PII, giving an under reporting rate of 8 out of 20 (40%, 95% CI 19-64%). Reasons for not reporting these incidents included the patient being low risk (2 out of 20, 10%), being up to date with vaccinations (2 out of 20, 10%), pressure of workload (2 out of 20, 10%) and the needle being unused prior to injury (2 out of 20, 10%).

3.3.2 Ancillary staff

Two hundred and thirty seven questionnaires were returned between December 2001 and November 2002. Of these, 226 were domestic staff, 2 were housekeepers and 9 did not make their profession known. In total, 218 out of 237 (92%) ancillary staff worked within the clinical area (figure 3.5).

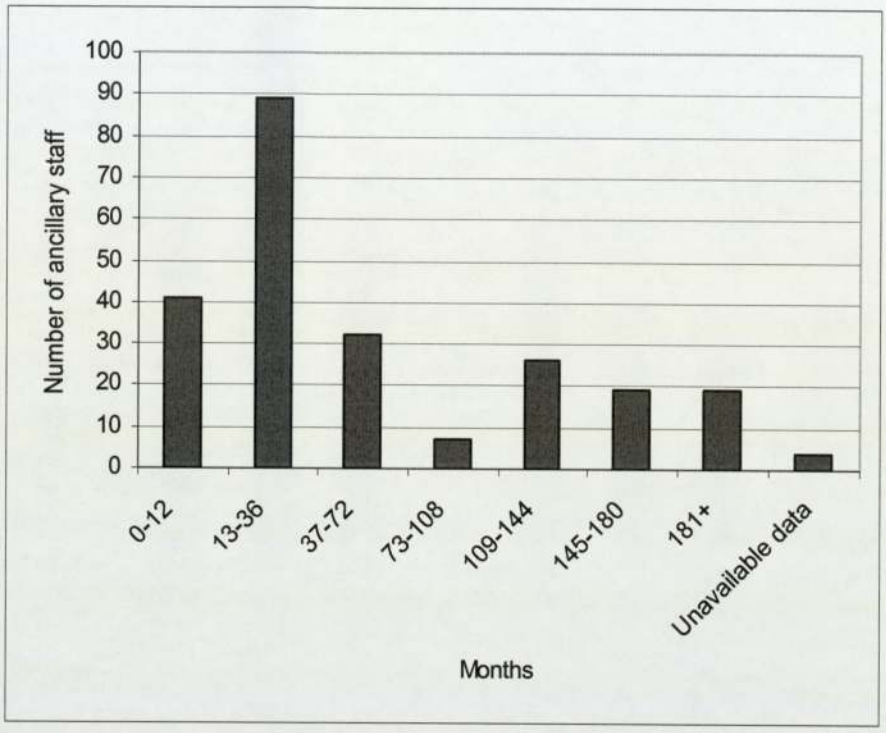
Figure 3.5: Work location of ancillary staff.



The length of time participants had worked within UHB NHS Trust varied (figure 3.6). Forty one out of two hundred and thirty seven (17%) ancillary staff had worked in the Trust for less than 12 months, compared with 89 out of 237 (38%) who had worked in the Trust for 13 to 36 months, 64 out of 237 (27%, 95% CI 21-33%) for more than 109 months and 130 out of 237 (55%, 95% CI 48-61%) for less than 36 months. The number of ancillary workers who had worked for less than 36 months was statistically

significant when compared with those who had been working for more than 109 months (p=0.0001, Fisher's Exact Test).

Figure 3.6: Length of time ancillary staff had worked at University Hospital Birmingham NHS Trust.



Between November 2001 and December 2002, 14 PIIs occurred. The clinical specialty in which they were sustained is described in table 3.6. PIIs occurred most frequently within cardiac services.

Table 3.6: Number of percutaneous inoculation injuries sustained, by clinical specialty.

Clinical specialty	Number of percutaneous inoculation injuries sustained
Neuroscience	4
Renal	1
Cardiac	5
Liver	2
Critical care	1
Unknown clinical area	1

One out of fourteen PIIs (7%) were not reported to anyone, however only 10 out of 14 (71%, 95% CI 42-92%) were documented to have been formally reported to Occupational Health and Safety or Accident and Emergency, Risk Management and manager, adhering to Trust policy. All of these incidents were reported to ancillary staffs' management. Three out of fourteen (21%) PIIs were reported informally to the injured person's supervisor. Table 3.7 illustrates cause of injury.

Table 3.7: Cause of percutaneous inoculation injuries sustained by ancillary staff.

Cause of injury	Number of incidents
Cleaning surfaces in the clinical setting	5
Needle on the floor or caught in cleaning mop	6
Needle disposed of in waste bag causing injury when waste bag replaced	1
Unavailable data	2

The most frequent cause of ancillary staff sustaining a PII was from needles discarded on work surfaces or dropped on the floor, within the clinical area. One injury was sustained from a needle being inappropriately discarded in a waste bag.

An under-reporting rate of 4 out of 14 (29%, 95% CI 8-58%) was calculated, using the Trust policy for comparison (Occupational Health and Safety or Accident and Emergency, Risk Management and manager). However, when an informal, verbal report was included, the under-reporting rate decreased to 1 out of 14 (7%, 95% CI 2-33%).

Forty four out of two hundred and thirty seven (19%, 95% CI 14-24%) ancillary staff experienced near miss incidents. However, overall, 89 near miss incidents occurred, with individual staff experiencing up to 10 incidents each per month. Only 2 HCWs did

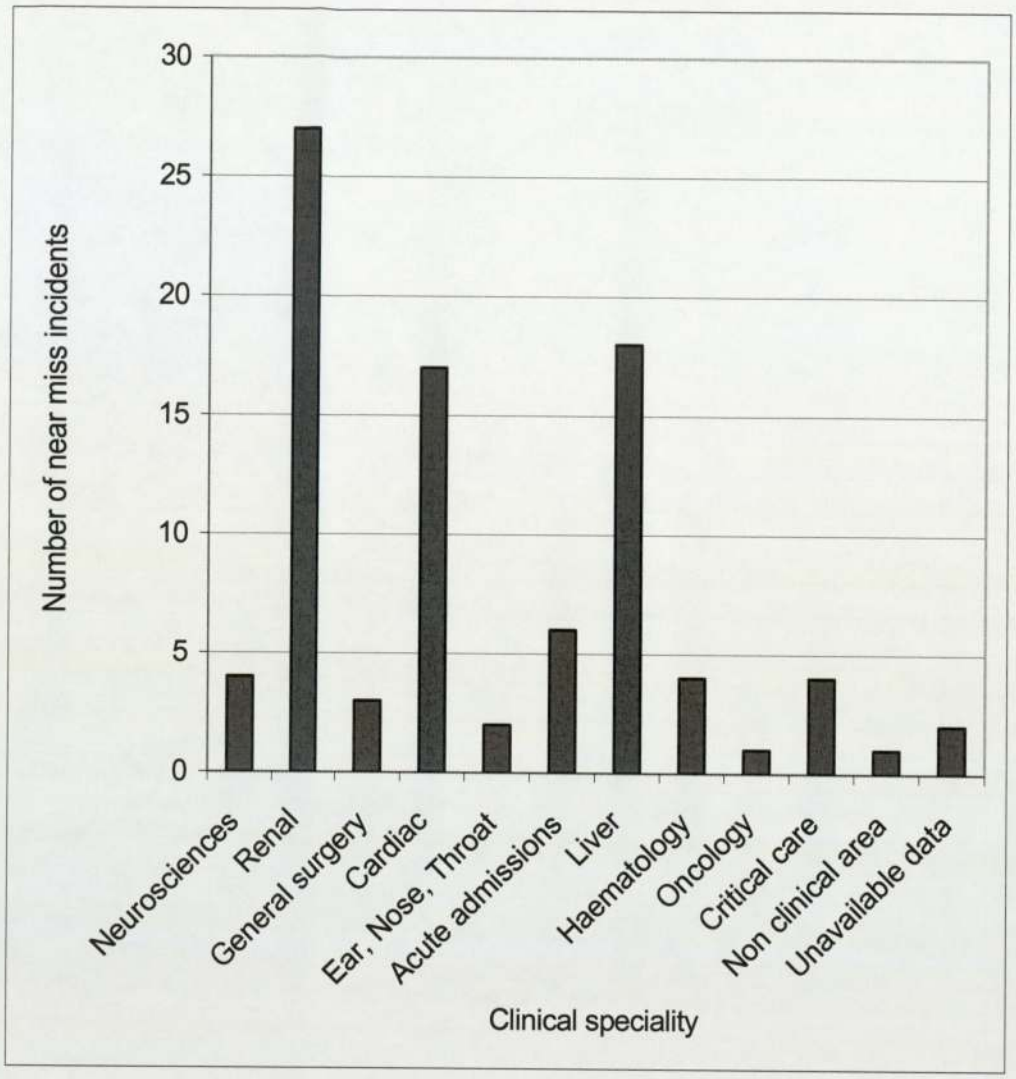
not report their incidents to anyone. Initial reports were directed to ancillary staff supervisors and nursing staff (21 out of 42, 50%), domestic supervisors (16 out of 42, 38%), nursing staff (4 out of 42, 10%) and other ancillary supervisors (1 out of 42, 2%). Action taken following the incident is illustrated in table 3.8.

Table 3.8: Description of action taken following near miss incidents involving ancillary staff (n=42).

Action taken	Number of incidents
Bloods taken from ancillary staff member	1
Nothing	3
Risk Management incident form completed	15
Needle removed from the location	3
Unsure of action taken	1
Incident form and needle removed from location	4
Discussions with clinical staff	4
Trust policy adhered to	1
Incident form and discussion with nursing staff	1
Incident form and bloods taken from ancillary staff member	1
Unavailable data	8

Overall, 22 out of 42 (52%, 95% CI 36-68%) ancillary staff completed a Risk Management incident form and thus adhered to Trust policy, indeed 3 out of 42 (7%) staff reported that no action was taken following the incident. The ward was notified in 5 out of 42 incidents (12%). The clinical area in which the near miss incidents occurred varied (figure 3.7). Overall, the under reporting rate was 22 out of 44 (50%, 95% CI 35-65%).

Figure 3.7: Clinical location of near miss incidents (n=89).



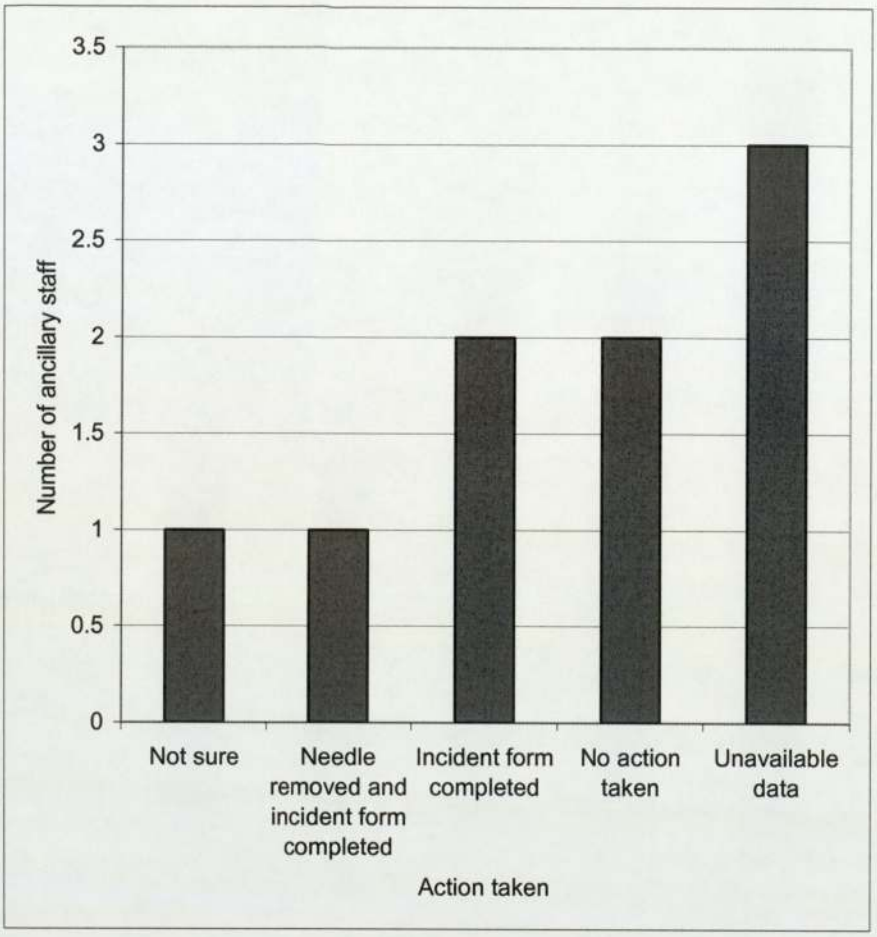
Near miss incidents occurred most frequently in renal (27 out of 89), cardiac (1 out of 89) and liver services (18 out of 89).

During November 2001, ancillary staff documented the number of PIIs and near miss incidents they experienced between November 2000 and November 2001. A total of 20 domestic staff completed questionnaires. Only 1 participant recalled sustaining 2 PIIs in the previous year, both caused by needles disposed of in waste bins. However,

it is unclear whether the incidents were reported in accordance with UHB NHS Trust policy. In both instances, discussions were held with the associated clinical areas.

Ten out of twenty (50%, 95% CI 27-73%) ancillary staff recalled experiencing a near miss incident. Of these, 4 out of 10 (40%) had 1 near miss, 1 out of 10 (10%) had 2 near miss incidents, 2 out of 10 (20%) had 3 near miss incidents, 2 documented they had experienced 'too many' (20%) and 1 'a few' (10%). In total, 14 near miss incidents were recalled. All the near miss incidents involved hypodermic needles found on floors (9), on a wash basin (1), behind a chair (1) and in waste bins (3). Four out of ten (40%) ancillary staff reported informally to their supervisor and 5 out of 10 (50%) reported to both their supervisor and the nursing staff on the ward. The other 2 ancillary staff reported their incidents to a nurse on the ward or a colleague. Only 3 out of 10 (30%, 95% CI 7-65%) ancillary staff completed a Risk Management incident form, thus adhering to UHB NHS Trust policy (figure 3.8). Therefore, the under reporting rate was 7 out of 10 (70%, 95% CI 35-93%).

Figure 3.8: Action taken by ancillary staff following near miss incidents.



3.4 Discussion

For the purpose of this discussion, results will be interpreted using study findings from December 2001 to November 2002. Findings from November 2000 to November 2001 will be discussed separately, due to the potential effect of recall bias from documenting PIIs, which may have occurred up to 1 year previously.

3.4.1 Clinical staff

This study identified an under reporting rate of 23%, amongst nurses, doctors, surgical theatre staff and phlebotomists. Reasons given for not reporting the injuries included an injury via a clean device and that the HCW was unaware of the reporting procedure. Data collected during November 2001, revealed that injuries were not reported because the patient was perceived to be low risk, the injured HCW was up to date with their vaccinations, pressure of workload and again that the device had not been used.

The under reporting of PIIs has been well documented in the literature since 1986 (Jackson *et al.*, 1986). Previous studies identified under reporting rates between 26 and 91%. Our finding of 23% was slightly lower than the lowest reported rate of 26% (Haiduven *et al.*, 1999). Furthermore, this study's finding was lower than the previously documented 65% in UHB NHS Trust (Dobie *et al.*, 2002). The lower under reporting rate, when compared with Dobie *et al.*, (2002) may reflect the efficacy of the awareness campaigns implemented in the Trust over the previous 2 years. Another reason may be that nearly three quarters of respondents were nurses, a professional group who report more injuries compared with doctors (Clarke *et al.*, 2002; Whitby and McLaws, 2002; EPINet, 1999).

Connington (2002), May and Brewer (2001) and Wilson (2001) suggested that being unaware of the reporting policy prevented HCWs from reporting injuries, which concurred with this study's findings. There is currently no standardised method for reporting and managing PIIs across the UK, despite DH (1998) guidelines. This is compounded by policy variations on whether the injury occurred within or outside working hours (Wilson, 2001). Subsequently, HCWs may have become confused with the different reporting procedures and adopted a self-developed strategy based on experience and potentially inaccurate information.

Healthcare workers frequently self-assessed the incident, instead of reporting, which concurred with previous research evidence (Metules, 2002; Short Life Working Group, 2001; Nash and Goon, 2000; Rabaud *et al.*, 2000; Rosenthal *et al.*, 1999; Burke and Madan, 1997). Metules (2002) also highlighted that an injury from an unused device and pressure of workload were causes for not reporting injuries, both identified in this study. The reason of being up to date with vaccinations was also reported by Shiao *et al.*, (1999). Furthermore, it may have been that HCWs did not report PIIs due to the absence of subsequent feedback and that they were not able to influence the outcome following injury (Rabaud *et al.*, 2000, Burke and Madan 1997).

The number of PIIs did not correspond to the number of injured clinical staff because individuals sustained more than one injury. Furthermore, nurses sustained more than half of the injuries. These findings supported previous evidence that nurses sustained the majority of PIIs (Whitby and McLaw, 2002; Nguyen *et al.*, 2002; Short Life Working Group, 2001; OSHA, 2001; Ling *et al.*, 2000; Gershon *et al.*, 1999). With 52% of PIIs sustained by nursing staff, this concurred with earlier studies, reporting a PII rate between 40 and 60% amongst nurses (Department of Health Services, 2002; Short Life Working Group, 2001; Porta *et al.*, 1999; Mercier, 1994). Interestingly, this study's

findings were similar to those of de Vries and Cossart (1994) in Australia. The 52% is, however, marginally higher than exposures to blood borne pathogens identified by the PHLS (May and Brewer, 2001). This may reflect the higher proportion of nurses to doctors within healthcare (RCN, 2001). Furthermore, nurses were involved with the majority of clinical procedures involving sharp devices, for example administering injections, undertaking venepuncture and inserting IV peripheral catheters (Bennett and Howard, 1994). It may also be, however, that nurses reported their injuries more frequently than doctors. Conversely, doctors may not have reported their injuries due to the potential restrictions on their clinical practice (Osborn *et al.*, 1999). This trend however, may change following the DH guidelines and consultation paper for HCV and HIV testing of HCWs undertaking exposure prone procedures (DH, 2003; DH, 2002). It may be that with the implementation of mandatory testing, doctors will voluntarily seek advice and guidance following PIIs due to the potential restrictions on practice and therefore reduce under reporting.

Doctors accounted for 33% of reported PIIs, concurring with findings of May and Brewer (2001) and Gershon *et al.*, (1999). Interestingly however, Mercier (1994) and Ng *et al.*, (2002) found a higher PII rate amongst doctors than nurses, which may reflect the proportionately higher injury rate of doctors when compared to their representation in the workforce (Ng *et al.*, 2002; Hanrahan and Reutter, 1997). Reasons for doctors sustaining PIIs were that, like nurses, they undertook many clinical procedures involving sharp devices, for example, suturing, insertion of CVCs and venepuncture (May and Brewer, 2001). Between November 2000 and November 2001, doctors sustained the majority of PIIs. It is unclear, however, as to why these findings conflicted with those identified between December 2001 and November 2002. It may be that doctors recalled PIIs that they had not reported, whereas nurses did not recall injuries if they reported them at the time of the incident.

Nearly half (40%) of PIIs were sustained by clinical staff who were inexperienced (qualified less than 36 months). In addition, half of these clinical staff undertook venepuncture and inserted IV peripheral catheters as part of their clinical practice. Despite this, no statistical significance was reached when clinical practice and PIIs were compared (p=1.000, Fisher's Exact Test). Interestingly, however, statistical significance was reached when the same comparisons were made between November 2000 and November 2001. These findings concurred with Doig (2000) and Osborn *et al.*, (1999) who reported that junior doctors were at risk of PIIs due to their inexperience and limited expertise. Similarly, Clarke *et al.,* (2002) identified those with less than 5 years experience and who undertook venepuncture and inserted IV peripheral catheters as part of their clinical practice were 50 to 100% more likely to report a PII than their more experienced colleagues. It may be that junior staff reported their injuries more frequently than senior staff due to the potential consequences on their clinical practice and concern of exposure to blood borne pathogens or due to their inexperience. A quarter of PIIs were sustained by HCWs with more than 109 months experience. This may be because of the increased probability of an injury with increased years in service (Clarke *et al.*, 2002).

Clinical procedures associated with PIIs included venepuncture, inserting IV peripheral catheters and other procedures, namely administering injections, which supported previous study findings (Metules, 2002; Department of Health Services, 2002). Doctors' most frequently sustained a PII during venepuncture, whereas nurses sustained their injuries whilst administering injections. This may reflect the professions' different clinical roles. It was the responsibility of the majority of junior doctors to obtain patient's blood samples, whereas nurses administered all patients' IV medication. In addition previous studies highlighted re-sheathing needles to be a high-risk practice (RCN, 2002; RCN, 2001); however, this was not identified in this study.

Nearly half of the PIIs were sustained after use of the device but before disposal. In addition, 3 occurred during disposal and 1 was a downstream injury where the injured HCW was not the original user of the device supporting the findings of the RCN (2002), Whitby and McLaws (2002) and May and Churchill (2001). It is unclear as to reasons why the majority of injuries occurred after use but before disposal. It may be that HCWs perceived that 'being careful' whilst practising inherently dangerous techniques would ensure their safety from exposure to blood borne pathogens or that current sharps disposal containers enabled HCWs to overfill them increasing the risk of injury during disposal of sharp devices (Hatcher, 2002). Anecdotal evidence suggested that HCWs did not dispose of sharp devices at the point of use. Instead, they transported them in a retainer or by hand to the sharps container thus increasing their risk of injury.

Other study findings were that the majority of participants in this clinical study were nurses, comprising 180 out of the 259 respondents. This may be because of the relative number of nurses to doctors within healthcare. Indeed, at Queen Elizabeth Hospital, UHB NHS Trust in 2001 there were 1125 nurses compared with 349 doctors (unpublished data). Nurses had been qualified for a longer time period than doctors. This may be because the relative number of senior nursing posts compared with medical posts was greater. In addition, 40% of clinical staff inserted IV peripheral catheters as part of their clinical practice; however, the majority of these were doctors because this practice historically lay with the medical profession. Interestingly, however, over a quarter of those inserting IV peripheral catheters were nurses. This may reflect the changes in professional practice, where nurses are increasingly taking on the clinical responsibilities of junior doctors, for example IV peripheral catheterisation. It will be interesting to monitor the number of PIIs sustained by nurses compared with doctors and the type of device causing injury over the next few years due to the reduction in junior doctors' working hours and the potential subsequent

increase in procedures, for example venepuncture and IV catheterisation being undertaken by nurses.

3.4.2 Ancillary staff

Twenty nine percent of PIIs were not reported according to the Trust policy, however, this figure decreased to 7% if informal reporting (to ancillary staff's supervisors) was considered. There was a paucity of evidence highlighting the under reporting of PIIs amongst ancillary staff. Previous studies only recruited clinical staff, or did not separate the under reporting rate of ancillary staff from doctors and nurses. However, one study in Taiwan reported that only 25.4% of ancillary workers reported their injuries, giving an under reporting rate of 74.6%. This study also highlighted the improper disposal of sharp devices, which frequently caused injury (Shiao *et al.*, 2001), which was found in this study.

Ancillary staff also experienced near miss incidents. Indeed some participants documented up to 10 incidents per month. Most frequently, reports were directed to the staff's supervisor, however over half completed a Risk Management incident form, thus adhering to UHB NHS Trust policy. The under reporting rate of near miss incidents was 50%. Similarly, there was a paucity of evidence evaluating the under reporting rate of near miss incidents among ancillary staff and therefore these findings could not be compared.

Ancillary staff were at risk of transmission of blood borne pathogens via a PII, despite never being the original user of the sharp device. All injuries were categorised as 'downstream' injuries, where the ancillary worker was not the original user of the device. This has been comprehensively documented in the literature (Adam and Elliott, 2002; May and Churchill, 2001). The RCN's surveillance study reported that both

housekeeper and domestic staff were at risk of 'downstream' injuries (RCN, 2002; EPINet, 1999) because of inappropriate disposal of sharp devices that was also found by May and Brewer (2001) and Puro *et al.*, (2001). Furthermore, a recent study in Glasgow, UK, found that 13.5% of all reported PIIs were sustained by ancillary workers (O'Connell *et al.*, 2003).

Interestingly, there were clusters of near miss incidents related to specific clinical settings. Renal, Cardiac and Liver units were areas associated with a higher number of near miss incidents. It is unclear, however, as to the reasons for this phenomenon. All clinical staff in each area received the same standardised training and education, and in some of these areas, additional educational measures were taken in an attempt to reduce the number of near miss incidents. This finding may reflect the locality of sharps disposal containers to the patient's bedside or the location where sharp devices were used. It may be that if clinical staff did not have sharps disposal containers close to hand following use of a sharp device, they may not have ensured its safe disposal.

There appears to be no one solution to improve PII reporting. In the current NHS environment, pressure of workload will continue to prevent HCWs following policy and procedure. Indeed, with staff shortages and increased pressure on HCWs to provide quality healthcare, procedures that require individuals to remove themselves from the clinical workplace will go unheeded.

Training and education are essential to raise awareness of the importance of reporting injuries. In addition, behaviour may be changed by the recent implementation of DH guidelines on HCV testing for HCWs (DH, 2002). Doctors may no longer be reticent about reporting injuries, with their serological status being examined prior to specific career pathways and therefore complacency amongst HCWs may decrease.

Educating all HCWs and ancillary staff in the reporting process following a PII is imperative. All senior HCWs should be aware and competent in managing such situations, to ensure that junior and ancillary staff, within their clinical area, receive the necessary treatment if required. Indeed, ancillary staff's supervisors should also be aware of how to manage and report such injuries, as it appeared that many of this staff group informed their supervisors rather than reporting the injury according to UHB NHS Trust policy. Raising the priority given to management of inoculation injuries is essential to ensure HCWs and ancillary staff are aware of the importance of reporting such incidents. Moreover, nursing and medical students must be educated in the appropriate procedures, to ensure they minimise their risk of exposure to blood borne pathogens and are not influenced by colleagues who encourage the non reporting of injuries (Osborn *et al.*, 1999).

One method to ensure all staff are knowledgeable regarding how to report a PII and to reduce confusion would be to standardise the management and reporting process across all hospitals in the UK with guidance from the DH. Ensuring the procedure is simple may increase the numbers who report. Preventing HCWs self-assessing the incident in the clinical setting would be difficult to prevent, however ensuring an accurate knowledge base may encourage appropriate reporting and management of incidents.

The efficacy of education and training has been highlighted in previous study findings, however, it is important to review the methods implemented, to ensure their continued efficacy in raising awareness and encouraging staff to report injuries. Pocket held information cards or information labels could be considered as a strategy to raise awareness and encourage PII reporting (Holodnick, 2000).

3.4.3 Limitations

The method used to recruit this sample was convenient, relying on staff with time to complete the questionnaire. Other methods to consider would be to post questionnaires to a random sample of staff, rather than visit ward settings, which may reduce the Hawthorne effect (Polit and Hungler, 1993). It may have been that the Clinical Research Nurses' presence may have affected staff acknowledging their non-compliance with Trust policy, which may have subsequently influenced their answers. However, in the healthcare environment, the rate of return on posted questionnaires can be minimal due to pressure of workload. Indeed, sending ancillary staff questionnaires may have presented difficulties because there was no central location to send them. In addition, accessing surgical theatre staff and consultant doctors was frequently difficult because this group of staff were often either inaccessible or were unable to complete the questionnaire due to workload. It would have been interesting to include these groups because previous evidence suggested that numerous PIIs were sustained during surgical procedures. One method to encourage participation may have been to contact the surgical theatre staffs' manager and send questionnaires to both this group and all consultants in the hospital.

The question relating to the number of near miss incidents experienced by ancillary staff resulted in some participants answering 'a few' or 'too many'. If this questionnaire were to be utilised again, it might be beneficial to either categorise the number, for example one to ten, eleven to fifteen or to ask participants to document the exact number, to enable more accurate data analysis.

Clinical staff were only asked to recall unreported PIIs, not near miss incidents. Further studies should include near miss incidents experienced by clinical staff to enable comparisons between ancillary and clinical staff to be made.

3.4.4 Recommendations

Factors that would increase HCWs reporting PIIs should be reviewed including HCWs' behaviour and perceptions of the reporting procedure. In addition, evaluation of the number of near miss incidents experienced by clinical staff and reporting behaviour could be compared with ancillary staff. A study evaluating the efficacy of a standardised method of reporting may assist with determining whether the variations in reporting created confusion amongst staff.

3.5 Summary

Clinical and ancillary staff did not report all PIIs sustained in the clinical setting. Indeed, ancillary staff did not report all near miss incidents. Overall, the under reporting rate for PIIs amongst clinical staff was 23%, 29% amongst ancillary staff and 50% for unreported near miss incidents amongst ancillary staff. Reasons for not reporting included pressure of workload, self-assessing the risk of exposure to blood borne pathogens following the incident and perceiving the source patient to be low risk. Nurses sustained the majority of PIIs when compared with doctors. Nurses sustained most PIIs whilst administering injections and doctors whilst performing venepuncture. Ancillary staff were at risk of sustaining 'downstream' PIIs and experiencing near miss incidents because sharp devices were not disposed of in the appropriate containers. Most frequently, these incidents were reported to their supervisors rather than adhering to Trust policy. These findings concurred with previous research evidence. A solution to improve reporting of PIIs is complex. This would involve both improvements in training and education as well as reviewing the reporting policy. However, until all staff report all PIIs, the true incidence will remain uncertain.

Chapter 4: Healthcare workers' knowledge of inoculation injuries and associated issues

4.1 Introduction

Healthcare workers' occupational risk of exposure to blood borne pathogens from PIIs has been well documented since 1984 following the first occupational transmission of HIV (CDSC, 2000). Consequently, universal precautions (CDC, 1987) were implemented, as well as education and training on the safe disposal of sharp devices to protect the HCW (Gershon *et al.*, 2000). Although these prevention strategies reduced the number of PIIs and improved awareness of the risks associated with such incidents, HCWs' level of knowledge of PIIs remained limited. Furthermore, compliance with clinical procedures aimed to reduce the risk of exposure to blood borne pathogens was demonstrated as sporadic (Godin *et al.*, 2000; Scouler *et al.*, 2000; Kim *et al.*, 1999; Akudman *et al.*, 1999).

The risk of transmission of blood borne pathogens was frequently underestimated (Diprose *et al.*, 2000; Scouler *et al.*, 2000; Leliopoulou *et al.*, 1999; Patterson *et al*, 1998). Healthcare workers lacked knowledge of the reporting process following a PII (May and Brewer, 2001), which increased their risk of exposure and potential transmission of blood borne pathogens. Indeed, self management of such incidents frequently occurred instead of completing a formal report (Short Life Working Group, 2001; Shiao *et al.*, 1999). Reasons for not reporting PIIs included pressure of workload, self assessment of the incident and source patient, potential restrictions on clinical practice, denial of personal risk and lack of awareness (Connington, 2002; Rabaud *et al.*, 2000; Osborn *et al.*, 1999; Burke and Madan, 1997).

UHB NHS Trust has a comprehensive inoculation injury awareness strategy, including training, education, support and advice available 24 hours a day for all HCWs. The aim of this clinical study was to evaluate the efficacy of the awareness strategy and gain an understanding of HCWs' level of knowledge regarding PIIs and associated issues.

4.2 Methods and materials

The knowledge of inoculation injuries, both percutaneous and mucocutaneous, of a range of HCWs at Queen Elizabeth Hospital, UHB NHS Trust was investigated. The Local Research Ethics Committee and the Trust's Clinical Governance and Research and Development departments granted approval of the study. Prior to participation, each HCW was given information about the aims of the study and verbal consent was obtained. Each participant was allocated a study number to ensure anonymity.

The study was carried out by means of a questionnaire (appendix 4A), designed by the Clinical Research Nurse (J Trim) and Clinical Nurse Specialist in Infection Control (D Adams), in conjunction with the Trust's Consultant Virologist (Dr S Osman) and Microbiologist (Professor TSJ Elliott). The questionnaire was divided into 11 sections and was piloted on 10 nursing staff for validity. No changes were made to the questionnaire following the pilot study. Initially, participants were asked to indicate their profession, grade and location in the hospital (questions 1 and 2) and each subsequent question referred to a specific issue associated with inoculation injuries. All responses were compared against current Trust policy (appendix 4B).

A sample size of 200 was utilised to ensure the width of the 95% CI was less than 15%. This was calculated on the assumption that 50% of respondents were correct and 50% were incorrect in their responses (a smaller sample size would have been required for any other correct/incorrect response ratio). Between January and June

2001, questionnaires were distributed prior to Infection Control mandatory update teaching sessions and during the Trusts' IV cannulation study day. Other HCWs were recruited by visiting clinical areas where HCWs' availability to complete the questionnaire was determined by pressure of workload and presence in the clinical areas during visits. The sample was convenient; however, HCW selection was unbiased because the data collectors (Clinical Research Nurse and Infection Control Nurses) had no influence on which HCWs attended the study sessions or HCWs' duty of work. This data collection method was chosen because it enabled doctors to be included in the study. By visiting clinical areas, medical and nursing staff of all grades were offered the opportunity to participate in the study.

4.2.1 Definition of an inoculation injury (question 3)

An inoculation injury is an incident where there is potential for exposure to blood or body fluid and transmission of blood borne pathogens (DH, 1998). Predominantly this occurs by cutaneous means, including a PII or direct inoculation of blood into cutaneous scratches, skin lesions, abrasions, from a bite breaking the skin, or mucocutaneously where blood or body fluid splash into the eye, nose or mouth.

Healthcare workers were given a list with a choice of 8 different inoculation injuries. All the choices, except a clean needle are defined as inoculation injuries.

4.2.2 The incidence of transmission of blood borne pathogens from a percutaneous inoculation injury (question 4)

To identify the incidence of transmission of HBV, HCV and HIV from a PII, HCWs were given a choice of 5 possible answers along a continuum, ranging from 1 in 0.3 to 1 in 3000. The question highlighted that the risk of transmission was from a positive source

patient to a negative un-vaccinated (or non-responder to immunisation) recipient. Responses marked between the allocated ranges were measured and recorded as the nearest incidence of transmission.

4.2.3 Risk of transmission of blood borne pathogens associated with device (question 5)

Eight sharp devices used in the clinical setting for various clinical procedures were included in this question. Healthcare workers rated the potential risk of transmission of blood borne pathogens if the device caused a PII. Devices were risk-rated between 1 and 8, 1 being the highest risk. Healthcare workers were scored as being correct if they risk rated an IV peripheral catheter, needle and syringe and vacutainer system (with needle) between 1 and 3, indicating a potentially high risk of transmission of blood borne pathogens following a PII. This scoring system was based on previous findings that HCWs were at greatest risk of exposure to blood borne pathogens following an injury from a hollow bore needle used to directly access an artery or vein (Department of Health Services, 2002; Goldmann, 2002). As such, the question was utilised to identify HCWs' level of awareness that hollow bore devices, for example IV peripheral catheters, needle and syringe and a vacutainer system posed a greater risk of exposure to blood borne pathogens following injury when compared with a blood glucose lancet or stitch cutter. No distinction was made to what the needle and syringe was used for, for example venepuncture, intramuscular injection or IV injection.

4.2.4 First aid action following a percutaneous inoculation injury (question 6)

Healthcare workers stated what they perceived to be the first 'first aid' action that should be undertaken following a PII. The Trust policy stated that the injured site should be washed and encouraged to bleed (by applying gentle pressure round the puncture site).

4.2.5 The process of reporting percutaneous inoculation injuries (question 7)

Healthcare workers were asked to document how they would report a PII. The Trust policy identified 3 steps for reporting these injuries and each step had to be documented. These included the Occupational Health and Safety department, Accident and Emergency department or Emergency Admissions Unit, manager or nurse in charge and completion of a Risk Management incident form.

4.2.6 Source patient blood testing (question 8)

Participants were asked whether the source patient should have their blood taken for serological testing following a PII and if so who should obtain the sample. Source patient blood should be taken for serological analysis following a PII by the medical team managing the patient's clinical care or if during the night, the night sister on duty.

4.2.7 Glove usage whilst handling sharp devices (question 9)

Eleven clinical procedures involving the use of sharp devices were listed. Healthcare workers recorded whether they would wear gloves whilst undertaking each procedure

in their routine clinical practice. Gloves should be worn for every procedure, in accordance with universal precautions (Ayliffe *et al.*, 2000; Godin *et al.*, 2000).

4.2.8 Reporting percutaneous inoculation injuries (question 10)

Healthcare workers' reporting behaviour following a PII was evaluated. Healthcare workers recorded whether they would report PIIs sustained during their clinical practice. All such injuries should be reported.

4.2.9 Needle protective devices (question 11 and 12)

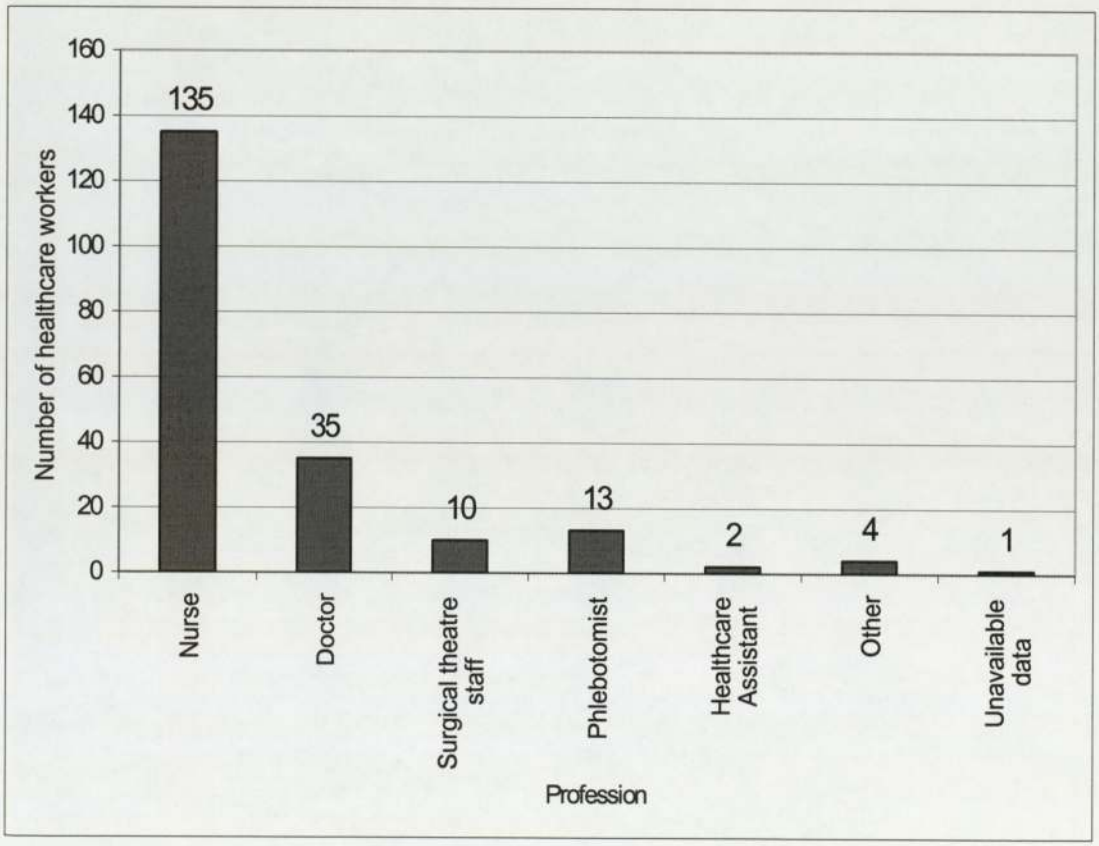
Healthcare workers were asked to document any NPD they knew of to evaluate the level of awareness of these devices and whether any product was currently used in the HCW's clinical setting.

Data were collected and entered into a Microsoft™ Access97 database for analysis. Non parametric statistical analysis, including Binomial Confidence Interval Test and Fisher's Exact Test were applied where appropriate using commercially available software (http://www.statpages.net).

4.3 Results

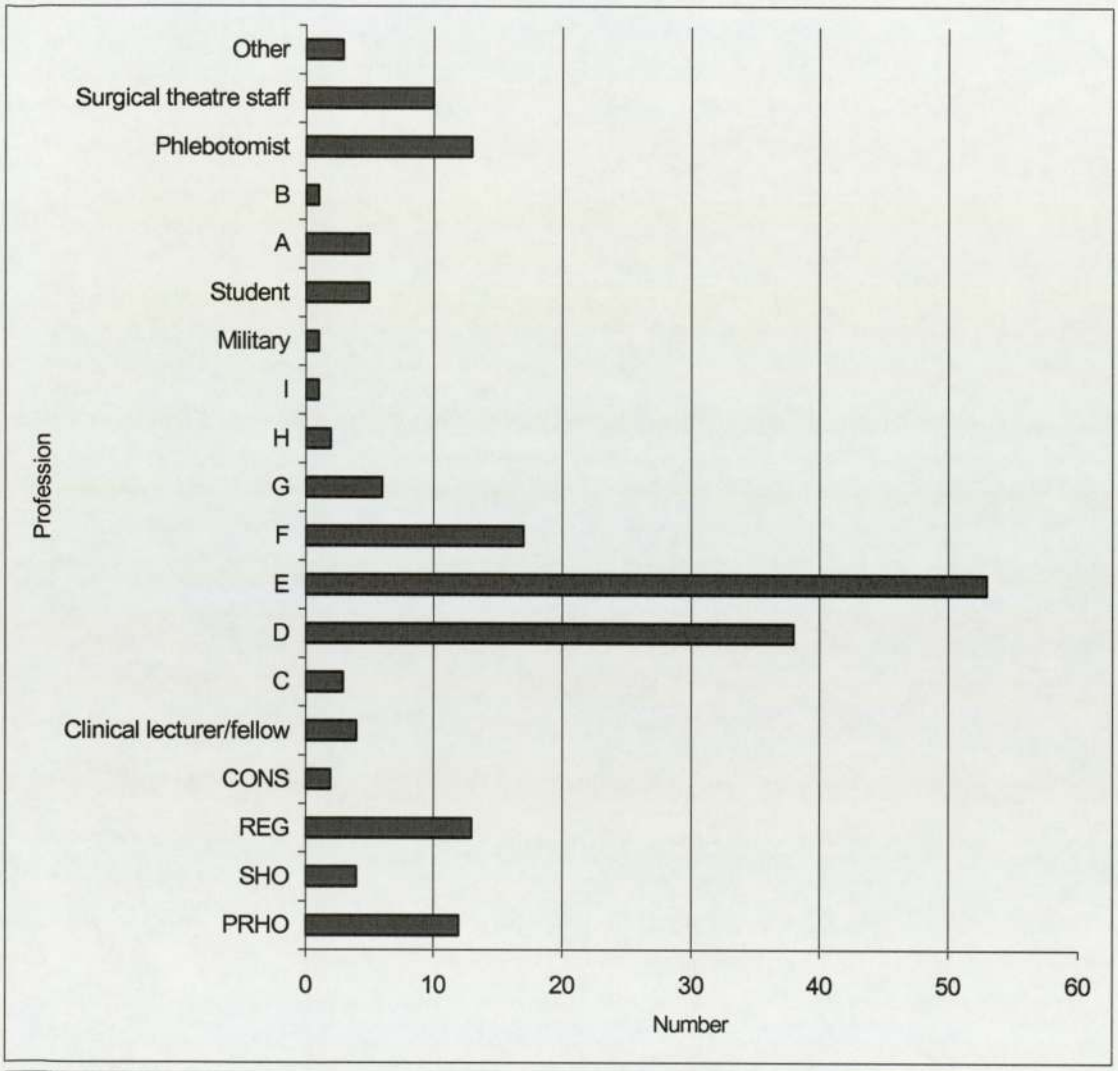
In 2001, 1125 nurses, 349 doctors and 13 phlebotomy staff worked at the Queen Elizabeth Hospital, UHB NHS Trust. The number of HCWs who participated in the study were 13 out of 13 (100%) phlebotomists, 135 out of 1125 (12%) nurses and 35 out of 349 (10%) doctors (figure 4.0). Participants also included 10 surgical theatre staff, 2 healthcare assistants, 4 'others' and 1 person did not make their profession known.

Figure 4.0: The number of healthcare workers who participated in the staff knowledge study.



Each grade of profession was represented in the sample group, with the majority of nurses being D and E grades (91 out of 135, 67%) and 25 out of 35 (71%) doctors were pre registration house officers or registrars (figure 4.1).

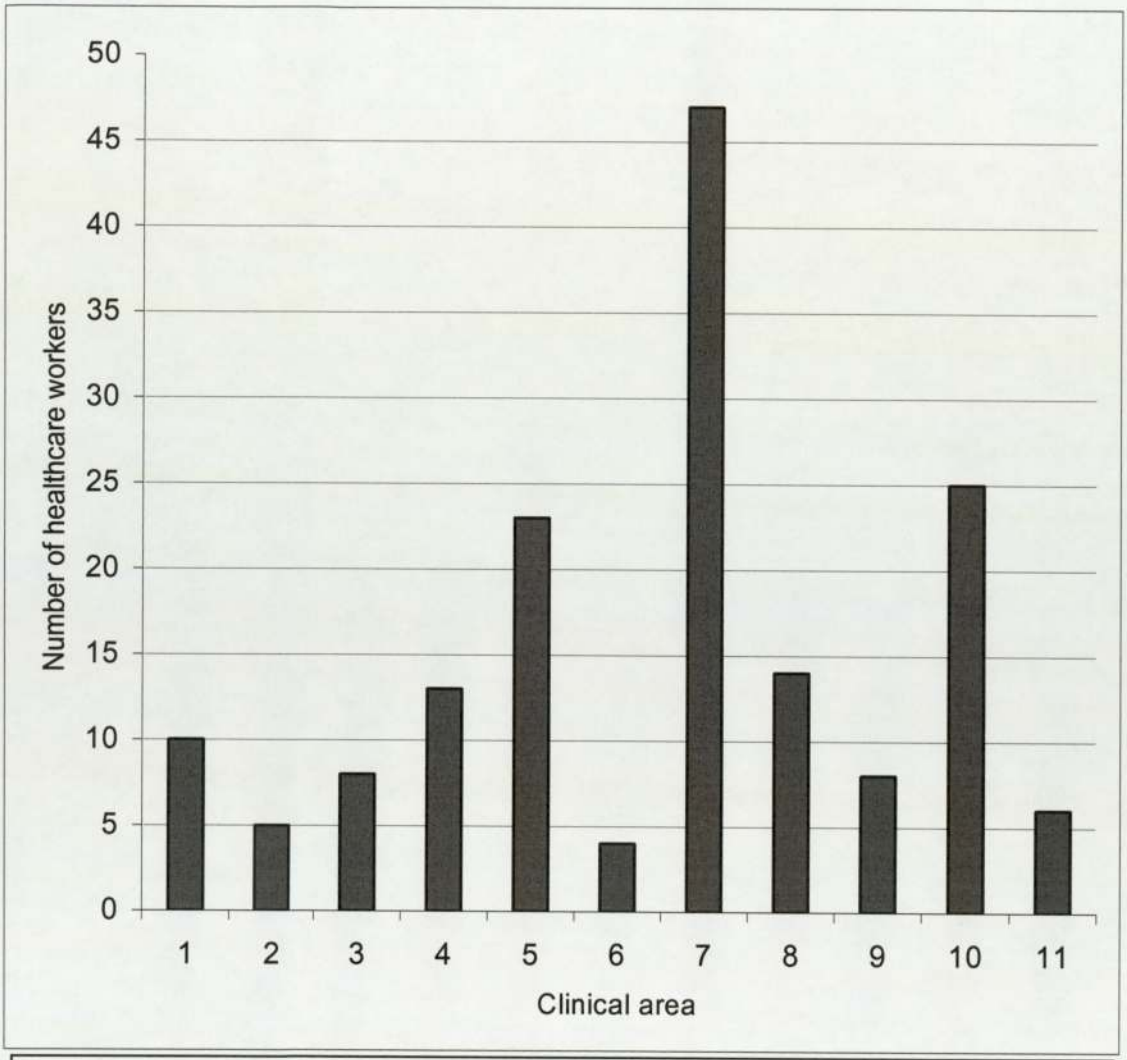
Figure 4.1: The grade and profession of all healthcare workers who participated in the staff knowledge study.



Key:
PRHO = pre registration house officer
SHO = senior house officer
REG = registrar
CONS = consultant
Clinical lecturer/fellow = medical
All letters refer to nursing grades (A and B = auxillary staff)
Student = student nurse
Military = military nurse

Clinical staff were located in a number of specialties; however, the majority of participants were situated in liver, renal, surgical theatres and neuroscience areas (figure 4.2).

Figure 4.2: Location of healthcare workers who participated in the staff knowledge study.



Key:
1 = Neurosciences
2 = Ear, Nose and Throat (ENT)
3 = Urology
4 = Medicine
5 = Surgery
6 = Investigation units
7 = Liver
8 = Renal
9 = Cardiac
10 = Critical Care
11 = Other

The results of the individual questionnaire sections are described below.

4.3.1 Inoculation injuries

Only 9 out of 200 (4.5%, 95% CI 2-8%) HCWs accurately defined an inoculation injury. These included 5 doctors (4 pre registration house officers and 1 registrar), 3 nurses (1 D grade and 2 E grades) and 1 surgical theatre staff. One hundred and eighty two out of two hundred (91%, 95% CI 86-95%) HCWs were aware that an injury involving a used needle was an inoculation injury, compared with an injury caused by a scratch (79 out of 200, 40%), blade (82 out of 200, 41%), bite (77 out of 200, 39%), scalpel (83 out of 200, 42%), spicule of bone or teeth (72 out of 200, 36%) or splash of body fluid (69 out of 200, 35%) (table 4.0). Eight out of ten (80%, 95% CI 44-97%) surgical theatre staff were not aware that an injury involving a blade or scalpel was an inoculation injury.

Nurses and healthcare assistants demonstrated a limited level of awareness of injuries categorised as inoculation injuries. More than 60% of nurses were not aware that each injury, except a clean needle injury, was an inoculation injury. Indeed, 4 nurses and 1 phlebotomist gave an inaccurate response for all categories. Only 1 phlebotomist, however, was aware that a splash of body fluid to the eyes or mouth was an inoculation injury. At least a quarter of all professions except 'others' believed an injury involving a clean needle could potentially transmit a blood borne pathogen; 10 out of 35 doctors (29%), 36 out of 135 nurses (27%), 4 out of 13 phlebotomists (31%), half of healthcare assistants (50%) and 4 out of 10 surgical theatre staff (40%). Furthermore, 18 out of 200 (9%) HCWs (2 doctors, 9 nurses, 3 phlebotomists and 4 surgical theatre staff) incorrectly perceived an injury with a used needle as having no risk of exposing the injured person to blood borne pathogens. Doctors (205 out of 280, 73% correct responses, 95% CI 68-78%) were significantly more knowledgeable regarding inoculation injuries than nurses (489 out of 1080, 45% correct responses, 95% CI 42-

48%) ($p=<0.0001$, Fishers' Exact Test). This was determined with the expectation that each professional group would correctly answer each question, for example, 8 correct answers multiplied by 35 doctors gives 280 correct responses.

Table 4.0: Healthcare workers' response to whether specific injuries or incidents involving sharp devices were defined as inoculation injuries.

Profession	Inoculation injury	% of total	No inoculation injury	% of total
SCRATCH				
Doctor	24	69	11	31
Nurse	43	32	92	68
Phlebotomist	7	53	6	46
Surgical theatre staff	4	40	6	60
Healthcare assistant	0		2	100
Other	1	25	3	75
BLADE				
Doctor	26	74	9	26
Nurse	49	36	86	64
Phlebotomist	4	31	9	69
Surgical theatre staff	2	20	8	80
Healthcare assistant	0		2	100
Other	1	25	3	75
BITE				
Doctor	23	66	12	34
Nurse	44	33	91	67
Phlebotomist	4	31	9	69
Surgical theatre staff	4	40	6	60
Healthcare assistant	0		2	100
Other	2	50	2	50
SCALPEL				
Doctor	26	74	9	26
Nurse	48	36	87	64
Phlebotomist	4	31	9	69
Surgical theatre staff	2	20	8	80
Healthcare assistant	1	50	1	50
Other	2	50	2	50
SPICULE OF BONE OR TEETH				
Doctor	25	71	10	29
Nurse	39	29	96	71
Phlebotomist	4	31	9	69
Surgical theatre staff	3	30	7	70
Healthcare assistant	0		2	100
Other	1	25	3	75
SPLASH				
Doctor	23	66	12	33
Nurse	41	30	94	70
Phlebotomist	1	8	12	92
Surgical theatre staff	2	20	8	80
Healthcare assistant	1	50	1	50
Other	1	25	3	75
CLEAN NEEDLE				
Doctor	10	29	25	71
Nurse	36	27	99	73
Phlebotomist	4	31	9	69
Surgical theatre staff	4	40	6	60
Healthcare assistant	1	50	1	50
Other	0		4	100
USED NEEDLE				
Doctor	33	94	2	6
Nurse	126	93	9	7
Phlebotomist	10	77	3	23
Surgical theatre staff	6	60	4	40
Healthcare assistant	2	100	0	
Other	4	100	0	

4.3.2 The risk of transmission of blood borne pathogens

The occupational risk of transmission of HBV, HCV and HIV from a PII was recalled by 9 out of 200 (4.5%, 95% CI 2-8%) HCWs, comprising 8 nurses of both senior and junior grade and 1 pre registration house officer. The risk of occupational transmission of HBV was identified by 42 out of 200 (21%) HCWs, HCV by 59 out of 200 (29.5%) and HIV by 53 out of 200 (26.5%) HCWs (figure 4.3). Fifty four out of two hundred (27%) HCWs believed the risk of transmission of HIV to be 1:3000, 10 times lower than the actual risk. In comparison, 114 out of 200 (57%) underestimated the risk of transmission of HBV and 43 out of 200 (22%) for HCV. Conversely, 55 out of 200 (28%) HCWs overestimated the risk of transmission of HIV, 7 out of 200 (4%) for HBV and 60 out of 200 (30%) for HCV. Indeed, 10 out of 200 (5%) HCWs did not know the risk of transmission of any blood borne pathogen. The remaining participants did not complete the question.

Eight out of thirty five (23%) doctors, 30 out of 137 (22%) nurses and healthcare assistants and 3 out of 13 (23%) phlebotomy staff were aware of the risk of occupational transmission of HBV from a PII. Eleven out of thirty five (31%) doctors, 40 out of 137 (29%) nurses and healthcare assistants and 4 out of 13 (31%) phlebotomy staff, knew the risk of transmission of HCV. Twelve out of thirty five (34%) doctors, 39 out of 137 (28%) nurses and healthcare assistants and only 1 (8%) phlebotomist knew the risk of transmission of HIV from a PII. Only 3 surgical theatre staff knew the risk of transmission of HCV and HIV and no surgical theatre staff member was aware of the risk of transmission of HBV. Of the 9% of doctors who knew the risk of HIV, 6 were pre registration house officers, 4 were registrars, 1 was a senior house officer and 1 a Clinical Lecturer.

No statistical significance was reached when junior and senior doctors' and junior and senior nurses' overall level of knowledge were compared (0.2840 and 0.3246 respectively, Fisher's Exact Test). No statistical significance was reached when the same comparisons were made for each blood borne pathogen. Indeed, there was no significant difference between doctors and nurses' knowledge of HBV, HCV and HIV (0.5366, 0.8368 and 1.000 respectively, Fisher's Exact Test).

Figure 4.3: Healthcare workers' knowledge of the risk of occupational transmission of hepatitis B, hepatitis C and human immunodeficiency virus from a percutaneous inoculation injury.

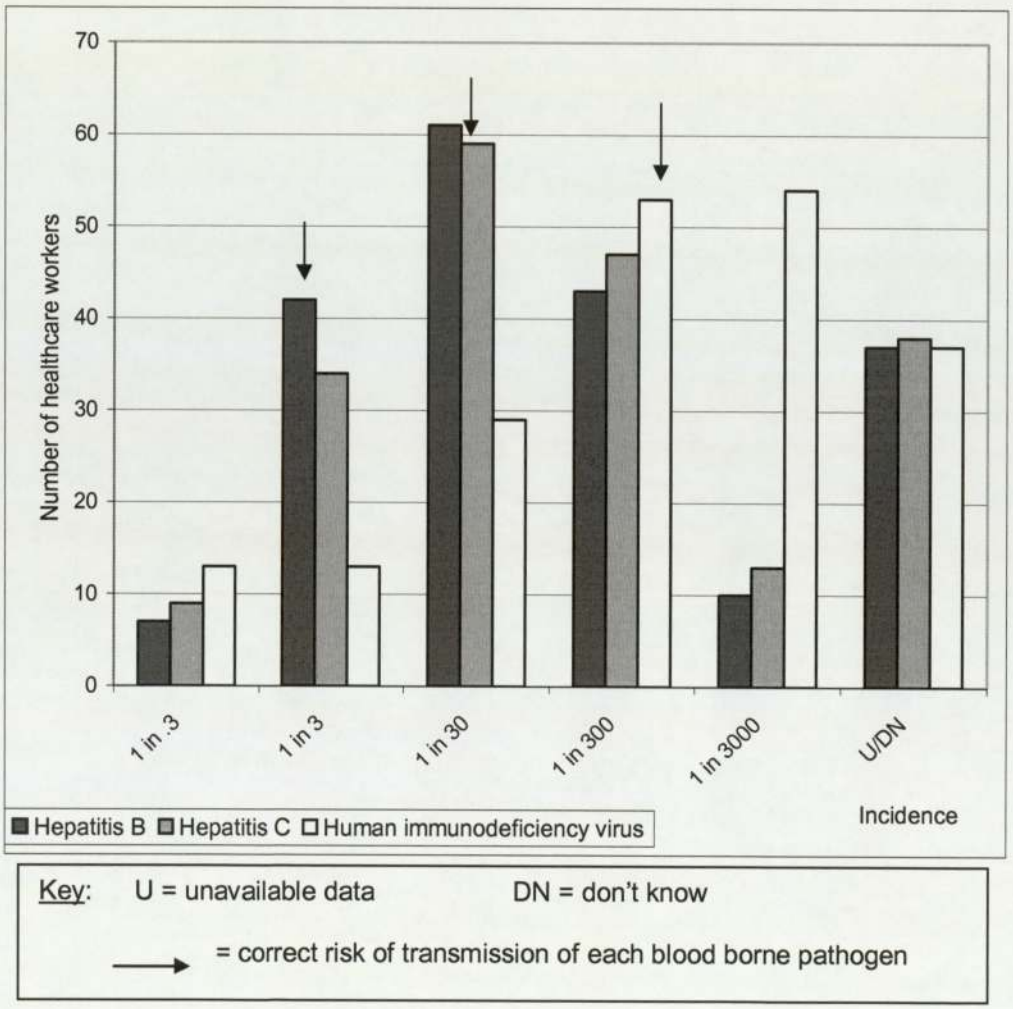


Table 4.1: Evaluation of the level of knowledge of the risk of occupational transmission of hepatitis B, hepatitis C and human immunodeficiency virus from a percutaneous inoculation injury by profession and grade.

Key: PRHO = pre registration house officer SHO = senior house officer
HCA = healthcare assistant % = percentage

Profession and total	Accurate hepatitis B	% of total	Accurate hepatitis C	% of total	Accurate HIV	% of total
Consultant Registrar Clinical lecturer/fellow (n=19)	3	50%	6	100%	5	83%
SHO PRHO (n=16)	5	31%	5	31%	7	44%
Senior nurses: I, H, G, F grade Military nurse (n=28)	8	29%	7	25%	11	39%
Junior nurses: E, D, C grade (n=94)	17	18%	31	33%	23	24%
Unqualified nurses: HCA, B, A grade Nursing students (n=15)	5	45%	1	7%	5	33%
Phlebotomy staff (n=13)	3	23%	4	31%	1	8%
Surgical theatre staff (n=10)	1	1%	2	2%	1	1%

4.3.3 The risk associated with sharp devices

Twenty nine out of two hundred (14.5%) HCWs rated an IV peripheral catheter, needle and syringe and vacutainer system between 1 and 3, inferring a high risk of exposure to blood borne pathogens if injured via these devices (table 4.2). Healthcare workers who were correct in their risk assessment comprised 21 out of 135 nurses, 6 out of 35 doctors, 1 out of 13 phlebotomists and 1 out of 10 surgical theatre staff. The risk of transmission of blood borne pathogens from an injury involving a suture needle, subcutaneous butterfly and blood glucose lancet were perceived to be lower (risk rated 4 to 8).

A subcutaneous butterfly was most frequently risk rated 6, 30 out of 200 times (15%), compared with an IV peripheral catheter risk rated 1, 43 out of 200 times (22%). A needle and syringe was perceived to be a high risk device by 71 out of 200 (36%) HCWs. An injury involving a suture needle was perceived to be higher risk than other devices with 55 out of 200 (28%) of HCWs rating the risk to be between 3 and 4. Similarly a blade was perceived to present a higher risk of transmission of blood borne pathogens following injury (51 out of 200, 26%). In comparison a blood glucose lancet was risk rated most frequently at number 5, 6 or 8 (81 out of 200, 41%), inferring a lower risk of occupational transmission of blood borne pathogens. The mean risk rating for an IV peripheral catheter was 2.1 compared with a blade 2.9, subcutaneous butterfly 2.8, vacutainer system 3.3, suture needle 4.4, needle and syringe 2.4, blood glucose lancet 5.3 and stitch cutter 6.4 (with a range of 1 to 8), indicating that injuries via hollow bore devices were rated as an increased risk of potential transmission of blood borne pathogens.

Table 4.2: Healthcare workers' perceived risk of occupational transmission of blood borne pathogens from an injury caused by specific sharp devices.

1 to 3 = higher risk, 4 to 8 = lower risk, 9 = unavailable data

Device Risk rating **Percentage of total healthcare workers**

	1	2	3	4	5	6	7	8	9	Total No.	1	2	3	4	5	6	7	8	9	Total %.
IVPC	43	42	20	17	12	3	7	7	49	**200**	22	21	10	9	6	2	3	3	24	**100**
B	22	18	24	27	28	14	10	5	52	**200**	11	9	12	14	14	7	5	3	26	**100**
SCB	4	14	27	22	19	30	22	9	51	**200**	2	7	14	11	9	15	11	5	25	**100**
SN	7	15	28	27	22	24	17	7	53	**200**	4	7	13	14	11	12	9	3	27	**100**
N/S	71	29	18	8	8	4	4	7	51	**200**	36	15	9	4	4	2	2	4	25	**100**
BGL	5	13	10	22	24	29	19	28	50	**200**	2	7	5	11	12	15	9	14	25	**100**
VS	20	20	22	12	13	15	24	24	50	**200**	10	10	11	6	6	8	12	12	25	**100**
SC	5	6	6	6	12	19	35	60	51	**200**	3	3	3	3	6	9	18	30	26	**100**

Key

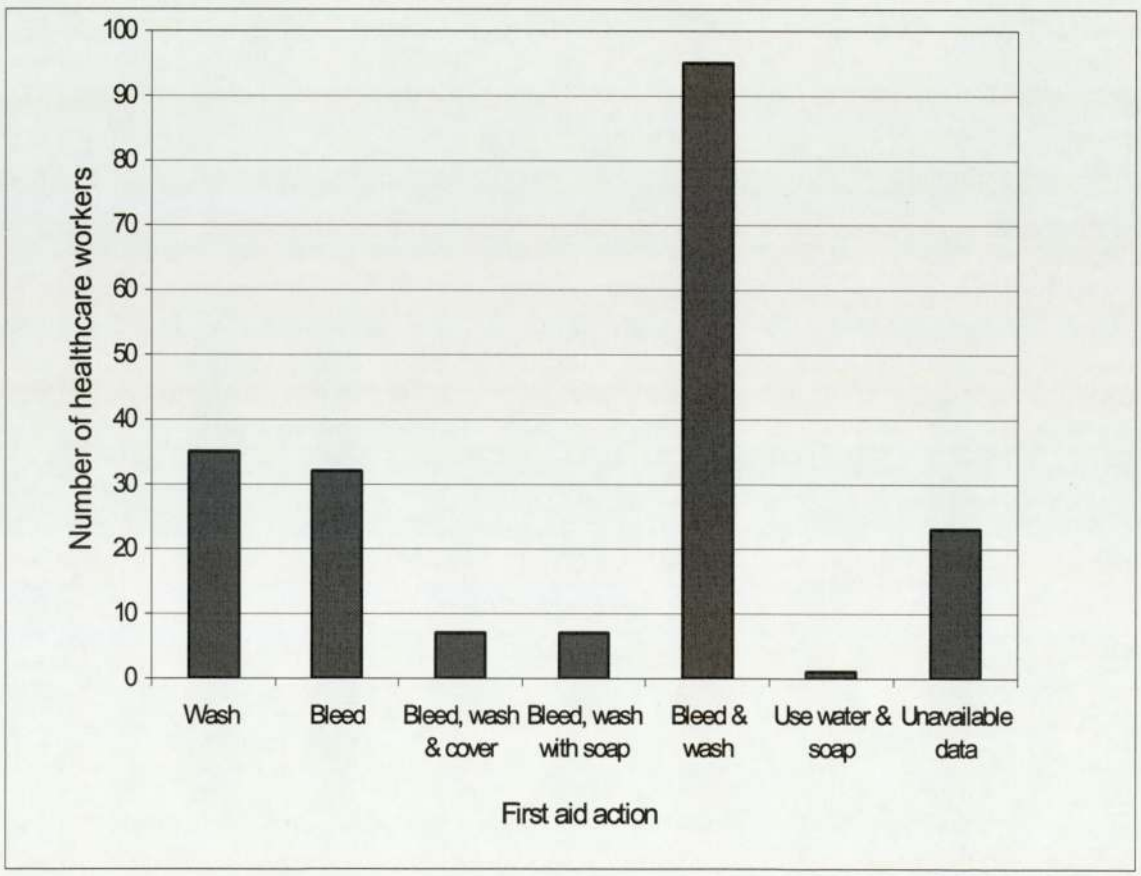
IVPC = intravenous peripheral catheter
SN = suture needle
N/S = needle and syringe
VS = vacutainer system
B = blade
SCB = subcutaneous butterfly (winged steel needle)
BGL = blood glucose lancet
SC = stitch cutter

4.3.4 The management of percutaneous inoculation injuries

4.3.4.1 First aid action

Bleeding the wound under water was the initial 'first aid' action taken by 95 out of 200 (48%) HCWs following a PII, however, an additional 14 HCWs would have also used soap or covered the wound (7%). Thirty five out of two hundred (18%) HCWs would have only washed the wound following a PII and 32 out of 200 (16%) would have only bled the wound (figure 4.4). The remaining 24 participants did not complete the question.

Figure 4.4: 'First aid' actions identified by healthcare workers following a percutaneous inoculation injury.



Seventy nine out of one hundred and thirty five (59%) nurses and half (50%) of healthcare assistants would have complied with the Trust's policy following a PII, compared with 18 out of 35 (51%) doctors (table 4.3).

Table 4.3: 'First aid' action undertaken following a percutaneous inoculation injury associated with profession.

'First aid' action	Profession	Number	Percentage of profession
Bleed and wash site	Nurse	71	53
	Doctor	15	43
	Phlebotomist	4	31
	HCA	1	50
	Surgical theatre staff	3	30
	Other	1	25
Bleed, wash, cover site	Nurse	4	9
	Phlebotomist	2	15
	Unknown	1	100
Bleed, wash with soap	Nurse	4	3
	Doctor	3	9
Bleed the site	Nurse	26	19
	Doctor	2	6
	Phlebotomist	1	8
	Surgical theatre staff	3	30
Wash the site	Nurse	19	14
	Doctor	12	34
	Phlebotomist	2	15
	Surgical theatre staff	1	10
	Other	1	25

Only 6 out of 13 (46%) phlebotomists would have performed the correct first aid action, compared with 3 out of 10 (30%) surgical theatre staff. Ninety one out of two hundred (46%) HCWs potentially remained at risk of full exposure to blood borne pathogens following a PII because the Trust's policy was not followed. Six HCWs incorrectly identified that skin disinfectant, for example, betadine, alcohol and chlorhexidine should be used to wash the affected site following a PII.

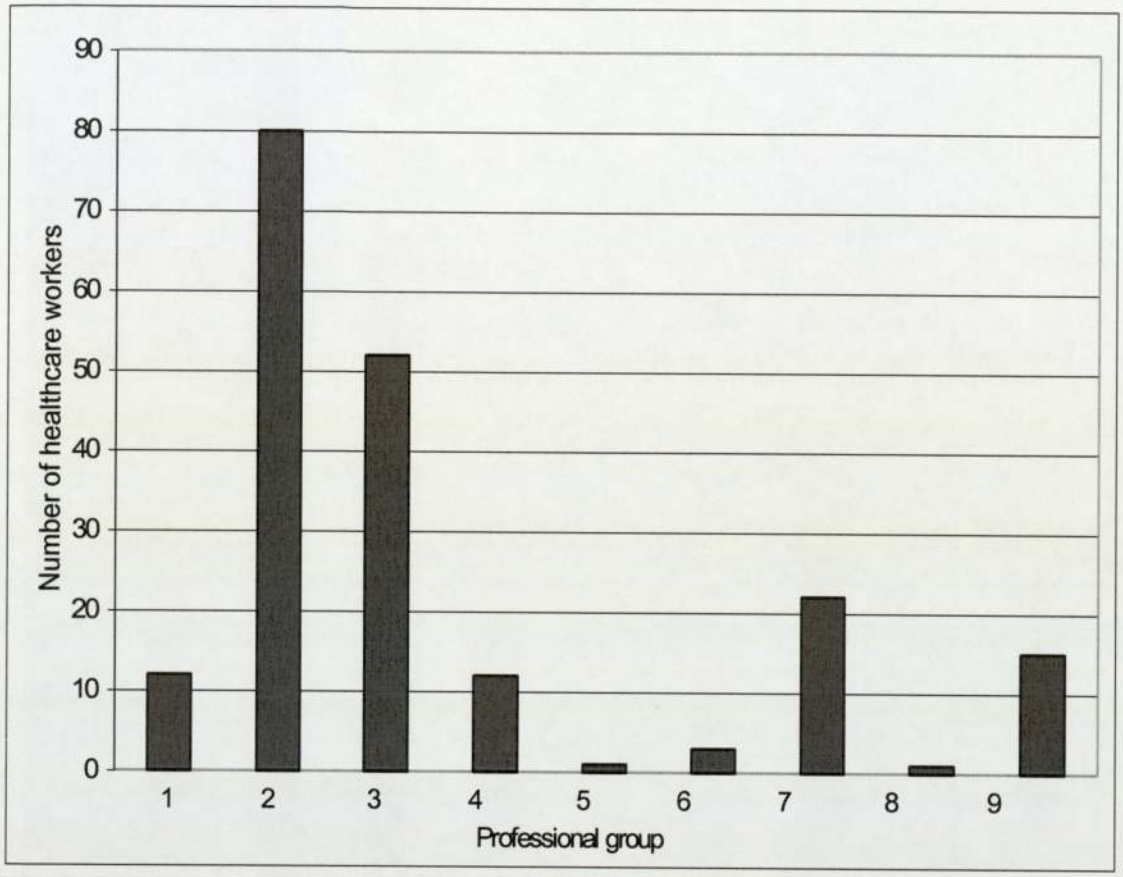
4.3.4.2 Serological testing

One hundred and eighty six out of two hundred (93%) HCWs agreed that the source patient should have blood taken for serological testing post PII. Of these, 33 out of 186 (18%) were doctors, 126 out of 186 (68%) were nurses, 8 out of 186 (4%) were surgical theatre staff, 12 out of 186 (6%) were phlebotomists, 4 out of 186 (2%) were 'others' and 1 out of 186 did not disclose their profession.

All senior nurses (F, G, H, I grades and military staff) demonstrated accurate knowledge regarding source patient blood testing, indeed 88 out of 94 (94%) junior nurses (E, D and C grades) were aware that source patients should have blood taken for serological analysis, compared with all (100%) HCAs, 15 out of 16 (94%) junior doctors and 14 out of 19 (74%) senior doctors. In addition, 12 out of 13 (92%) phlebotomists and 8 out of 10 (80%) surgical theatre staff were also aware that source patient blood should be taken for serological testing. Six participants did not disclose their grade.

Eighty out of two hundred (40%) (95% CI 33-47%) HCWs correctly designated the medical team to undertake drawing of source patient blood, in addition to 22 out of 200 (11%) who perceived the responsibility to be with the medical team or ward manager. The Occupational Health and Safety department was incorrectly highlighted to take source patient blood by 52 out of 200 (26%) HCWs, indeed 12 out of 200 (6%) HCWs identified they would have taken the blood themselves if they were injured (figure 4.5). Of these, 1 was a phlebotomist, 5 were doctors and 6 were nurses.

Figure 4.5: Departments or individuals identified by healthcare workers, to draw source patient blood following a percutaneous inoculation injury.



Key:
1 = Recipient
2 = Medical team (correct answer)
3 = Occupational Health and Safety department
4 = Medical team and Occupational Health and Safety department
5 = Night sister
6 = Recipient and medical team
7 = Medical team and manager
8 = A&E
9 = Unavailable data

Four out of fifteen (27%) comments documented regarding source patient blood being drawn for serological testing revealed that HCWs were aware that consent must be gained from the source patient prior to blood being drawn. Other comments displayed a limited level of awareness of the process (table 4.4).

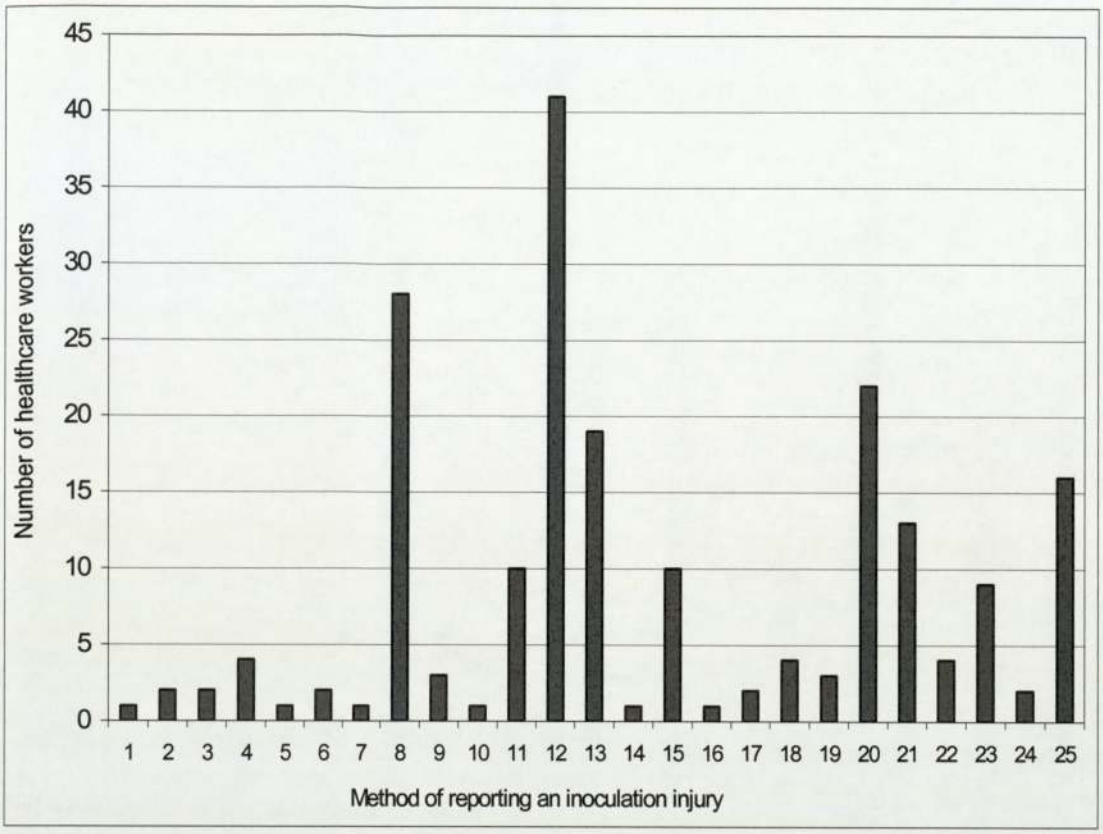
Table 4.4: Healthcare workers' documented comments regarding the drawing of source patient blood following a percutaneous inoculation injury (n=15).

Comment	Number of healthcare workers
Whoever is available can take the source patient blood	1
Either yourself, the medical team or Occupational Health and Safety department can take source patient blood	2
The person dealing with the incident should take the source patient blood	1
Either yourself or Occupational Health and Safety department should take the source patient blood	1
Consent should be attained prior to source patient bloods being obtained	4
The phlebotomist can take source patient bloods following a PII	1
Whoever can do venepuncture can draw source patient blood	1
It doesn't matter who draws source patient blood	1
Counselling is part of drawing source patient blood	1

4.3.4.3 Reporting percutaneous inoculation injuries

Twenty out of two hundred (10%, 95% CI 6-15%) HCWs were aware of the Trust's policy for reporting a PII (figure 4.6). Of these, 19 out of 20 (95%) HCWs were nurses and 1 out of 20 (5%) was 'other'. The nurses were represented by 1 G, 3 F, 7 E, 6 D grades and 1 healthcare assistant.

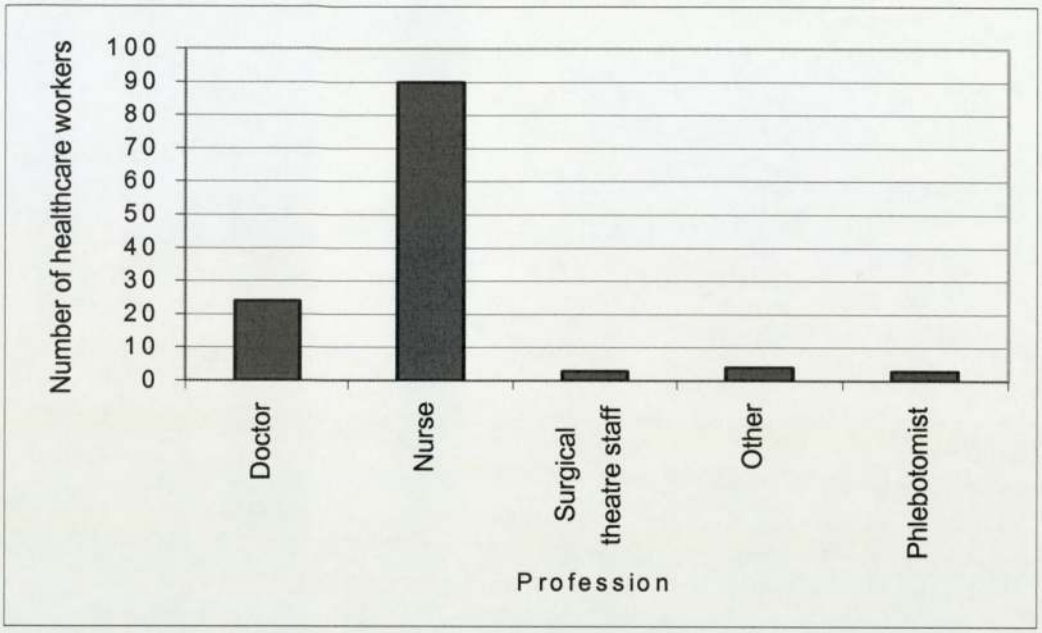
Figure 4.6: How healthcare workers would report an inoculation injury (n=200).



Key:
1 = Nurse in charge/Accident and Emergency
2 = Accident and Emergency
3 = Accident and Emergency/Manager
4 = Don't know
5 = Emergency Admissions Unit/Accident and Emergency
6 = Infection control/Occupational Health and Safety
7 = Infection control/Occupational Health and Safety/Incident form
8 = Incident form
9 = Incident form/Accident and Emergency
10 = Incident form/Infection control
11 = Incident form/manager
12 = Incident form/Occupational Health and Safety
13 = Incident form/Occupational Health and Safety/manager (**correct answer**)
14 = Incident form/manager/Accident and Emergency (**correct answer**)
15 = Manager
16 = Medical team/Incident form
17 = Nurse in charge/Incident form
17 = Nurse in charge/Occupational Health and Safety
18 = Nurse in charge
19 = Occupational Health and Safety
20 = Occupational Health and Safety/Accident and Emergency
21 = Occupational Health and Safety/Accident and Emergency/Incident form
23 = Occupational Health and Safety/Manager
24 = Other
25 = Unavailable data

Four out of two hundred (2%, 95% CI .05-5%) HCWs would have reported a PII to the Occupational Health and Safety or Accident and Emergency and Risk Management departments, however would have omitted to inform their manager. These HCWs accounted for 1 doctor and 3 nurses. However, 124 out of 200 (62%, 95% CI 55-69%) HCWs, following a PII, would have sought advice from Occupational Health and Safety, Accident and Emergency or Emergency Admissions Unit, all areas in the hospital designated to manage such an incident (figure 4.7). The majority of these HCWs were nurses (90 out of 124, 73%), compared with doctors (34 out of 124, 27%), surgical theatre staff (3 out of 124, 2%) and phlebotomy staff (3 out of 124, 2%). Indeed, all HCWs categorised in the 'other' group would have contacted an area designated to manage percutaneous inoculation injuries.

Figure 4.7: Healthcare workers, by profession, who would have sought advice from an area within University Hospital Birmingham NHS Trust, allocated to manage percutaneous inoculation injuries.



Forty out of two hundred (20%) HCWs (4 doctors, 33 nurses, 1 surgical theatre staff and 2 phlebotomists) would have contacted the Occupational Health and Safety department and completed a Risk Management incident form. Indeed, 27 out of 200 HCWs (14%, 95% CI 9-19%) would have reported a PII to Risk Management alone, inferring that they would not have blood taken for serological testing. Four out of thirty five doctors (11%) did not know how to report such an incident. Infection Control were incorrectly identified to manage inoculation injuries by 5 out of 200 HCWs and the medical team in addition to completing an incident form was documented by 1 HCW.

One hundred and fifty eight out of two hundred HCWs would have reported a PII (79%, 95% CI 73-84%), however 11 out of 200 (5.5%, 95% CI 3-10%) would not have reported any inoculation injury and 15 out of 200 (7.5%, 95% CI 4-12%) would sometimes have reported such incidents. The remaining 16 participants did not

complete the question. Nurses most frequently always reported inoculation injuries (114 out of 158, 72%, 95% CI 64-72%), compared with 8 out of 158 (5%) surgical theatre staff, 22 out of 158 (14%, 95% CI 9-20%) doctors, 8 out of 158 (5%) phlebotomists and 3 out of 158 (2%) 'other' staff. Significance was reached when comparing the reporting behaviour of nurses and doctors (p=0.0304, Fisher's Exact Test). Reasons for reporting injuries are documented in table 4.5.

Table 4.5: Healthcare workers' reasons for reporting, not reporting and sometimes reporting inoculation injuries.

Key: HCA = Healthcare assistant

Response	Doctor	Nurse/ HCA	Phlebot-omist	Surgical theatre staff	Other, unavailable data
'No' reporting					
Never had an inoculation injury	2	5			
Workload pressure	2				
Patient's serological status known	1				
Patient's blood taken for serological testing	1				
Vaccinations up to date	1				
'Yes' reporting					
Health and safety	4	17			
Follow up after the incident		2			
Record keeping/audit		11			
Clinical treatment following the incident		4			
Trust policy		13		1	
Medico-legal		19		1	
Never had an inoculation injury	3				
Clinical work area	1	1			
Risk of infection	1	2			
Infection control		19	2	4	2
To seek advice		1			
To assess cause of injury	5	1			
Training and education					
Safer devices	1	3			
Report if a used device		1			
		1			
'Sometimes' reporting					
Low risk patient	1				
Only if patient is positive for a blood borne pathogen	1				
Determined by the type and seriousness of injury	1				
Workload pressure	3				
Do not report clean device injuries		1	2		
If it is perceived to be a risk to self and others	2	1			
If it is a needlestick injury		1			
To maintain records		1			
Scratches are common, but needlestick injuries are an increased risk		1			

Health and safety, the risk of exposure and potential transmission of blood borne pathogens were most frequent reasons for reporting inoculation injuries. Reasons for not reporting injuries included never having had such an injury (6 out of 135 nurses), lack of time (2 out of 35 doctors), the patient's serological status was known (1 doctor), the patient had blood drawn for serological testing (1 doctor) and the recipient's vaccinations were up to date (1 doctor).

4.3.5 Gloves and sharp devices

Gloves were not routinely worn by all HCWs when using sharp devices in the clinical setting (table 4.6).

Table 4.6: Glove use associated with specific sharp devices and profession.

NA = Not applicable UD = Unavailable data % = percentage of participating profession

Profession	Yes	%	No	%	NA	%	UD	%
Subcutaneous butterfly								
Phlebotomist					3	23	10	77
Other	1	25			1	25	2	50
Surgical theatre staff	6	60	1	10	1	10	2	20
Nurse/HCA	67	49	9	7	35	5	26	19
Doctor	10	29	16	46	9	26		
Intramuscular injection								
Phlebotomist			2	15	4	31	7	54
Other	1	25			1	25	2	50
Surgical theatre staff	7	70	1	10	1	10	1	10
Nurse/HCA	79	58	45	33	8	6	5	4
Doctor	11	31	15	43	9	26		
Intravenous injection								
Phlebotomist			1	8	6	46	6	46
Other	1	25			1	25	2	50
Surgical theatre staff	7	70	1	10	1	10	1	10
Nurse/HCA	93	68	24	18	14	10	6	4
Doctor	15	43	13	37	7	20		
Intravenous peripheral catheter								
Phlebotomist	1	8	1	8	6	46	5	38
Other	1	25			1	25	2	50
Surgical theatre staff	6	60			2	20	2	20
Nurse/HCA	86	63	4	3	41	30	6	4
Doctor	21	60	14	40				
Central venous catheter								
Phlebotomist	2	16	1	8	5	38	5	38
Other	1	25			1	25	2	50
Surgical theatre staff	7	70			2	20	1	10
Nurse/HCA	58	42	1	1	70	51	8	6
Doctor	31	89	2	8	2	8		
Blood glucose lancet								
Phlebotomist	1	8	1	8	6	46	5	39
Other	2	50					2	50
Surgical theatre staff	8	80			1	10	1	10
Nurse/HCA	104	76	20	15	7	5	6	4
Doctor	4	11	17	49	14	40		
Venepuncture								
Phlebotomist	3	23	8	62	1	8	1	8
Other	1	25			1	25	2	50
Surgical theatre staff	8	80			1	10	1	10
Nurse/HCA	86	63	10	7	35	26	6	4
Doctor	19	54	15	43	1	3		
Arterial stab								
Phlebotomist	1	8	2	16	5	38	5	38
Other	1	25			1	25	2	50
Surgical theatre staff	8	80			1	10	1	10
Nurse/HCA	55	40	1	1	67	49	14	40
Doctor	22	63	13	37				
Subcutaneous butterfly								
Phlebotomist	4	31	6	46	2	16	1	8
Other	1	25			1	25	2	50
Surgical theatre staff	7	70	1	10	1	10	1	10
Nurse/HCA	82	60	22	16	25	18	8	62
Doctor	14	40	16	46	5	14		
Intravenous butterfly								
Phlebotomist					3	23	10	77
Other	1	25			1	25	2	50
Surgical theatre staff	6	60	1	10	1	10	2	20
Nurse/HCA	66	48	9	7	36	26	26	19
Doctor	17	49	14	40	1	3	3	9

Fourteen out of thirty five (40%, 95% CI 24-58%) doctors did not wear gloves when handling IV peripheral catheters compared with 4 out of 135 (3%, 95% CI 0.8-7%) nurses (p=0.0001, Fisher's Exact Test) (figure 4.8). Similarly 10 out of 135 (7%, 95% CI 3-13%) nurses did not wear gloves performing venepuncture, compared with 15 out of 35 (43%, 95% CI 26-60%) doctors (p=0.0001, Fisher's Exact Test). No statistical significance was reached when junior and senior doctors' use of gloves were compared. Senior nurses (18 out of 24, 75%, 95% CI 53-90%) and junior nurses' (60 out of 60, 100%, 95% CI 94-100%) use of gloves, when inserting IV peripheral catheters, was significantly different (p=0.0003, Fisher's Exact Test). Similarly, senior nurses (18 out of 24, 75%, 95% CI 53-90%) and junior nurses (56 out of 59, 95%, 95% CI 86-99%) use of gloves when performing venepuncture was significantly different (p=0.152, Fisher's Exact Test).

Figure 4.8: Nurses and doctors' use of gloves in the clinical setting associated with hollow bore devices used for direct access to a patient's artery or vein.

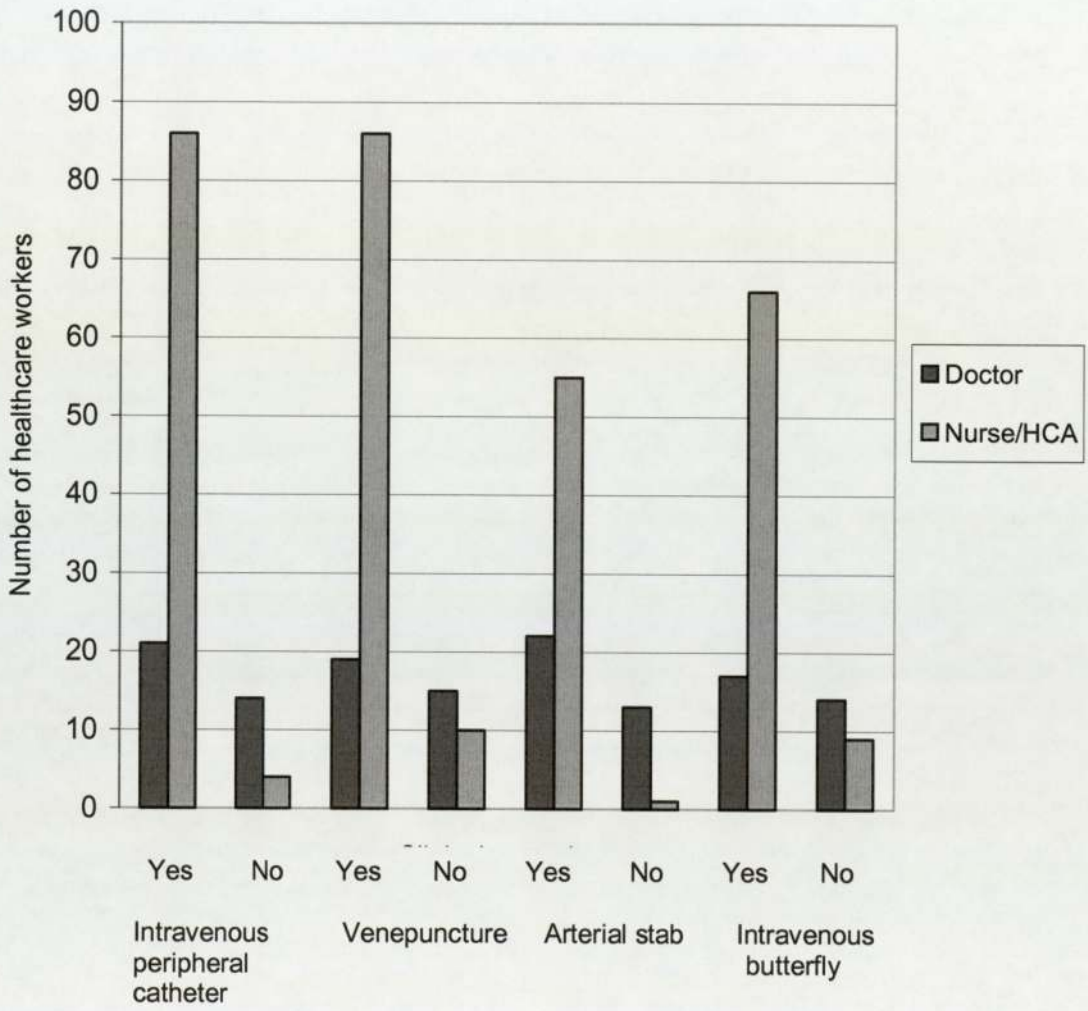


Table 4.7 illustrates overall glove use associated with a variety of clinical procedures involving sharp devices. Eighty four out of one hundred and ten (76%) HCWs wore gloves when administering a subcutaneous injection, compared with 98 out of 161 (61%) when administering an intramuscular injection, 116 out of 155 (75%) for administering an intravenous injection, 115 out of 134 (86%) for an IV peripheral catheter, 99 out of 103 (96%) for a CVC, 117 out of 155 (75%) when using a blood glucose lancet, 117 out of 150 (78%) when performing venepuncture, 87 out of 103 (84%) when undertaking an arterial stab, 108 out of 153 (71%) for a subcutaneous butterfly needle and 90 out of 114 (79%) for an intravenous butterfly needle. For each device, gloves were worn by at least 60% of HCWs. Gloves were not worn most frequently when administering an intramuscular injection (63 out of 161, 39%).

Table 4.7: Glove use associated with clinical procedures.

Profession	Wear gloves	Do not wear gloves	Total
Subcutaneous injection	n=84	n=26	
Doctor	10	16	26
Nurse	65	9	74
Phlebotomist	0	0	0
'Other'	1	0	1
Surgical theatre staff	6	1	7
Healthcare assistant	2	0	2
Intramuscular injection	n=98	n=63	
Doctor	11	15	26
Nurse	78	45	123
Phlebotomist	0	2	2
'Other'	1	0	1
Surgical theatre staff	7	1	8
Healthcare assistant	1		1
Intravenous injection	n=116	n=39	
Doctor	15	13	28
Nurse	92	24	116
Phlebotomist	0	1	1
'Other'	1	0	1
Surgical theatre staff	7	1	8
Healthcare assistant	1	0	1
Intravenous peripheral catheter	n=115	n=19	
Doctor	21	14	35
Nurse	85	4	89
Phlebotomist	1	1	2
'Other'	1	0	1
Surgical theatre staff	6	0	6
Healthcare assistant	1	0	1
Central venous catheter	n=99	n=4	
Doctor	31	2	33
Nurse	57	1	58
Phlebotomist	2	1	3
'Other'	1	0	1
Surgical theatre staff	7	0	7
Healthcare assistant	1	0	1
Blood glucose lancet	n=117	n=38	
Doctor	4	17	21
Nurse	102	20	122
Phlebotomist	1	1	2
'Other'	0	0	0
Surgical theatre staff	8	0	8
Healthcare assistant	2	0	2
Venepuncture	n=117	n=33	
Doctor	19	15	34
Nurse	84	10	94
Phlebotomist	3	8	11
'Other'	1	0	1
Surgical theatre staff	8	0	8
Healthcare assistant	2	0	2
Arterial stab	n=87	n=16	
Doctor	22	13	34
Nurse	53	1	54
Phlebotomist	1	2	3
'Other'	1	0	1
Surgical theatre staff	8	0	8
Healthcare assistant	2	0	2
Subcutaneous butterfly needle	n=108	n=45	
Doctor	14	16	30
Nurse	80	22	102
Phlebotomist	4	6	10
'Other'	1	0	1
Surgical theatre staff	7	1	8
Healthcare assistant	2	0	2
Intravenous butterfly needle	n=90	n=24	
Doctor	17	14	31
Nurse	65	9	74
Phlebotomist	0	0	0
'Other'	1	0	1
Surgical theatre staff	6	1	7
Healthcare assistant	1	0	1

4.3.6 Knowledge of needle protective devices

Healthcare workers' knowledge of NPDs was minimal with only 18 out of 200 (9%) HCWs identifying safer IV peripheral cannulae and needles were a method of increasing safety. Table 4.7 demonstrates HCWs knowledge of NPDs and techniques.

Table 4.8: Healthcare workers' knowledge of needle protective devices and techniques used in the clinical setting to reduce the risk of occupational exposure of blood borne pathogens (n=67).

Needle protective device or clinical practice	Number of healthcare workers
Cannulae	14
Kidney dish/tray	3
Sharps disposal container (taken to the patient when using sharp devices).	11
Gloves increase risk of injury when inserting intravenous peripheral catheters	1
Self sheathing needle holders	1
Vacutainer system	3
Sharps pad in theatres	2
Gloves	6
Blunt needles	1
Diathermy	1
Being careful	1
Hand washing	1
Infection control team	1
Not re-sheathing needles	8
Green bags	1
Retractable needles	1
Blade removers	1
Luer lock syringes	1
Universal precautions	1
Safer techniques	1
Closed system circuits	1
Don't know/No	35

One hundred and four out of two hundred (52%) HCWs did not know of any NPDs available to reduce the risk of PIIs. Indeed 1 HCW perceived wearing gloves would increase the risk of injury when inserting an IV peripheral catheter, however, 18 out of 200 (9%) HCWs identified that wearing gloves would increase their safety. Eight out of

two hundred HCWs identified that not re-sheathing needles would reduce the risk of exposure to blood borne pathogens.

The majority of HCWs did not answer the question asking whether their clinical area was using NPDs. Of those that did respond, only 3 out of 200 HCWs' clinical areas were using such devices.

4.4 Discussion

The HCWs included in this study were representative of the various professions and grades within Queen Elizabeth Hospital, UHB NHS Trust. The level of knowledge of inoculation injuries was limited, demonstrated by only 9 out of 200 correct responses. Interestingly, doctors were significantly more aware than nurses with regard to inoculation injuries. Previous studies demonstrated that HCWs did not have an adequate level of knowledge regarding exposure to blood borne pathogens (May and Brewer, 2001; Diprose *et al.*, 2000; Duff *et al.*, 1999), however, no previous available study focused on defining injuries and therefore comparisons could not be made. Doctors' significantly higher level of knowledge may be due to the repetitive reinforcement of these issues, during under-graduate years and the inclusion of blood borne pathogens in the curriculum taken during the initial years of clinical practice. Furthermore, it may be that doctors were more aware due to the potential devastating impact a seroconversion may have on their career, following exposure to blood borne pathogens.

Nurses' inadequate level of knowledge was unexpected because this group should complete mandatory annual update sessions, however there was no robust method for monitoring attendance. No central data collection facility was available, however as an alternative, individual clinical settings maintained HCW records, seldom using a computerised database. In addition, it may be that with nurse shortages and the number of mandatory update sessions nurses were required to attend on an annual basis, complete attendance was impossible. Consequently, knowledge of inoculation injuries may not have been maintained.

All HCWs demonstrated limited knowledge of the risk of transmission of blood borne pathogens following a PII, with only 9 out of 200 HCWs able to cite the risk of

transmission of HBV, HCV and HIV, of which 8 were nurses. The number of HCWs over and underestimating the risk of transmission for HBV, HCV and HIV concurred with previous findings (Stein *et al.*, 2003; Diprose *et al.*, 2000; Burke and Madan 1997). However, caution should be taken with comparisons because Diprose *et al.*, (2000) studied anaesthetic clinicians, whereas, Burke and Madan (1997) and this study included a variety of professions. These findings also concurred with other studies that demonstrated HCWs' poor level of knowledge of the risk of transmission of blood borne pathogens and the need for further educational input (Stein *et al.*, 2003; Leliopoulou *et al.*, 1999; Scoular *et al.*, 2000; Duff *et al.*, 1999).

Reasons for this limited knowledge may be that PIIs were not perceived as a clinical priority because the patients in the clinical area were deemed low risk and personal practice was sufficient to ensure safety (Connington, 2002). These perceptions encourage complacency, minimising the emphasis to update knowledge. It is unclear as to why nurses were most knowledgeable regarding the risk of transmission of blood borne pathogens, when they could not identify injuries defined as inoculation injuries. It may have been that although doctors were aware which injuries were categorised as inoculation injuries, unlike nurses, they had not retained the knowledge of the relative risk of each blood borne pathogen.

Hollow bore devices were accurately identified as increasing the risk of exposure to blood borne pathogens by only 29 out of 200 HCWs, with devices, for example, blood glucose lancets and subcutaneous butterfly needles rated as a lower risk. There was a paucity of evidence with a focus on HCWs' knowledge of the risk associated with individual sharp devices. It is documented, however, that the risk of transmission of blood borne pathogens increased with an injury from a hollow bore needle used to directly access a vein or artery (Department of Health Services, 2002; Goldmann, 2002; RCN, 2001). The limited knowledge of which device posed the greatest risk of

exposure to blood borne pathogens, following an injury, is interrelated to HCWs' overall deficient knowledge base.

Over half of all HCWs correctly documented the actions to be taken immediately following a PII. Misconceptions were evident, for example skin disinfectants as necessary following injury. Furthermore, the most recent American guidelines, did not advocate squeezing the puncture wound due to the absence of evidence base (Metules, 2002; CDSC, 2001), however this practice is still recommended in the UK. The limited knowledge of actions to be taken following a PII supported previous study findings. Diprose *et al.*, (2000) reported that only 68% of anaesthetists knew which 2 first aid actions should be taken following a PII.

The UK DH and previous studies emphasised the importance of training and education to raise awareness of the risks associated with PIIs (DH, 2002; Heinrich, 2000; DH, 1998; Mercier, 1994). Indeed, some studies demonstrated that such educational input increased awareness (Richard *et al.*, 2001; Kim *et al.*, 2001; Seto *et al.*, 1989). In addition, the RCN, UNISON and other such influential groups have campaigned to raise awareness of this issue. UHB NHS Trust has a comprehensive education and awareness programme including formal education, written policy and procedures, poster information displays within each clinical area and more recently, a 24 hour occupational health and advisory service. The information provided in this programme is continually updated and the most recent policy was updated in 2002. Despite this, the efficacy of the teaching and education programmes associated with PIIs appeared to have little impact on HCW awareness. This concurred with May and Brewer (2001) who reported that despite awareness campaigns HCWs continued to demonstrate deficits in their knowledge base. Furthermore, Goodfellow and Claydon (2001) identified that pre registration house officers did not recall any training associated with PIIs. Connington (2002) reported that nurses in Scotland did not perceive such training

to have an impact on their clinical practice and if nurses were aware of the risk of exposure following a PII, they were unable to implement change in their clinical setting.

Reasons for this may be that HCWs do not retain the information provided because they do not perceive it as important to their clinical practice (Connington, 2002) or that the methods for training are not suitable. Much of the information provided for doctors, on commencing work in a hospital, is provided during their induction programme. However, as Doig (2000) noted, this was not conducive for retaining important information because staff were overwhelmed by the volume of information received during induction training and they did not realise the importance of retaining information regarding PIIs. Although HCWs within UHB NHS Trust had access to the inoculation injury policy and procedure in all clinical areas and on the Trust intranet, this may have had little impact on their clinical practice because the information may not have been utilised. Furthermore, the risk of transmission of blood borne pathogens may not have been perceived as important.

Healthcare workers were aware that the source patient should have blood tested following a PII; however, only 80 out of 200 correctly identified the medical team as responsible for this procedure. There is a paucity of evidence focusing on HCWs' knowledge of source patient testing, however, Wareham and Breuer (2000) reported that although source patients were tested in most situations, only half of participating institutions tested high-risk patients and 9% did not test source patients. With the lack of a standardised method for managing PIIs, it may be that HCWs become confused with actions taken following injury. Subsequently, they may rely on self-developed strategies, which may not be evidence based.

Healthcare workers demonstrated limited awareness of the Trust policy regarding reporting PIIs. Only 20 out of 200 identified the correct process for reporting injuries,

19 of which were nurses. Despite this limited awareness, 124 out of 200 would have sought advice from a clinical area competent in managing these incidents. Of these, 90 were nurses. It was concerning that 27 out of 200 HCWs only reported their PII to Risk Management using an incident form. This implied that no blood samples were obtained from either the source patient or the recipient. These findings supported those of Connington (2002) who reported that 71% of nurses in Scotland identified that their employer had a PII policy, however only 10% were aware of its details. Furthermore, 20% of junior doctors were unaware of whom to contact following a PII (Sidwell *et al.*, 1999). It is interesting to note that only one doctor was aware of how to report a PII. This may reflect training deficits and emphasise the importance of ensuring update sessions, however, may also highlight the inefficiency of hospital induction programmes. Junior doctors move hospitals on a regular basis as part of their training and education. As such, these doctors should attend hospital induction with each move and therefore should receive information on how to report adverse incidents, for example PIIs. Doctors' limited knowledge of reporting procedures may be due to a lack of appropriate information and training or due to confusion resulting from a non standardised procedure.

Healthcare workers did not always report their PIIs and nurses reported significantly more PIIs than doctors ($p=0.0304$, Fisher's Exact Test), which was also found in Stein *et al.*, (2003) recent study. Reasons included workload pressure, knowing the serological status of the patient and the injured HCW assessing the risk of exposure. These findings supported those of Rabaud *et al.*, (2000), May and Brewer (2001) and Osborn *et al.*, (1999) who highlighted the potential stigma attached to reporting such injuries in addition to the fear of a positive result. Moreover, HCWs did not know how to report a PII, despite comprehensive education strategies. In addition, it may reflect the frequency with which the reporting procedure is used. The majority of HCWs do not have to utilise this procedure on a daily basis and therefore recalling the procedure

may become more difficult with time post training. It is unclear, however, why HCWs do not consult the procedure manual, available in every clinical area and on the Trust intranet. Alternatively, it may be that the procedure required to report PIIs was perceived as laborious and time consuming. Therefore, HCWs adopted their own method of reporting. Not reporting PIIs may also reflect HCWs' despondence because evidence of change or action may be limited.

Doctors' reporting behaviour appeared to depend upon their workload and their risk assessment of the injury. Indeed, knowing the source patient's serological status was also highlighted in chapter 3 as a factor that determined the reporting of PIIs. These findings supported those of Scoular *et al.*, (2000), who reported that 27% of those who sustained a PII took no medical advice. Furthermore, the Short Life Working Group (2001) in Scotland, highlighted that HCWs self assessed PIIs rather than following formal reporting procedure and that pressure of workload influenced reporting behaviour (Metules, 2002). If HCWs are not aware of the true risk of exposure to blood borne pathogens, their risk assessment of the incident will be based on inaccurate information (Lelopoulou *et al.*, 1999). Indeed, Patterson *et al.*, (1998) found that surgeons demonstrated only slight or moderate concern of contracting HIV, with 4% having no concern at all.

Reasons as to why nurses reported their PIIs more often than doctors may be associated with their ability to manage the incident. Doctors are able to obtain blood samples, consent the source patient for testing and access the necessary patient information without formally reporting the incident. In comparison, nurses require medical input to be able to follow the procedure required to obtain source blood samples because not all nurses undertake venepuncture and the Trust policy indicated that medical staff should take blood for serological testing post PII.

Not reporting PIIs is well documented in the literature (Dobie *et al.*, 2002; Haiduven *et al.*, 1999; Lynn *et al.*, 1999). Failing to follow guidelines poses immediate risk to the HCW (Roy and Robillard, 1994). It was suggested that the lack of investment in education and a limited understanding of HCWs' safe behaviour in the workplace were causal factors (Henderson, 2001). When compared with UHB NHS Trust, investment has been made in educating HCWs in the risks associated with PIIs. However, HCWs' safe behaviour in the workplace has not, to date, been studied. Other reasons for not reporting PIIs have been identified as the HCW not being able to influence the outcome, lack of awareness of the reporting procedure and being advised by others not to report (Connington, 2002; Rosenthal *et al.*, 1999). Alternatively, it may be that HCWs are unable to carry out the correct procedure following injury due to the practicalities of attending Accident and Emergency outside working hours or Occupational Health and Safety within working hours.

Gloves were not worn routinely by HCWs and nurses wore gloves significantly more often than doctors when inserting IV peripheral catheters. Previous studies identified selective glove use by all HCWs (O'Connell and Hayes, 2003), determined by patient risk factors (Bermingham and Kippax 1998; Hettiaratchy *et al.*, 1998). In addition, there was substantial evidence to suggest doctors' infrequent use of gloves (Stein *et al.*, 2003; Nobile *et al.*, 2002; Hettiaratchy *et al.*, 1998; Bermingham and Kippax, 1998; Wooley *et al.*, 1991). Reasons for this are unclear. The DH recommended that HCWs with long experience of performing venepuncture without wearing gloves might prefer to continue not wearing them to avoid the perceived reduction in manual dexterity and possible increased risk of PII (DH, 1998). These guidelines did not however define 'long experience' but did comment that medical students and other inexperienced HCWs should become accustomed to wearing gloves. Historically, doctors undertook venepuncture and inserted IV peripheral catheters. Consequently, it may be that when junior doctors were trained to undertake these procedures, they were advised or

trained by senior colleagues without wearing gloves. Anecdotal evidence from junior doctors suggests that their senior colleagues frequently teach venepuncture and IV peripheral catheterisation without emphasising the need to wear gloves. Indeed, some trainers positively advocate not wearing gloves.

Other reasons for non-compliance with glove use included reduced dexterity, forgetting to comply, protective equipment was not available, HCWs did not bother to wear protective clothing and gloves did not fit appropriately (Stein *et al.*, 2003; Nelsing *et al.*, 1997). The importance of correctly fitting gloves was highlighted by Clarke *et al.*, (2002). Poorly fitting gloves were reported to interfere with dexterity, caused friction, excessive sweating and could affect the muscles and fingers resulting in finger fatigue. Indeed, ambidextrous gloves exerted a greater force than fitted gloves, contributing to vascular constriction and nerve compression (Powell *et al.*, 1994).

This study's findings concurred with other previous reports that HCWs did not adhere to universal precautions in the clinical area (Lynn *et al.*, 1999, Nelsing *et al.*, 1997). It was suggested that working conditions and workload pressure influenced adherence (Godin *et al.*, 2000) in addition to HCWs' perception of risk and knowledge of routes of transmission of blood borne pathogens (Willy *et al.*, 1990).

Healthcare workers' level of knowledge regarding NPDs was minimal. There is limited research evidence in the literature to support these findings because this technological development is relatively new to healthcare. In the UK, introduction of NPDs is slow, in part due to the paucity of cost analysis and evaluative studies (Jagger, 2002; Connington 2002; Munro 2001; Godfrey 2001). It is essential, therefore, that training and education on PIIs should include information of NPDs, to encourage use and evaluation.

To address the issues highlighted in this study, a review of education provision is essential. Methods of teaching, the course material, in addition to the environment in which HCWs are taught, should be evaluated for their efficacy. For example, a study evaluating HCWs' degree of information retention over time post training, including both induction and update sessions, should be undertaken. Indeed, monitoring attendance of mandatory teaching sessions should be centralised and computerised to enable audit of reasons for non-attendance that may also assist in understanding why HCWs could not recall PII information.

A review of the provision of education for doctors should be undertaken to establish current practice. In addition, implementation of a mandatory, annual education programme for doctors throughout their medical training should be considered, be it an attended course or alternatively a monitored distance learning package to be completed at their convenience.

Implementation of evidence based guidelines to support the Trust policy may encourage HCWs to adhere to policy and procedure. This could include rationale for the procedure as well as suggested reading material. However, guidelines may also be detrimental to HCW knowledge due to the volume of existing guidelines within healthcare.

It would be of benefit to gain information from the HCWs themselves as to the reasons for this evident limited knowledge base. Furthermore, a review of work practices and the clinical organisational climate may assist in identifying reasons for poor knowledge base and non-adherence to Trust policy.

The Trusts' approach to reduce the incidence of inoculation injuries corresponded with other strategies that highlighted the importance of safety awareness in the work

environment and provision of information and training as essential to reducing the risk of injury (DH, 2002; Short Life Working Group, 2001; Heinrich, 2000). Two strategies implemented by UHB NHS Trust included an Inoculation Review Group (described in chapter 2). To date, training and education for staff required to manage all inoculation injuries, annual sharps awareness days for the Trust and standardised evaluation tools for NPDs have been implemented. It is essential, however to ensure that HCWs in acute settings who manage PIIs are equipped to assess the potential for blood borne pathogen transmission and determine the need for treatment and testing. These HCWs should also be competent to administer PEP and refer exposed HCWs for appropriate follow up medical and psychological care (Gerberding, 2003).

4.4.1 Limitations

Obtaining information via questionnaires may have limited HCWs' response. In addition, it was not possible to evaluate what effect, if any, having the data collectors present had on HCWs' response (Hawthorne effect) (Polit and Hungler, 1993). Alternative methods of data collection to be considered are interviews or focus groups, which may encourage in depth discussion and more detailed data. However, the time required to participate in and facilitate such sessions may be impractical for an already pressurised workforce. Alternatively, questionnaires could be posted to a randomised sample of Trust HCWs. However, this method may result in a poor response rate and the availability of current details of all HCWs within the Trust may present confidentiality issues.

The method used to risk-rate the eight sharp devices in question 5 was utilised to highlight the increased risk associated with hollow bore needles. However, because no distinction was made between a needle and syringe used to perform venepuncture or administer a subcutaneous or intramuscular injection, it was not made clear as to the

exact knowledge demonstrated by HCWs. If this study were to be repeated, identifying the needle and syringe by clinical procedure may produce more detailed information. Furthermore, no direct rating was stipulated for sharp devices other than the hollow bore devices. In repeated studies, clarification could be achieved by determining a standardised rating prior to data collection.

4.4.2 Recommendations

To evaluate the utilisation of the annual mandatory update sessions, a review of attendance lists across the Trust should be undertaken. This information may assist in gaining an understanding of whether the sessions were ineffective or whether staff were not attending. In addition, if staff do not attend, reasons for this should be investigated. Indeed, with the introduction of a centralised data collection facility regarding training and education, this information could be collated and available for audit purposes.

Training and education on blood borne pathogens and inoculation injuries should be implemented for medical students and doctors to ensure knowledge and skill updates. Indeed, a study reviewing staffs' behaviour with regard to safe practice in the clinical setting may highlight why HCWs do not adhere to policy and procedure. Feedback from the Risk Management department to individual clinical areas involved with PIIs may encourage HCWs to support change and safe work practices.

Other methods to increase awareness may be to implement a pocket size booklet including information regarding issues such as inoculation injuries. As such, the Trust is currently reviewing the possibility of introducing a 'passport to health', which would include this type of information for HCWs. In addition, the availability of pre-packed inoculation injury packs consisting of a flow chart of actions post injury in addition to the

necessary equipment required to comply with policy (blood bottles and request forms) may encourage HCWs.

4.5 Summary

Healthcare workers lacked awareness and knowledge of the risks associated with inoculation injuries. The number of HCWs able to define an inoculation injury, the risk of transmission of HBV, HCV and HIV and the policy and procedure following a PII was unsatisfactory. UHB NHS Trust provided a comprehensive education strategy, however this made limited impact on HCWs' knowledge base. Healthcare workers placed themselves at risk of exposure to blood borne pathogens because the appropriate guidelines were not followed. The findings gave some insight into the reasons for not adhering to policy and procedure, including self-assessment of the risk of exposure, pressure of workload and not knowing how to report. Attempts to improve HCWs' knowledge must include a review of current education programmes to identify their efficacy, evaluating HCWs' degree of information retention post training and evaluation of HCWs' work practices in the clinical arena to identify causal factors for the limited knowledge of inoculation injuries.

Chapter 5: Evaluation of a needle protective intravenous peripheral catheter: Safelon™ Pro

5.1 Introduction

The most recent PII prevention strategy has focused on NPDs (Twitchell, 2003). With advances in technology, product companies developed IV peripheral catheters, incorporating a safety feature to reduce the risk of PII. Furthermore, in the USA legislation in November 2001 mandated that NPDs be implemented in the clinical setting (Pugliese *et al.*, 2001). Currently in the UK, there is no such legislation, however a Needlestick Injury Bill was presented by Laura Moffatt MP to the House of Commons for consideration in July 2003 (Brewer, 2003).

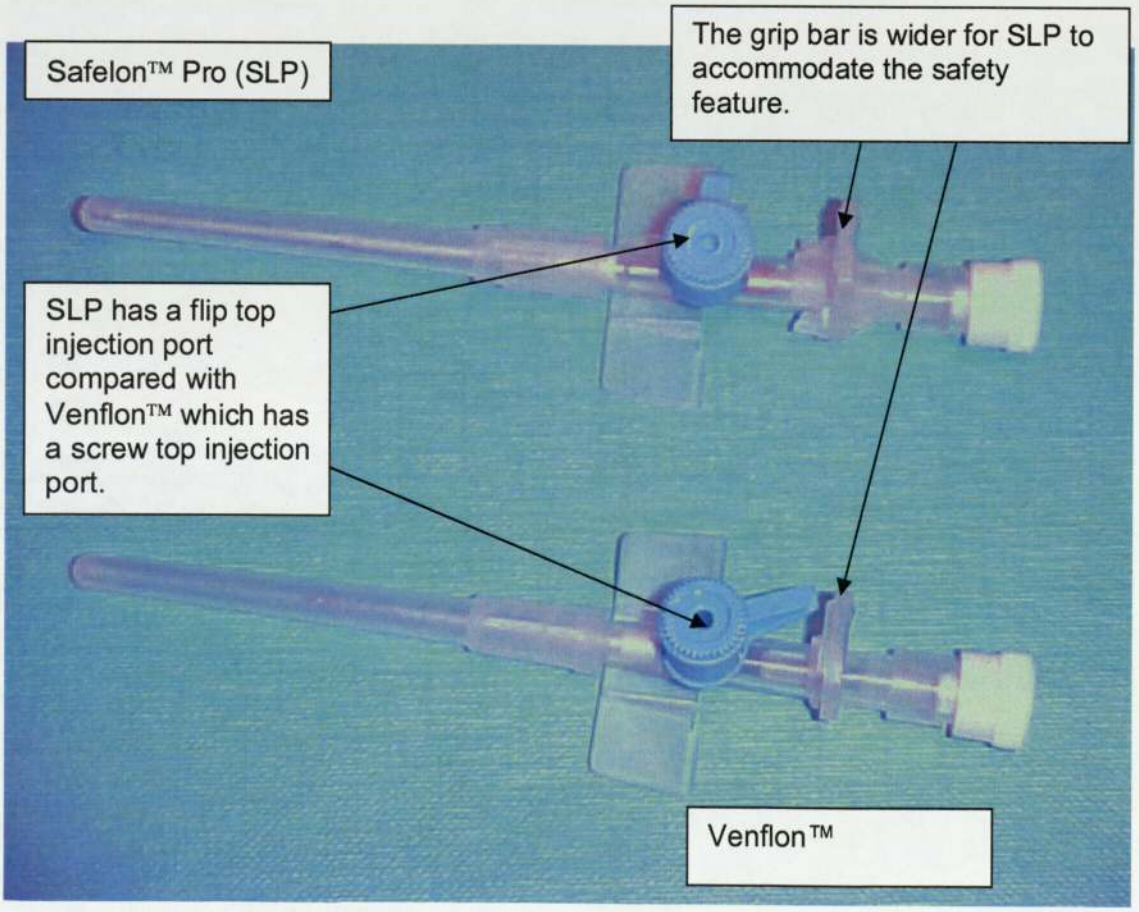
Six studies have evaluated 5 IV peripheral catheter NPDs; BD Safelon™ (Mummery 2002; Watters *et al.*, 1995), BD Insyte™ Autoguard™ (Asai *et al.*, 1999; Asai *et al.*, 2002), Johnson and Johnson Protectiv Acuvance™ (Asai *et al.*, 2002; Mummery 2002), Johnson and Johnson Protectiv Plus™ (Mendelson *et al.*, 2000) and B Braun Introcan Safety IV catheter (B Braun, 2003). However, only BD Insyte™ Autoguard™ (Mendelson *et al.*, 2000) and Introcan Safety IV catheter (B Braun, 2003) have been evaluated for their efficacy in preventing PIIs. Two studies were undertaken in the USA (Mendelson *et al.*, 2000), 2 in Japan (Asai *et al.*, 1999; Asai *et al.*, 2002) and 2 in the UK (Mummery, 2002; Watters *et al.*, 1995). Three products, BD Safelon™, BD Insyte™ Autoguard™ and Johnson and Johnson Protectiv Acuvance™ were evaluated in more than 1 study.

Safelon™ Pro (SLP) was a new product incorporating safety engineered technology, not previously available or evaluated in the clinical setting. In accordance with current

literature, it was important to evaluate the product's clinical usability and acceptability, in addition to its efficacy in reducing PIIs (Jagger, 2002; NIOSH, 1999).

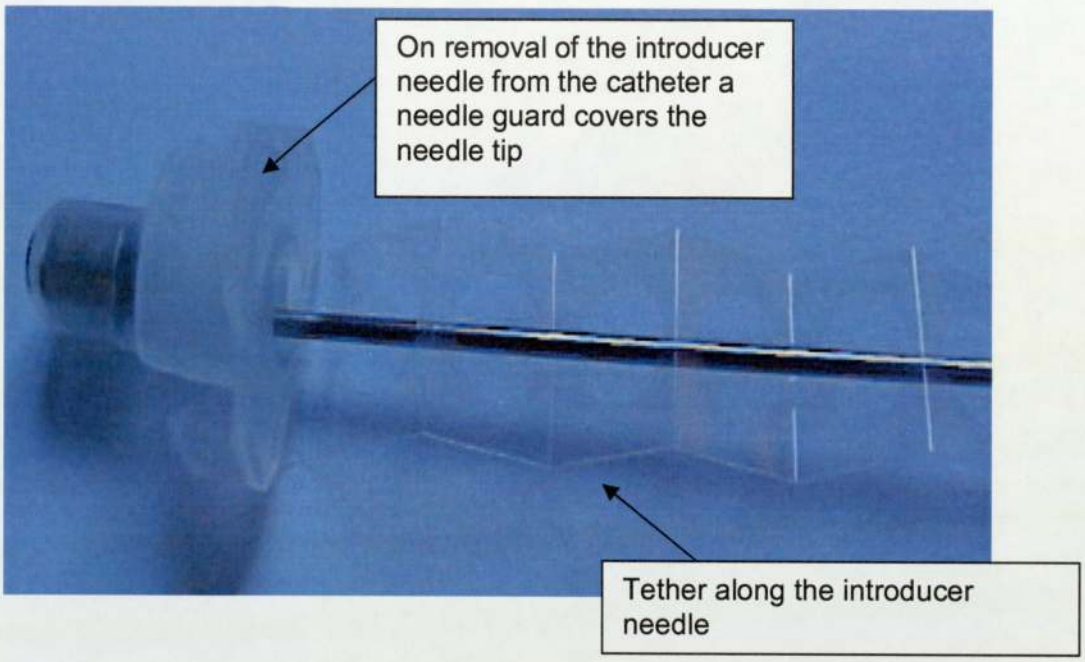
The product was originally designed utilising the basic structure of BD Venflon™, incorporating a safety mechanism (figure 5.0). Unlike Venflon™, whose catheter was produced from Teflon™, SLP's catheter was produced from a polyurethane material, Vialon™. This improved ease of penetration (Gaukroger *et al.*, 1988), was less resistant to the adherence of microorganisms (Kerrison and Woodhull, 1994), reduced the risk of infiltration and phlebitis with subsequent reductions in cost, increased indwell time (Stanley *et al.*, 1992; Maki and Ringer, 1991; McKee *et al.*, 1989) and exhibited greater kink resistance (Jaquot *et al.*, 1989)

Figure 5.0: Comparisons between BD Venflon™ and Safelon™ Pro.



The safety feature comprised a needle guard and tether along the introducer needle (figure 5.1).

Figure 5.1: The safety feature incorporated in Safelon™ Pro.



The needle guard was located in the back of the catheter (figure 5.2). As the introducer needle was withdrawn from the catheter, the tether extended. On final separation of the introducer needle from the catheter, the needle guard deployed. Once in place, the needle did not pass back through the needle guard due to a spring mechanism (figure 5.3).

SLP complied with NPD guidelines (NIOSH, 1999; FDA, 1992). When SLP was compared with criteria for evaluation described by ECRI (2001), the only factor not adhered to was that the NPD was not available in all gauge sizes, because it had not been launched commercially.

Figure 5.2: Location of Safelon™ Pro's needle guard prior to activation.

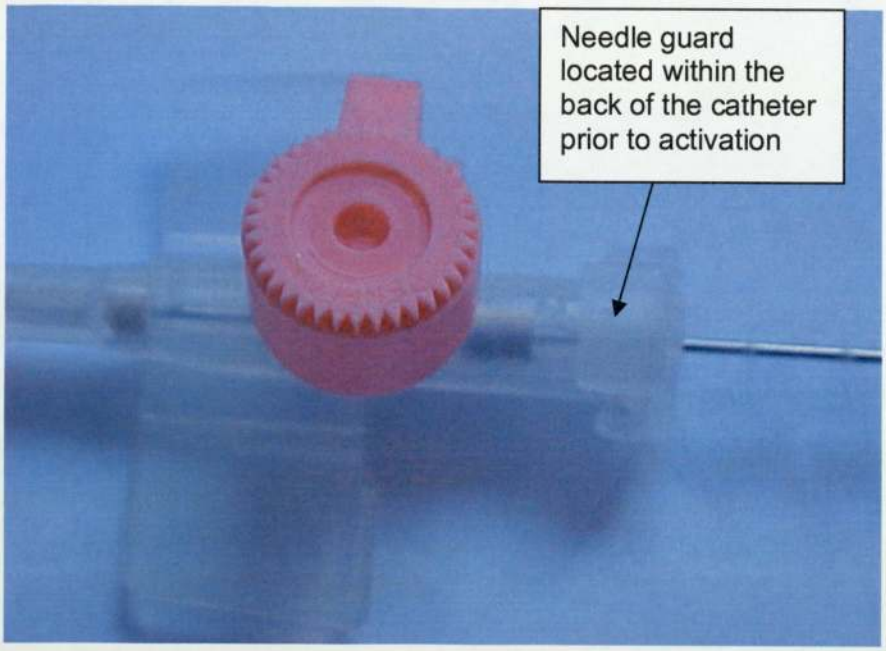
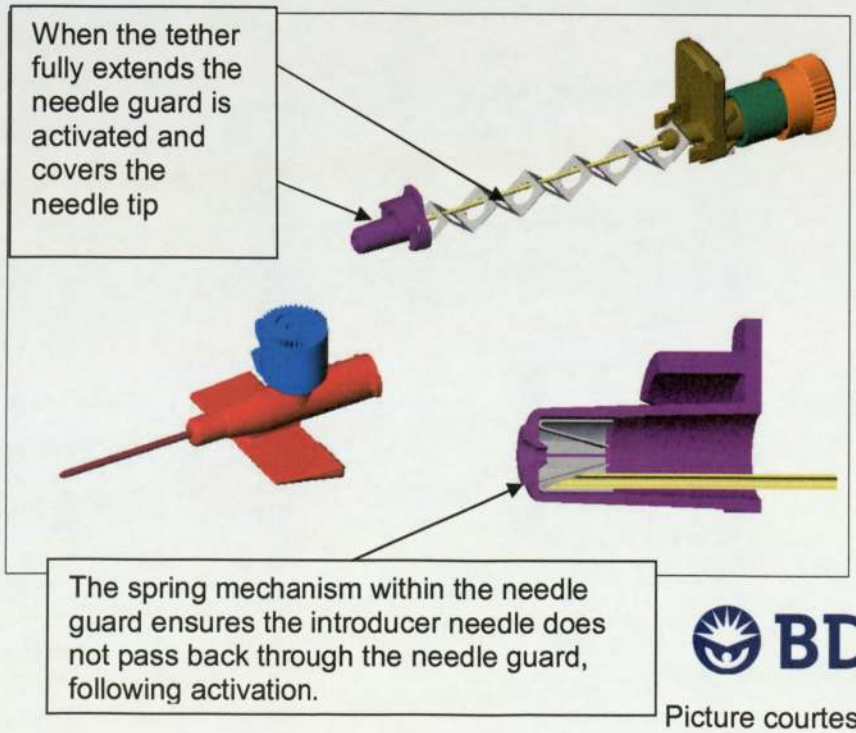


Figure 5.3: Safelon™ Pro and its safety mechanism.



Picture courtesy of BD

5.2 Pilot study: clinical usability and acceptability

5.2.1 Methods and materials

Prior to commencing this study, the Local Research Ethics Committee, the Trusts' Clinical Governance and Research and Development departments granted approval of the study. Four specialties within Queen Elizabeth Hospital, UHB NHS Trust were selected to participate in the SLP pilot study. Specialties included cardiac, renal, general surgery and urology, which ensured diverse clinical settings, patient condition and vein quality. Consultants and ward managers within these areas were approached, the study explained and agreement gained to use the NPD in their areas.

In total, 16 doctors and 2 nurses agreed to participate in the study. Fifteen doctors were initially contacted following approval from their consultant and the other HCWs (1 doctor and 2 nurses) participated following interest in the study. Prior to their agreement to participate, the aims of the study were explained (appendix 5A). The 18 HCWs were introduced to SLP and its features during a training session, either in a group or on an individual basis, determined by their workload and availability during the training period. A one day training programme was organised, divided into hour sessions. The HCWs were contacted and they selected a training session convenient to their daily activities. Each training session comprised no more than 4 participants to ensure a one to one or one to two ratio of trainer to participant. Training was standardised, including a presentation on PIIs and SLP, followed by a practical session, which enabled the HCWs to use the NPD on a simulator arm (Ambu® I.V. Trainer). On completing the training session, each HCW received an information sheet (appendix 5A) and signed for a study number to maintain anonymity during the study and agree participation.

A 2 month period was allocated to complete the pilot study. Each HCW was asked to insert 20 sequential SLP catheters, giving a total sample size of 360. The product company (BD) predetermined the sample size accounting for trials of the same product undertaken at the same time across Europe. The HCWs commenced using SLP over a 2 week period to enable provision of clinical support. Healthcare workers working in cardiac and surgical specialties commenced evaluation of the NPD during the first week, followed by those working in urology and renal areas in week 2. An initial demographic questionnaire was completed by each participating HCW at the start of the pilot study (appendix 5B). To minimise untrained HCWs using SLP, participating HCWs were provided with an individual supply of the device, distributed and stocked by the Clinical Research Nurse (J Trim) on a daily basis. The device was not stocked in the clinical area or on resuscitation trolleys and was not routinely used by participating HCWs during emergencies.

The HCWs inserted SLP catheters sequentially for any patient requiring IV peripheral access as part of their clinical management. Following each catheterisation with SLP, a standardised evaluative questionnaire was completed (appendix 5C). If the catheterisation was successful, the whole questionnaire was completed, however if catheterisation was unsuccessful, HCWs only completed question 1 documenting reasons for the failed attempt. In addition, HCWs were asked to document how preventing blood leak and evidence of blood splash whilst inserting SLP catheters, compared with conventional products. The conventional products were those used by the HCWs within the Trust at the time of the study, identified in the summative questionnaire (appendix 5D). Blood splash was defined as the spread or scatter of blood in the manner of splashed liquid. The summative questionnaire was completed by each HCW either on completion of the 20 SLP insertions or at the end of the pilot study. This questionnaire included a comparative analysis of SLP with conventional products and HCWs' product preference. On completion of the pilot study, all SLP

catheters were collected and withdrawn from the clinical setting for the period of data analysis.

Data from the usability and acceptability pilot study were collated and analysed utilising a Microsoft™ Access97 database. Non-parametric statistical tests were applied, where appropriate using commercially available software (http://www.statpages.net).

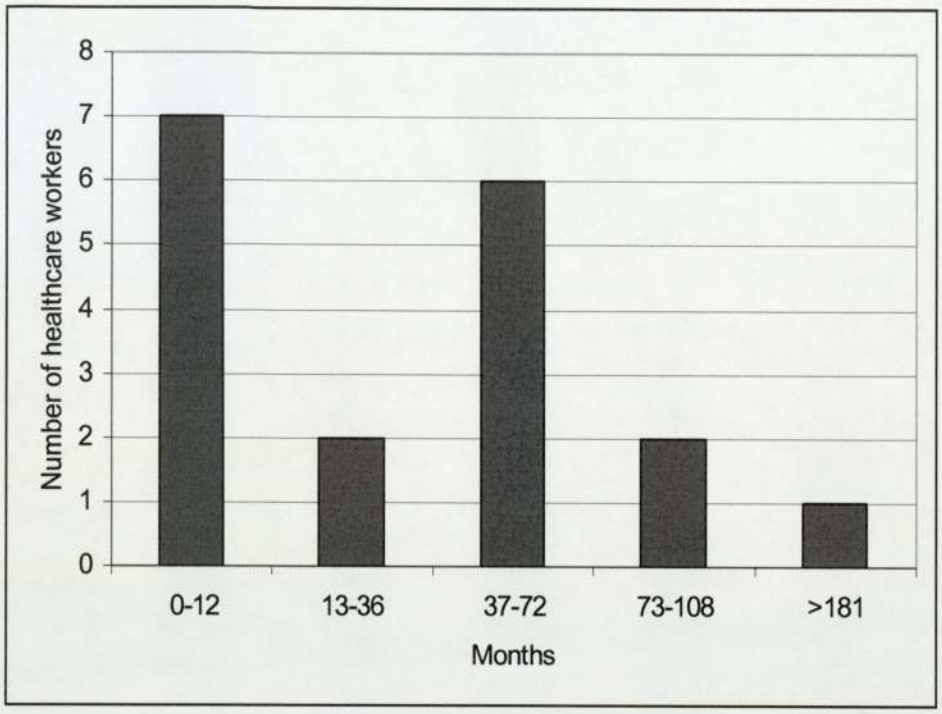
5.2.2 Results

The 18 participating HCWs, working in the 5 selected specialties, had varying levels of clinical experience (table 5.0). The majority of HCWs were junior medical staff. Seven out of eighteen HCWs were qualified less than 1 year and 6 out of 18 between 3 and 6 years. Only 1 doctor had been qualified more than 15 years. Both nurses were senior members of staff, qualified between 6 and 9 years. The mean length of time HCWs had been qualified was 4 years, with a range from 3 months to 26 years (figure 5.4).

Table 5.0: Healthcare workers who participated in the Safelon™ Pro intravenous peripheral catheter pilot study.

Clinical specialty	Number of healthcare workers	Profession and grade of healthcare workers
Cardiac	5	Senior house officers
Renal	1 2	Registrar Senior house officers
General surgery	4 1 1	Pre registration house officers Nurse F grade Nurse E grade
Urology	3	Pre registration house officers
Anaesthetics	1	Consultant

Figure 5.4: The length of time healthcare workers were qualified at the time of the pilot study.



Following the initial training programme 1 HCW withdrew from the study, however they completed the demographic and summative questionnaire.

The time to complete the pilot study was extended from 2 to 3 months, because some HCWs did not complete their 20 SLP insertions within the initial 2 month pilot study period. Reasons for this included annual leave, time off work and patients not requiring IV peripheral catheters. Despite this extension, not all HCWs completed 20 SLP insertions; however, 5 out of 18 inserted more than 20 SLP catheters, 9 out of 18 between 10 and 20 SLP catheters and 3 out of 18 completed less than 9 SLP insertions.

The length of time HCWs had been inserting IV peripheral catheters varied. Six out of eighteen (33%) had 3 to 6 years experience, compared with 7 out of 18 (39%) with up

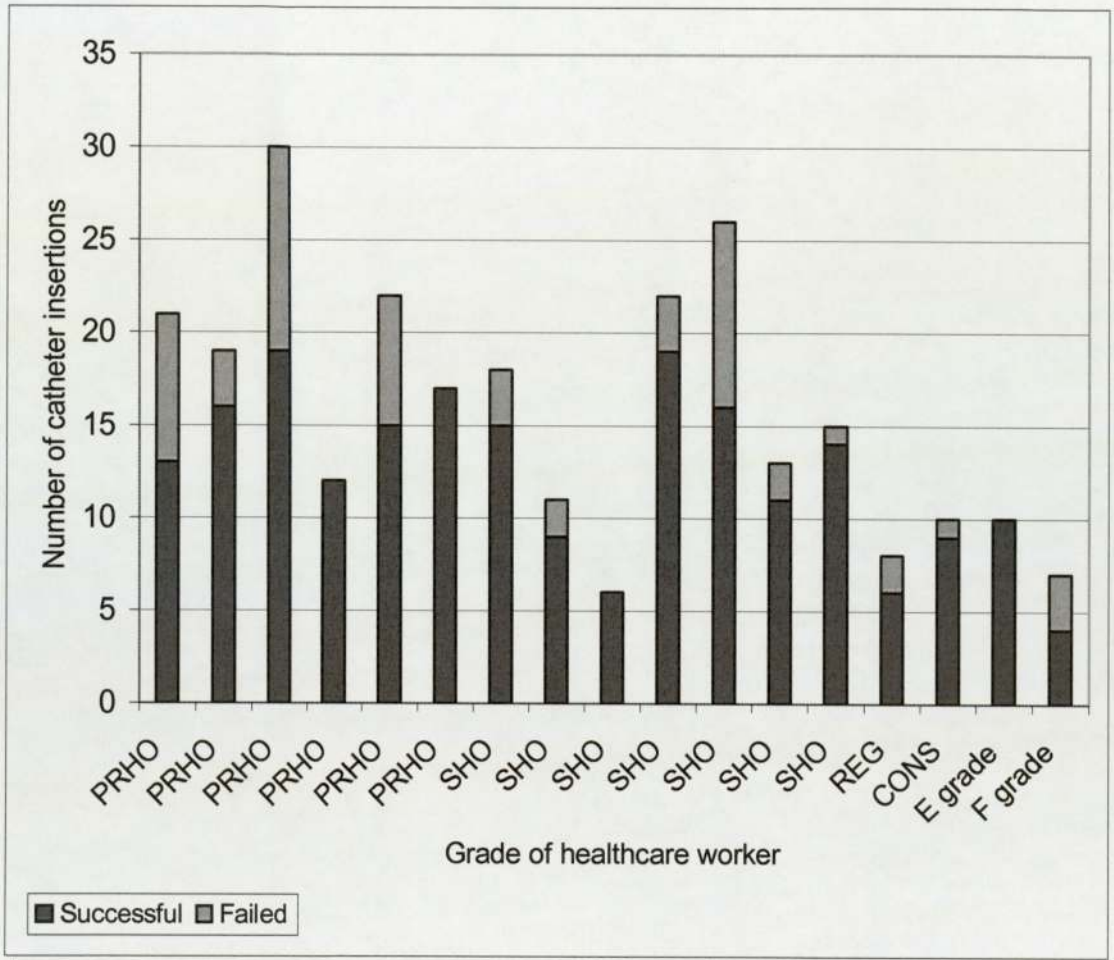
to 1 years experience and 2 out of 18 (11%) with 1 to 3 years of experience. Only 1 out of 18 HCWs had inserted IV peripheral catheters for more than 15 years and 2 out of 18 (11%) HCWs had between 6 and 9 years of experience. The mean length of time inserting IV peripheral catheters was 4.5 years, with a range from 3 months to 25 years.

Eight out of eighteen (44%) HCWs inserted between 6 and 15 IV peripheral catheters per week and 6 out of 18 (33%) inserted more than 16 IV peripheral catheters per week. Three out of eighteen (17%) inserted between 1 and 5 IV peripheral catheters and 1 HCW did not disclose this information. Conventional catheters used in the clinical setting included BD Venflon™ (9 out of 18, 50%) and Optiva™ (Johnson and Johnson) (3 out of 18, 17%). Five out of eighteen (28%) HCWs used both conventional catheters and 1 HCW did not complete the question). Eighteen and 20 gauge catheters were most frequently used for IV peripheral catheterisation.

A total of 267 SLP catheters were used during the pilot study. This was 93 less than the initial sample size because not all HCWs completed 20 SLP catheterisations. Two hundred and eleven out of two hundred and sixty seven (79%) insertions were successful (95% CI 74-84%) and 56 out of 267 (21%) failed (95% CI 16-26%). Individual HCWs' rate of success varied (figure 5.5). Only 3 out of 18 (17%) HCWs (2 pre registration house officers and 1 E grade nurse) successfully inserted all SLP catheters used during the pilot study. These participants inserted 12, 17 and 10 SLP catheters respectively. Ninety one out of one hundred and twenty one (74%) catheters inserted by pre registration house officers were successful, compared with 90 out of 111 (81%) by senior house officers. Indeed, senior house officers had an overall lower failure rate of 21 out of 111 (19%) compared with 30 out of 121 (25%) for pre registration house officers, however, no statistical significance was reached (p=0.3414, Fisher's Exact Test). The registrar's success rate was 6 out of 8 (75%) compared with

the consultant (9 out of 10, 90%), E grade nurse (10 out of 10, 100%) and F grade nurse (4 out of 7, 57%).

Figure 5.5: Total number of successful and failed attempts at inserting Safelon™ Pro catheters by each healthcare worker.



Key
PRHO = pre registration house officer
REG = registrar
E grade = nurse
SHO = senior house officer
CONS = consultant
F grade = nurse

Reasons for failed insertion attempts were categorised into operator, patient, product and other related issues (table 5.1). In total 67 reasons for failures were documented because some HCWs gave more than 1 reason for an individual failure.

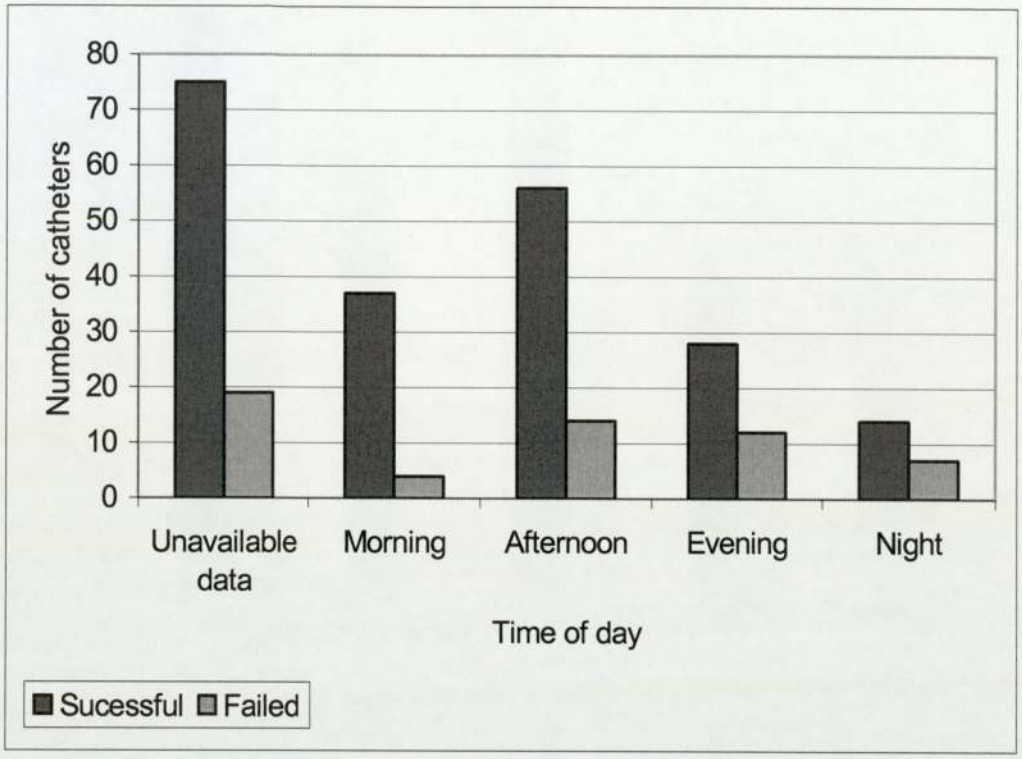
Table 5.1: Reasons identified by healthcare workers as to the cause of failed attempts at inserting Safelon™ Pro catheters (n=67).

Reason for failed attempt	Number
Operator related	
No flashback visualised	1
Poor technique	5
Haematoma developed	2
The catheter did not advance into the vein	5
Patient related	
Poor quality veins	31
Unco-operative patient	1
Product related	
The safety feature did not activate	1
Other	
The catheter 'tissued' immediately after insertion.	6
A conventional product was used following failure to insert a Safelon™ Pro catheter.	5
Unavailable data	6

Healthcare workers identified poor quality veins as the most frequent cause of failed attempts at inserting SLP catheters (31 out of 67, 46%). Other causes of failure included poor operator technique (5 out of 67), the catheter not advancing into the vein (5 out of 67) and the catheter 'tissued' following insertion (6 out of 67). In 5 out of 67 situations, a conventional IV peripheral catheter was used following a failed attempt to insert SLP.

The time of day SLP catheters were inserted was documented (figure 5.6). From the available data, SLP catheters were most frequently inserted during the afternoon, between 12.00 and 18.00 hours (70 out of 267, 26%), compared with mornings between 06.00 and 12.00 hours (41 out of 267, 15%), evenings between 18.00 and 24.00 hours (40 out of 267, 15%) and during the night between 24.00 and 06.00 hours (21 out of 267, 8%). Data were not available for 94 catheter insertions.

Figure 5.6: Time of day Safelon ™ Pro catheters were inserted by participating healthcare workers during the pilot study.



Key
Morning = 06.00 to 12.00 hours
Afternoon = 12.00 to 18.00 hours
Evening = 18.00 to 24.00 hours
Night = 24.00 to 06.00 hours

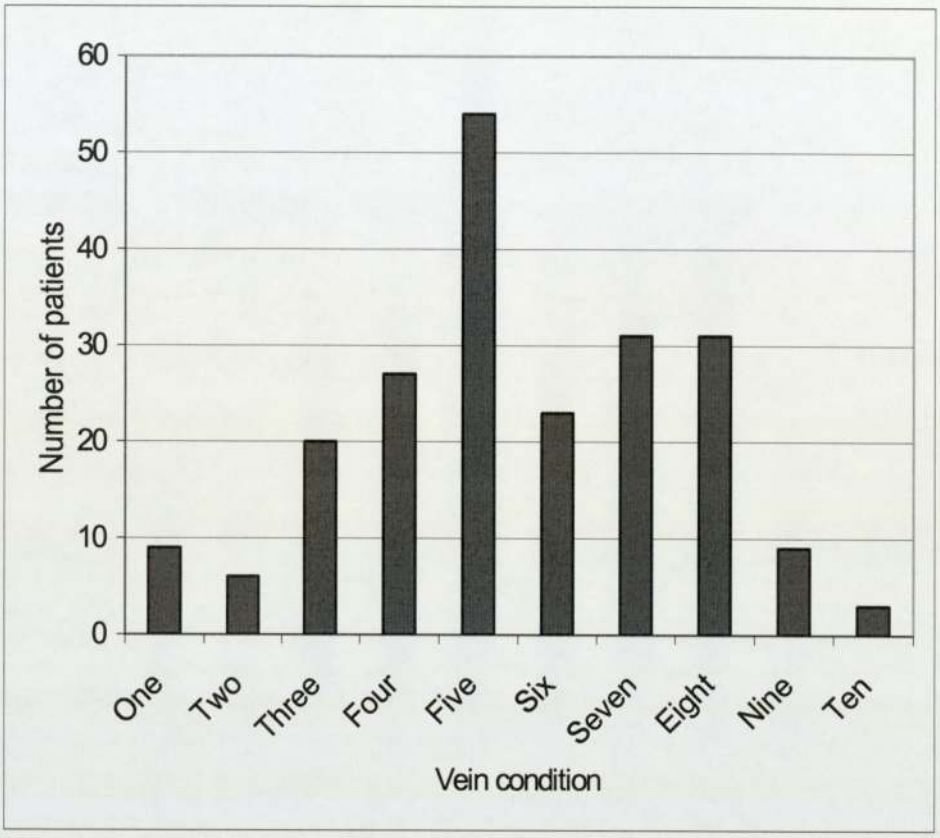
Ninety nine out of two hundred and eleven (47%, 95% CI 40-53%) successful catheters were inserted into veins in the patient's hand, compared with veins in the forearm (69 out of 211, 33%, 95% CI 26-39%) and antecubital fossa (41 out of 211, 19%, 95% CI 14-25%).

The condition of patient's veins was assessed in relation to ease of catheterisation, prior to inserting SLP catheters (figure 5.7). In 54 out of 211 (26%) successful SLP insertions, the patient was evaluated to have normal veins, indicated by a number 5. Forty seven out of two hundred and eleven (22%) patient's veins were assessed as being between optimal and normal and were allocated a number 3 or 4. Seventy four

out of two hundred and eleven (35%) patients' veins were assessed as being 7 or more, which indicated poor quality veins and therefore difficult to cannulate.

Pre registration house officers rated patient's veins to be normal (32 out of 91, 35%, 95% CI 25-46%) significantly more often than senior house officers (15 out of 90, 17%, 95% CI 10-26%) (p=0.0064, Fisher's Exact Test). The consultant rated 6 out of 9 (67%) patient's veins to be optimal (1), with the remaining 2 veins rated 2 and 5. Pre registration house officers rated the patient's veins to be between 1 and 3 for 12 out of 91 (13%) successful insertions, compared with 13 out of 90 (14%) insertions completed by senior house officers. However, in 16 out of 91 (17%) successful insertions completed by pre registration house officers, the patient's veins were perceived to be very difficult to cannulate, demonstrated by a rating between 8 and 10, compared with 24 out of 90 (27%) SLP catheter insertions by senior house officers. The registrar perceived patient's veins to be between 6 and 8, with one patient's veins rated as 3. Both nurses rated all patients' veins between 3 and 8. The mean rating for patient's vein condition was 6, with a range from 1 to 10.

Figure 5.7: Evaluation of the condition of patients' veins when inserting Safelon™ Pro catheters.



The amount of pain experienced by patients, during the process of inserting SLP catheters, was assessed by HCWs. One hundred and twenty five out of two hundred and eleven (59%) HCWs perceived the patient to experience mild pain, compared with 22 out of 211 (10%) who experienced moderate pain. No patient was observed to have experienced severe pain whilst inserting SLP catheters and 66 out of 211 (31%) patients experienced no pain.

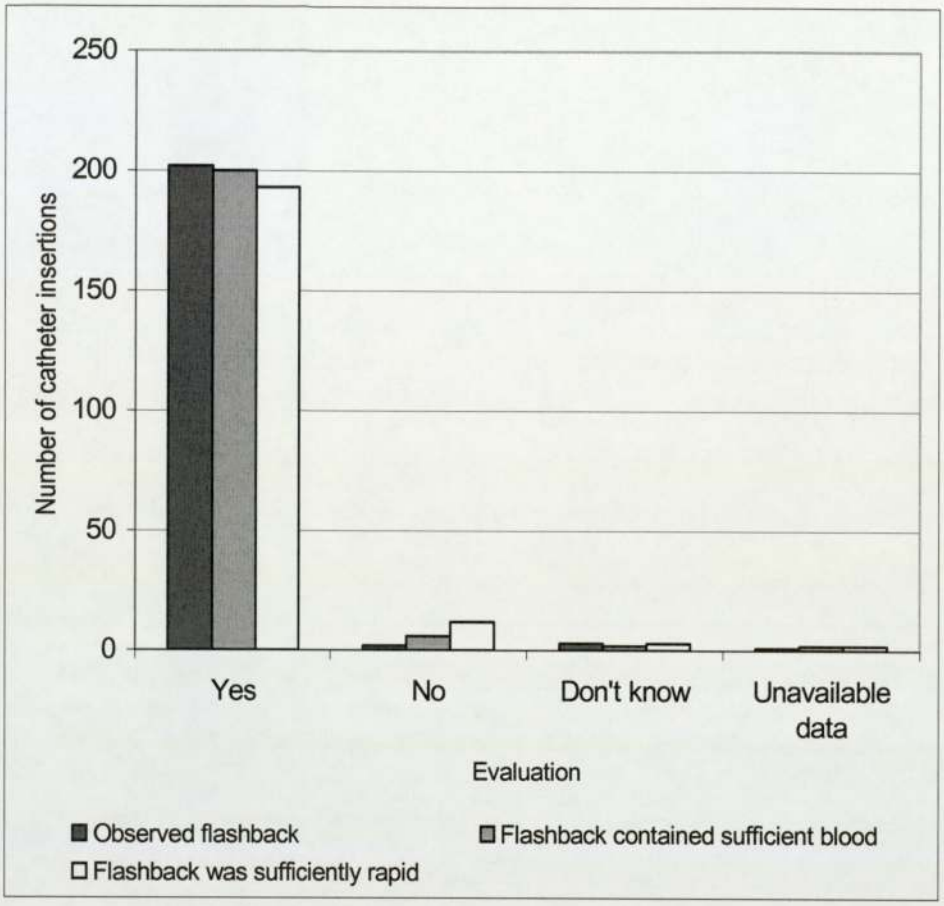
One hundred and seventy five out of two hundred and eleven (84%) successful insertions were achieved on the first attempt. Of these, 70 out of 175 (40%) were achieved by pre registration house officers and 79 out of 175 (46%) by senior house

officers. The registrar achieved 6 out of 175 (3%) successful first attempts, the consultant 9 out of 175 (5%), the E grade nurse 9 out of 175 (5%) and 2 out of 175 (1%) were achieved by the F grade nurse. However, 9 out of 10 (90%) of the consultants' SLP insertions were achieved first time, compared with 6 out of 8 (75%) for the registrar, 4 out of 7 (50%) for the F grade nurse and 9 out of 10 (90%) for the E grade nurse.

Two insertion attempts were documented by 6 pre registration house officers, accounting for 20 SLP insertions, and 5 senior house officers accounting for 9 SLP insertions. The nurses both required second attempts at 2 insertions and 2 pre registration house officers and 1 senior house officer required 3 attempts to insert a SLP catheter.

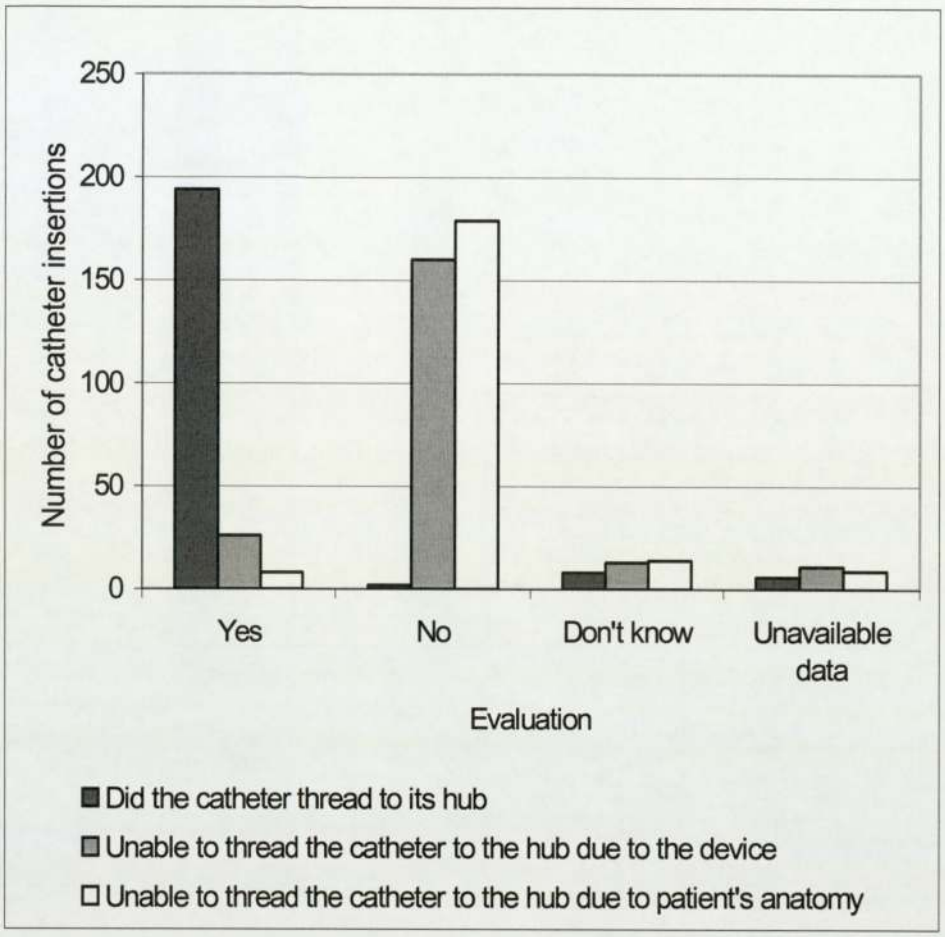
Healthcare workers evaluated the flashback properties of SLP catheters. In 3 incidents, flashback was observed, however the procedure failed. Flashback was observed in 202 out of 211 (96%, 95% CI 92-98%) SLP insertions. Of these 200 out of 211 (95%, 95% CI 92-98%) were evaluated to have contained a sufficient amount of blood. Furthermore, the flashbacks were sufficiently rapid in 193 out of 211 (91%, 95% CI 87-95%) SLP insertions (figure 5.8).

Figure 5.8: Evaluation of the efficacy of the flashback when inserting Safelon™ Pro catheters.



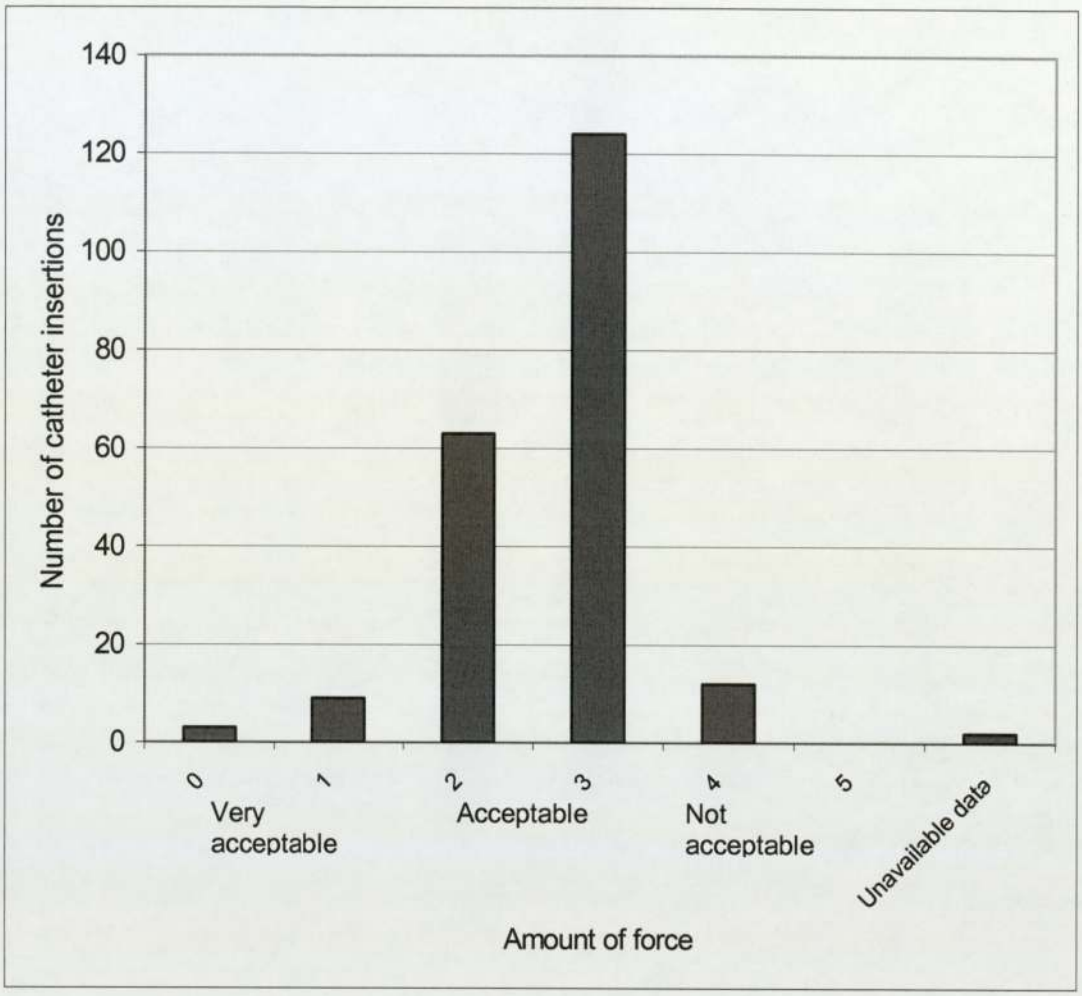
The catheter threaded to the hub (the ability to insert the entire catheter into the vein) 194 out of 211 (92%) times. Only 2 catheters were documented as not threading to the hub. The remaining evaluations included the HCW not knowing if the catheter had threaded to the hub and 6 HCWs did not complete the question. However, despite only 2 catheters not threading to the hub, a total of 34 reasons were recorded, 26 due to the device and 8 due to the patient's anatomy (figure 5.9).

Figure 5.9: Evaluation of the ability to thread Safelon™ Pro catheters to the hub during insertion.



The force to penetrate the skin with the introducer needle was evaluated using a range of 1 to 5. One inferred a very acceptable, 3 an acceptable and 5 an unacceptable amount of force to initially penetrate the skin using the introducer needle. One hundred and twenty four out of two hundred and eleven (59%) skin penetrations were perceived to be acceptable to the HCW, indeed 65 out of 211 (31%) were evaluated as a force of 2. No HCW rated the force to be unacceptable (figure 5.10).

Figure 5.10: The amount of force required to penetrate patients' skin using Safelon™ Pro catheter introducer needles.

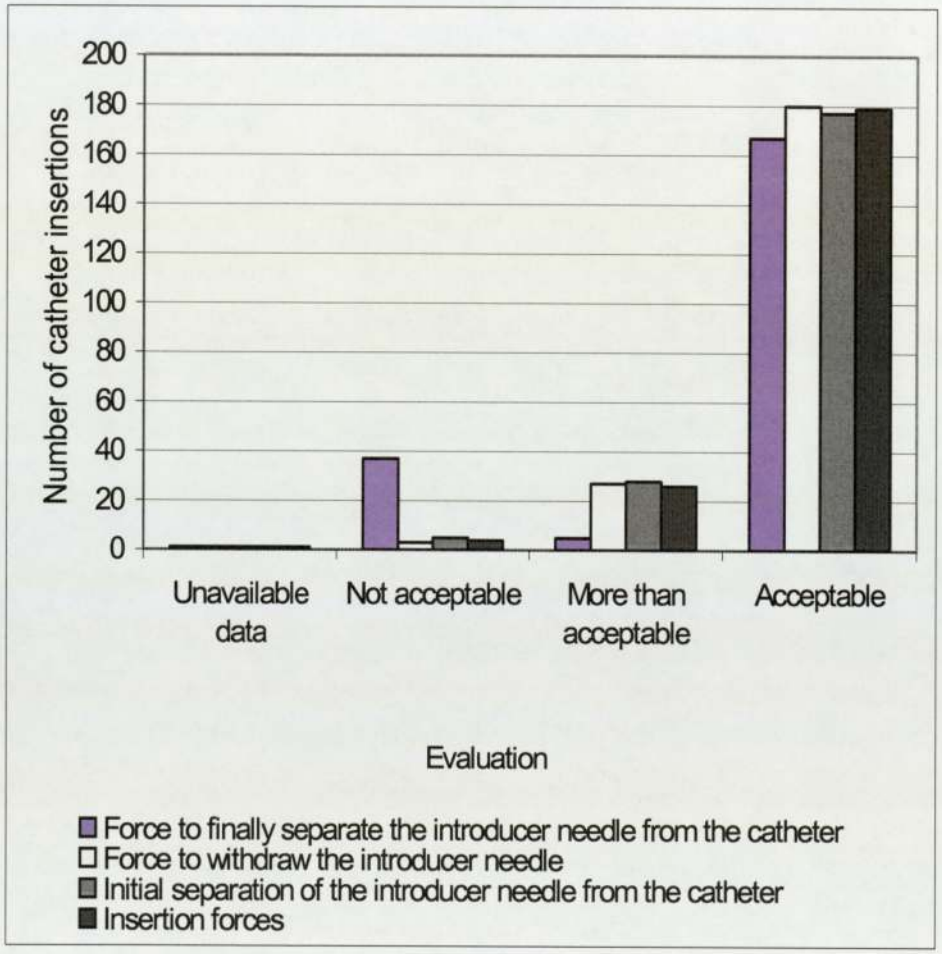


Overall insertion forces associated with inserting SLP catheters were evaluated for all successful insertions. The overall insertion forces were unacceptable in only 4 out of 211 (2%) SLP catheter insertions. The initial separation force was acceptable in 177 out of 211 (84%) and more than acceptable in 28 out of 211 (13%) catheter insertions, with a total overall acceptability of 205 out of 211 (97%). Data were not available for 1% of overall insertion forces.

The force to withdraw the introducer needle from the catheter was acceptable in 180 out of 211 (85%) and more than acceptable in 27 out of 211 (13%) SLP catheter

insertions, a total overall acceptability of 207 out of 211 (98%). The final separation force was acceptable in 167 out of 211 (79%) and more than acceptable in 5 out of 211 (2%) SLP insertions, with an overall acceptability of 169 out of 211 (81%) (figure 5.11).

Figure 5.11: The insertion forces associated with inserting Safelon™ Pro catheters.



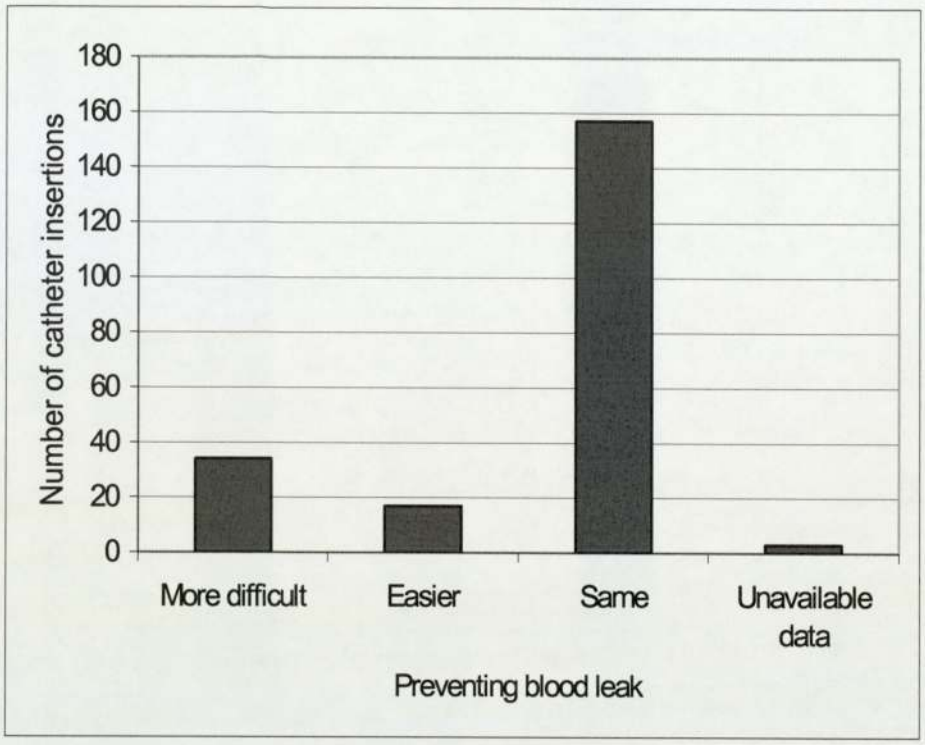
Blood leak was defined as blood that spilled from the catheter or vein as a result of inserting SLP catheters. For 31 out of 211 (15%, 95% CI 10-20%) SLP catheter insertions, blood leaked. Thirteen out of thirty one (42%) incidents were perceived to be due to the procedure and 8 out of 31 (26%) due to the device. The remaining HCWs did not complete the question. Causes for blood leaking were documented by a number of HCWs (table 5.2).

Table 5.2: Cause and location of blood leak during insertion of Safelon™ Pro catheters.

Cause and location of blood leak	Frequency
Cause of blood leak	
Due to inadequate vein occlusion by the operator when the introducer needle was withdrawn.	1
The patient was uncooperative.	1
The catheter came out of the vein once inserted.	1
The plastic cap at the back of the catheter came off prior to completing the insertion.	2
Location of blood leak	
Catheter	1
Insertion site	2
Back of the catheter	4
End of the needle	2
Along the tether	4

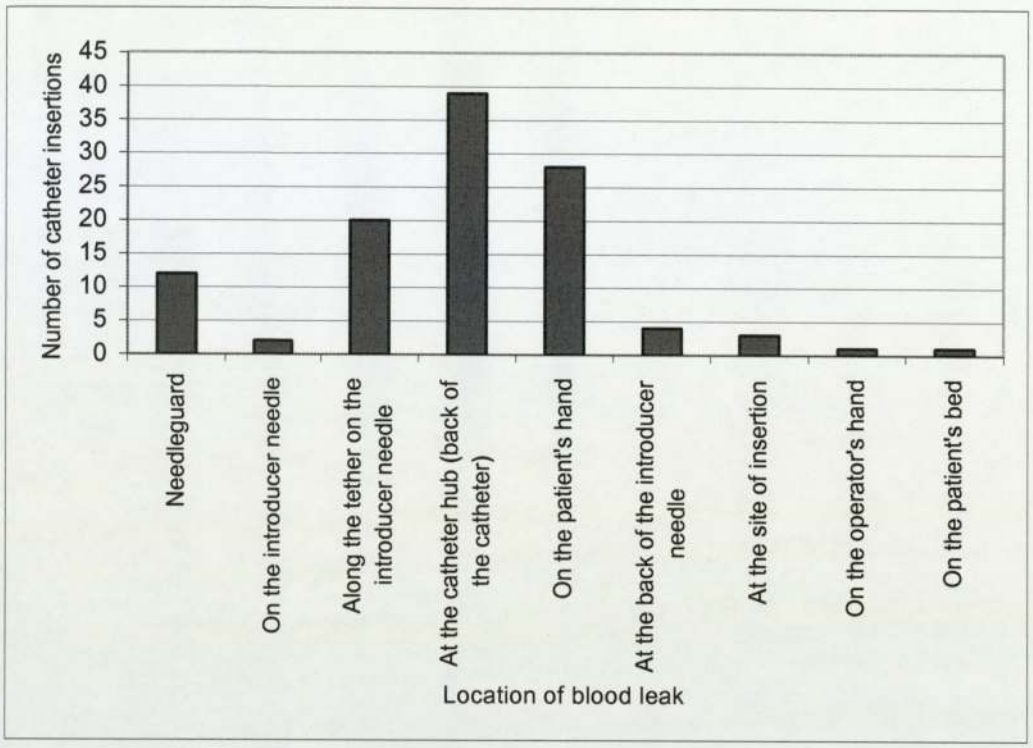
Healthcare workers' ability to prevent blood leak and remove the introducer needle whilst inserting SLP catheters was described as easier when compared with conventional products in 17 out of 211 (8%) insertions. Indeed, in 157 out of 211 (74%) insertions, preventing blood leak was described as the same as with conventional products. In only 34 out of 211 (16%) SLP catheter insertions, HCWs found it more difficult to prevent blood leak (figure 5.12).

Figure 5.12: Preventing blood leak associated with inserting Safelon™ Pro catheters.



Blood leak was visible on removing SLP introducer needles in 62 out of 211 (29%, 95% CI 23-36%) successful insertions. The location of blood was documented by HCWs and in some instances was located in more than one place either on the catheter or on the patient (figure 5.13). Blood most frequently leaked from the back of the catheter and onto the patient's hand.

Figure 5.13: Location of leaked blood following removal of the introducer needle during insertion of Safelon™ Pro catheters.



Blood splashed during 18 out of 211 (9%) SLP insertions, which was more than observed using conventional products in 16 out of 18 (89%) incidents. The cause of blood splash was frequently due to removing the introducer needle (11 out of 18), inadequate occlusion of the patient's vein (3 out of 18) and removing the catheter's hub (1 out of 18). The level of blood splash was acceptable in 7 out of 18 (39%) SLP catheter insertions compared with 10 out of 18 (56%) where it was not acceptable (1 question was not completed). Indeed, 10 out of 18 (56%) HCWs would not have used SLP catheters due to the splashing of blood compared with 8 out of 18 (44%) who would have continued using the product.

The needle guard deployed in 204 out of 211 (97%, 95% CI 93-99%) SLP insertions and remained in place until the device was disposed. Of the 7 SLP insertions where the needle guard failed, only 3 incidents were reported to the Clinical Research Nurse.

Documented reasons for these failures included the needle guard slipping back uncovering the needle tip, the needle and guard being removed when withdrawing the introducer needle and the needle guard having an 'odd' angle.

Of the 3 safety mechanism failure incidents reported to the Clinical Research Nurse, 2 incidents were caused by operator error. On removal of the introducer needle, the tether was held, together with the needle, preventing the tether fully extending and therefore preventing needle guard deployment. In the third incident, the failure of the needle guard was perceived to be a product error, however the device was disposed of and therefore a cause could not be determined.

5.2.2.1 Summative evaluation

On completing the pilot study, all HCWs documented their overall evaluation of the NPD. SLP catheters were acceptable to 9 out of 18 (50%) HCWs after 4 to 6 insertions. Of these, 4 were pre registration house officers, 4 were senior house officers and 1 an F grade nurse. A further 7 out of 18 (39%) found SLP acceptable to use after 1 to 3 insertions (the registrar and consultant, 2 senior house officers, 1 pre registration house officers and the E grade nurse). Only 1 HCW did not find SLP acceptable and this was the participant who withdrew from the trial and 1 HCW did not complete the question.

Catheterisation technique had to be modified by 10 out of 18 (56%, 95% CI 31-78%) HCWs (table 5.3). Seven HCWs did not complete the question and 1 HCW did not have to modify their catheterisation technique whilst inserting SLP catheters. One HCW gave 2 reasons for technique modification.

Table 5.3: Reasons documented by healthcare workers for modifying their catheterisation technique when inserting Safelon™ Pro catheters (n=11).

Reason for modifying catheterisation technique	Number of healthcare workers
Increasing the force required to separate the introducer needle from the catheter	6
Using a two handed technique	1
Modifying occlusion technique	2
Removing the luer lock cap before inserting the catheter	1
Having to press on the luer lock cap when withdrawing the catheter	1

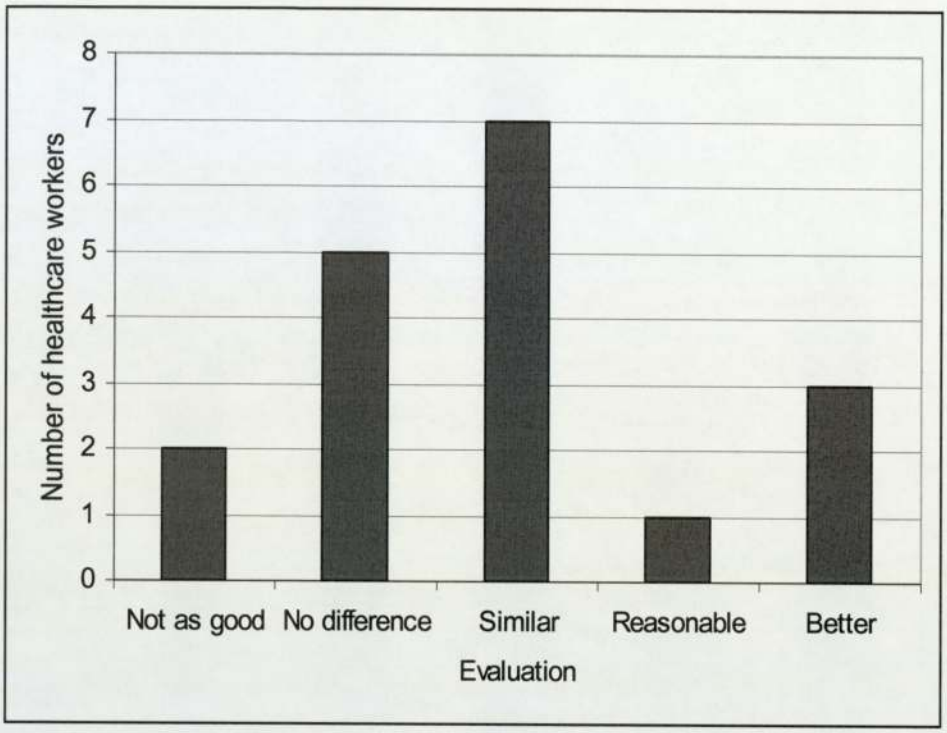
Healthcare workers' perceived level of safety whilst inserting SLP catheters was evaluated. Seventeen out of eighteen (94%) HCWs regarded SLP catheters as a safe product because the introducer needle tip was covered (6 out of 18) and the product reduced the potential for PIIs (3 out of 18). One HCW reported an increased risk of blood splash and 8 out of 18 HCWs did not respond to the question. The most favourable features of SLP catheters were their ease of use (3 out of 18), the safety mechanism preventing PIIs (11 out of 18), similarity to conventional products such as Venflon™ (4 out of 18) and the safety mechanism remained deployed (1 out of 18) until disposal. Only 1 HCW did not respond, however other HCWs gave more than 1 response. Healthcare workers were requested to document their concerns regarding the new NPD (table 5.4). Two HCWs did not have any concerns.

Table 5.4: Healthcare workers' concerns regarding Safelon™ Pro catheters.

Concern of using Safelon™ Pro catheters	Number of healthcare workers
Failure of the safety device	2
Using a two handed technique	1
Difficulty with using the product when it is difficult to catheterise the vein	2
Blood leak and splashing	4
Difficulty in separating the introducer needle from the catheter	4
Tendency to hold the needle on disposal	1
Disconnection of the luer lock cap and the clear plastic holder	1
Similar to other catheters	1
Unavailable data	2
Total number of healthcare workers who completed the questionnaire	**16**

Healthcare workers were asked to compare SLP catheters with conventional IV peripheral catheters currently used in the clinical setting. Three out of eighteen (17%, 95% CI 3-41%) found the new product to be better than conventional IV peripheral catheters, 7 out of 18 (39%, 95% CI 17-64%) compared the product as similar, 5 out of 18 (28%, 95% CI 9-53%) thought there was no difference between products and 1 HCW reported the new product as reasonable. Only 2 HCWs perceived the new NPD to be not as good as conventional devices (figure 5.14).

Figure 5.14: Comparative evaluation of Safelon™ Pro catheters with conventional products.



Nine out of eighteen HCWs (50%) would have preferred to use SLP catheters or had no preference. Seventeen out of eighteen (94%) would have used SLP catheters in the clinical setting and the HCW who would not have used the catheter withdrew from the study.

5.3 Clinical trial of Safelon™ Pro needle protective device

5.3.1 Methods and materials

Prior to commencing this study, Local Research Ethics Committee and the Trust's Research and Development and Clinical Governance departments' approval was sought and granted. One clinical specialty, liver surgery and medicine, was selected to participate in the clinical trial of SLP at the Queen Elizabeth Hospital UHB NHS Trust. Liver services was identified as an area of high risk for potential occupational transmission of blood borne pathogens from PIIs due to its patient group as well as an area with a higher incidence of PIIs when compared with other units at UHB NHS Trust. Liver intensive care was excluded because the unit was due to merge with general intensive care within the trial period. Following agreement with appropriate medical and nursing management, all HCWs who inserted IV peripheral catheters, as part of their clinical practice, were identified and invited to participate in the study.

The aims of the clinical trial were communicated to all HCWs prior to agreement to participate. Each HCW completed a standardised training programme. This included a staff knowledge questionnaire (appendix 4A), which was discussed following completion, information on SLP and its new features and a practical session using the new product on a simulator arm (Ambu® I.V. Trainer) until satisfaction was achieved. On completing the training programme, each HCW signed to agree their training and participation in the clinical trial (appendix 5E). All HCWs were trained by the Clinical Research Nurse (J Trim) in groups of no more than 2, determined by staff availability and pressure of workload.

Following completion of the training programme, the Trust supplies department exchanged all conventional 18, 20 and 22 gauge IV peripheral catheters with

corresponding sizes of SLP. Safelon™ Pro catheters were used for all patients requiring IV peripheral access as part of their clinical management. The Clinical Research Nurse was available to provide support for all users. Participants completed an evaluative questionnaire (appendix 5F) on a daily basis that evaluated SLP, its insertion properties and compared these with conventional products used in the clinical setting at the time of the study.

Data were collated and analysed utilising a Microsoft™ Access97 database. Non-parametric statistical tests were applied where appropriate including Binomial Confidence Interval and Fisher's Exact Test, using commercially available software (http://www.statpages.net).

5.3.2 Results

The total number of HCWs who inserted IV peripheral catheters as part of their clinical practice and who completed the training programme was 39. Of these, 25 out of 39 worked within liver surgery, 10 out of 39 worked within liver medicine and 4 out of 39 worked in both liver surgery and medicine. Overall 19 out of 39 (49%) were nurses and 20 out of 39 (51%) were doctors.

The clinical trial of SLP commenced on 13th May 2002 following exchange of all conventional 18, 20 and 22 gauge IV peripheral catheters for the same gauge size SLP catheters. Two weeks later the clinical trial was suspended because HCWs experienced excessive blood splash and leak when inserting SLP catheters, with the potential risk of mucocutaneous inoculation injury. In total, 112 SLP catheters were used during the clinical trial. Twenty gauge catheters were most frequently used (67%), indeed only two 22 gauge catheters were used. (table 5.5).

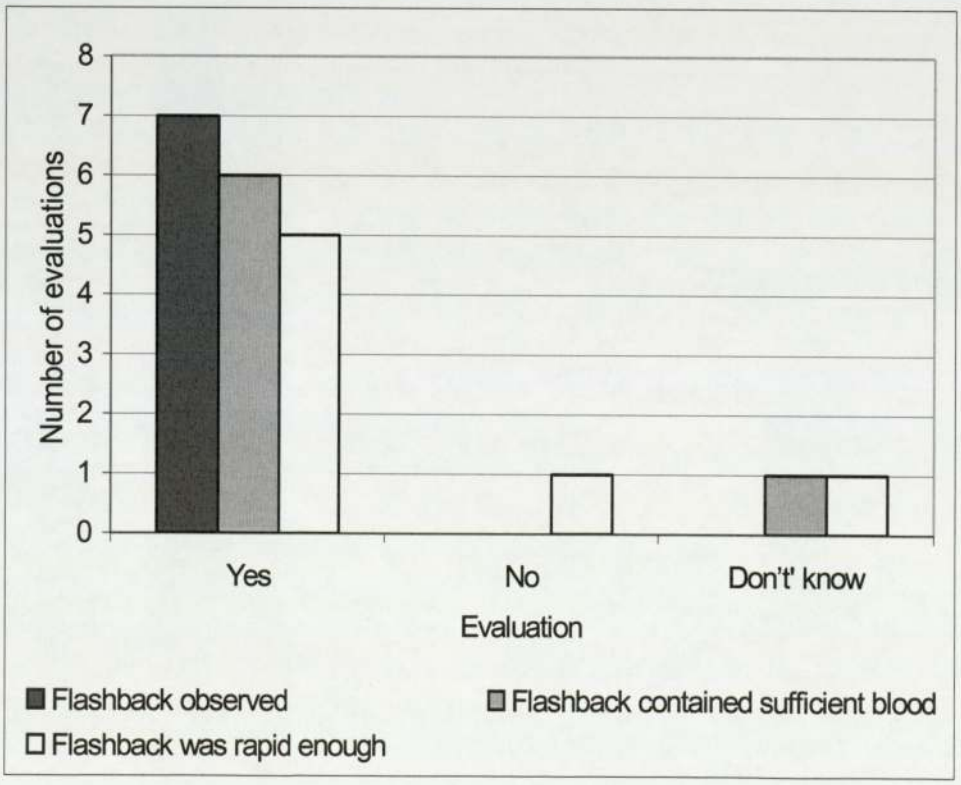
Table 5.5: The total number of Safelon™ Pro catheters used during the clinical trial.

Number of Safelon™ Pro intravenous peripheral catheters used during the clinical trial	Percentage of total devices used
18 gauge (green) 35	31%
20 gauge (pink) 75	67%
22 gauge (blue) 2	2%

Eleven out of thirty nine (28%) HCWs used SLP catheters prior to the trial suspension. During weeks 1 and 2 of the trial, 5 out of 11 (45%, 95% CI 17-77%) HCWs identified difficulties whilst inserting SLP catheters. Of these, 4 out of 5 were doctors and 1 out of 5 was a nurse. In total, 7 evaluation forms were completed by 5 HCWs, however the evaluations were summative and not for individual SLP catheter insertions. Furthermore, verbal evaluations were also reported to the Clinical Research Nurse.

In all 7 (100%) evaluations, flashback was observed when inserting SLP catheters and in 6 out of 7, the amount of blood in the flashback chamber was sufficient (1 HCW did not know). Furthermore, the speed of the flashback was evaluated to be rapid in 5 out of 7 when inserting SLP catheters. One HCW did not know if the flashback was rapid enough and 1 HCW gave a negative response (figure 5.15).

Figure 5.15: Flashback properties associated with inserting Safelon™ Pro catheters.



In 6 out of 7 (86%, 95% CI 42-99%) evaluations, SLP catheters threaded to the hub; 1 HCW did not know if the catheter threaded to the hub. However, the catheter did not thread to the hub with ease in 3 reports, 1 due to the device alone, 1 due to the device and patient's anatomy and 1 due to the patient's anatomy alone.

The flashback and ability to thread the catheter to the hub were compared with conventional products, BD Venflon™ and Johnson and Johnson Optiva™ (table 5.6).

Table 5.6: Comparison of insertion properties of Safelon™ Pro catheters with conventional catheters.

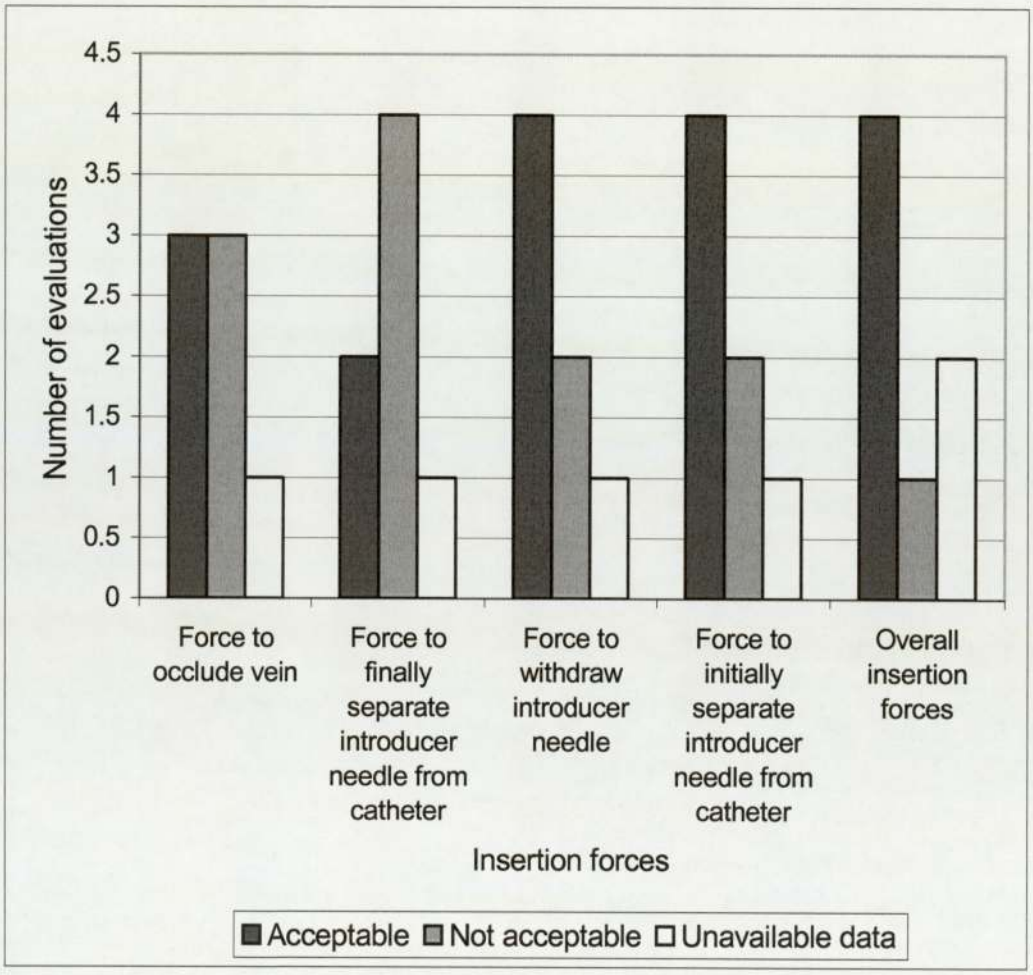
Insertion property	Better	Same	Worse	Unavailable data	Total
Flashback visibility	1	3	3	0	7
Volume of blood contained in the flashback	0	5	1	1	7
Speed of flashback	0	5	1	1	7
Ability to thread the catheter to the hub.	2	4	0	1	7
Difficulty threading the catheter to the hub due to the device	0	4	2	1	7
Difficulty threading the catheter to the hub due to the patient's anatomy	0	3	1	3	7

Out of a total of 42 comparative evaluations, only 3 identified SLP catheters to be better. Twenty six out of forty two (62%, 95% CI 46-76%) compared SLP as the same as conventional products and in 13 out of 42 responses (31%, 95% CI 18-47%) SLP was perceived as worse than conventional devices.

The force to penetrate the patient's skin using the introducer needle was acceptable in 5 out of 7 (71%, 95% CI 29-96%) evaluations. In 1 evaluation, the force was

described as more than acceptable and 1 rated between acceptable and not acceptable. When compared with conventional products, the force to penetrate the patient's skin was the same in 2 evaluations, better in 1 and worse in 1 evaluation. More specific insertion forces associated with inserting SLP catheters were evaluated (figure 5.16).

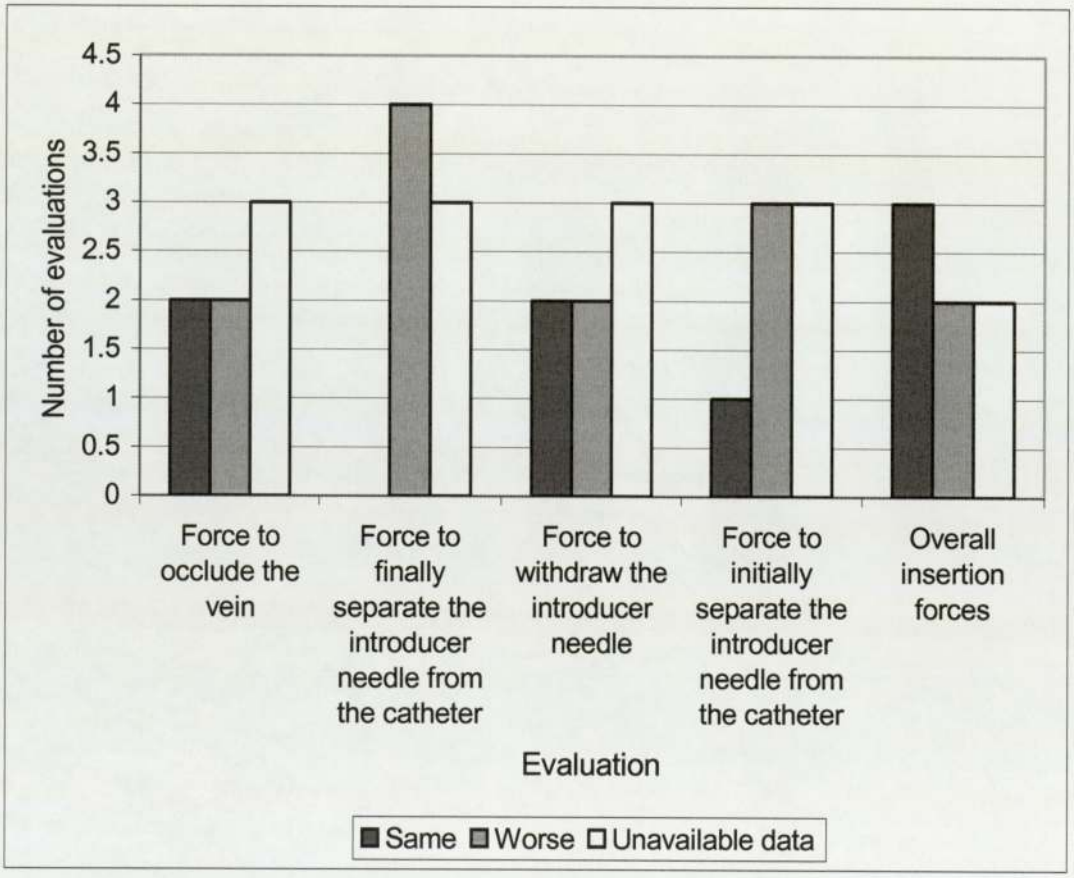
Figure 5.16: Evaluation of insertion forces associated with inserting Safelon™ Pro catheters.



Overall insertion forces, the force to initially separate the needle and to withdraw the needle were all acceptable in 4 out of 7 (57%) evaluations. Two evaluations identified the force to initially separate and to withdraw the needle to be unacceptable, however

overall insertion properties were only unacceptable in 1 evaluation. The force to finally separate the introducer needle from the catheter was, however, unacceptable in 4 out of 7 (57%) evaluations. The force to occlude the patient's vein was unacceptable in 3 out of 7 (43%) and acceptable in 3 out of 7 (43%) evaluations, with 1 not completed. These forces were compared with conventional peripheral catheters (figure 5.17).

Figure 5.17: Healthcare workers' comparison of insertion forces of Safelon™ Pro catheters compared with conventional catheters.



Out of a total of 35 comparative evaluations, 13 out of 35 (37%, 95% CI 21-55%) were identified as being worse than conventional products and 8 out of 35 (23%, 95% CI 10-40%) the same. No SLP catheter insertion force was evaluated as being better than conventional products.

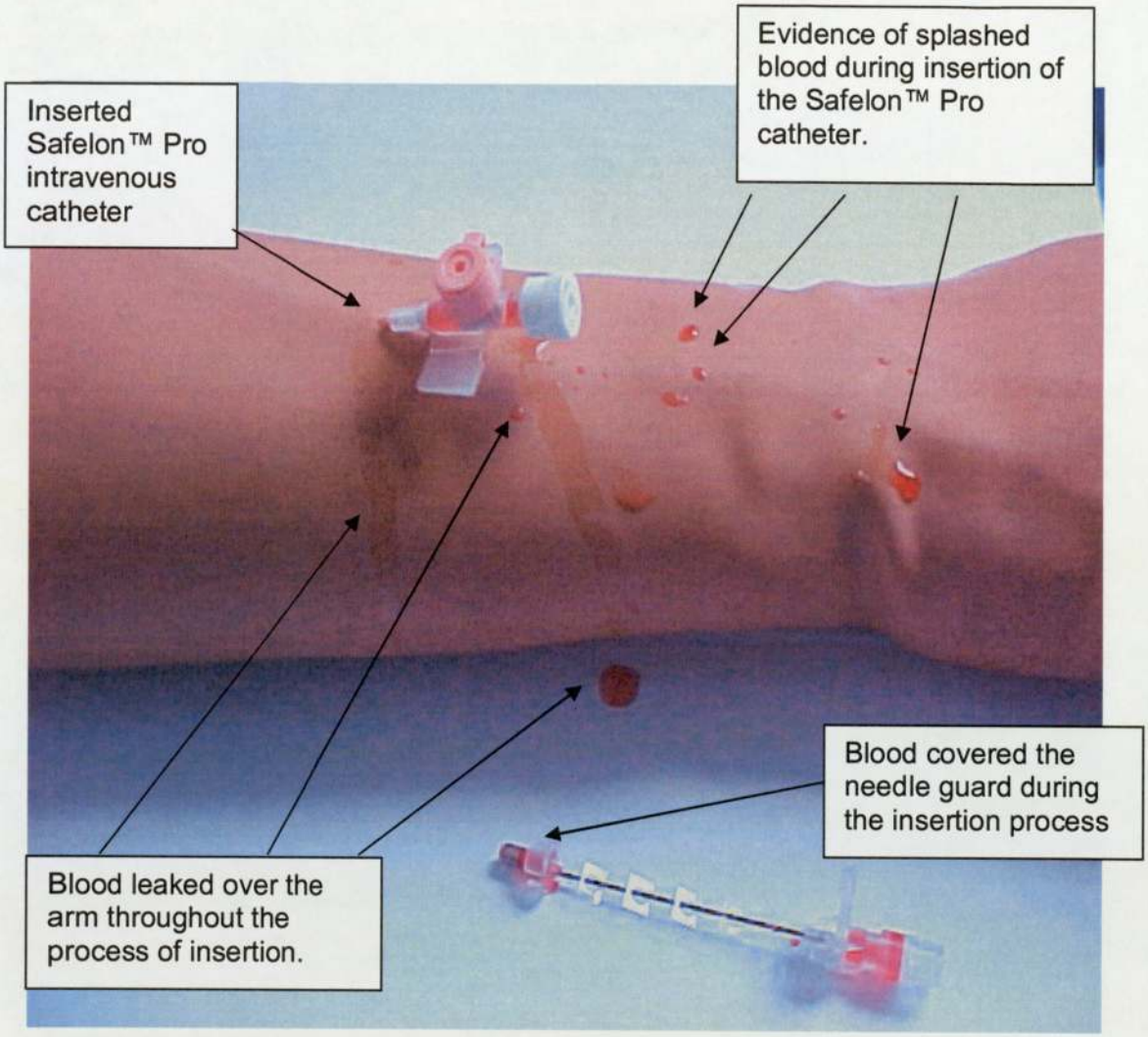
In 6 out of 7 (86%, 95% CI 42-99%) evaluations, HCWs experienced blood leak. When compared with conventional IV peripheral catheters, blood leak associated with SLP was worse in 5 out of 7 evaluations (71% 95% CI 29-96%), and in 2 evaluations it was the same (29%).

Blood leaked when the introducer needle was withdrawn from the catheter (4 out of 7, 57%). This occurred from the back of the catheter onto the patient and their hand, before the needle could be fully withdrawn from the catheter. In addition, 1 user was not able to remove the introducer needle from the catheter. In this incident, blood leaked onto the patient, the user and the floor. The remaining 2 evaluations did not identify location of blood leak. When compared with conventional IV peripheral catheters, all HCWs identified blood leak to be worse.

The frequency of blood that splashed during the insertion process was evaluated. In 5 out of 7 (71%) evaluations, blood splashed (1 user did not experience blood splash and 1 user did not complete the question). Overall, 4 out of 7 evaluations highlighted either occasional or frequent blood splash when inserting SLP catheters (1 did not complete the question). When compared with conventional products, 4 out of 5 (80%) evaluated blood splash using SLP catheters as worse and 1 the same (20%). Furthermore, the needle guard failed to deploy on 1 occasion (1 out of 112, < 1%). With all other catheter insertions, the needle guard remained in place until disposal.

Following trial suspension, the amount of blood splash when inserting SLP catheters was demonstrated using a simulator arm (Ambu® I.V. Trainer) in a non-clinical setting (figure 5.18).

Figure 5.18: Blood splash during insertion of Safelon™ Pro catheters using a simulator arm (Ambu® I.V. Trainer).



Following discussion with the principal investigator and BD, it was agreed that the trial be suspended to enable BD to address the issues of blood leak and blood splash highlighted in the trial.

5.4 Discussion: pilot study and clinical trial

These studies evaluated the usability and acceptability of SLP in the clinical setting, in relation to HCWs' overall acceptability of the new product in addition to specific properties required for successful insertion of IV peripheral catheters. It was not possible to determine any reduction in PIIs associated with the NPD because the clinical trial was suspended prematurely. On completing the pilot study, HCWs found SLP catheters to be an acceptable, safe and beneficial NPD. Following the clinical trial, however HCWs did not find the product acceptable due to frequent blood leak and splash during the insertion process.

The majority of HCWs found SLP's flashback to be satisfactory, which concurred with Watters' *et al.*, (1995) findings. Conversely, Asai *et al.*, (2002) reported inadequacies with the flashback for Johnson and Johnson's Protectiv Acuvance™ and BD Insyte™ Autoguard™. It is essential for the flashback to be rapid and contain enough blood volume because this is the HCW's first indication that the IV peripheral catheter is within the vein.

Overall insertion forces were, in the majority, acceptable to HCWs, however they were not perceived to be better than conventional products. The final separation force, removing the introducer needle from the catheter was least acceptable. Comparisons could not be made with previous studies because Watters *et al.*, (1995) did not document specific insertion properties and Asai *et al.*, (2002) utilised different evaluative tools. The final separation force was not acceptable to HCWs because it affected their ability to stabilise the catheter in the vein whilst removing the introducer needle, particularly when inserting small gauge catheters in fragile veins. Consequently, this increased resistance experienced with SLP catheters accentuated the difficulty of the procedure. Alternatively, participants' competence with

conventional products may have been challenged when using new unfamiliar products. Indeed, the necessity for HCWs to modify their insertion technique may have influenced their ability to succinctly insert SLP catheters.

To insert SLP catheters successfully, a two handed technique was required. This involves occluding the vein and supporting the catheter with one hand and removing the introducer needle with the other hand. During the pilot study, 10 out of 18 HCWs modified their insertion technique. This may infer that the majority of HCWs used a one handed technique (occluding the vein with one hand and removing the introducer needle with the other hand; the sited catheter is not stabilised).

Modifying insertion technique may reflect the way in which HCWs were trained to insert IV peripheral catheters. Currently all nursing staff that complete the Trust's cannulation study day are taught a two handed technique, however medical staff, who learn from each other develop a one handed technique. Interestingly, Watters *et al.*, (1995) reported that BD Safelon™ did not require any significant change in catheterisation technique. The degree to which HCWs modify their catheterisation technique may influence the ease with which NPDs are accepted and implemented into the clinical setting (ECRI, 2001). However, as Rivers *et al.*, (2003) found, adequate training improved the use of and implementation of NPDs. The importance of training and education has been emphasised in the literature (Metules, 2002; Adams and Elliott, 2002; Godfrey, 2001; Eck *et al.*, 2000; OSHA, 1999, Osborn *et al.*, 1999), however it is essential these new products do not require extensive training and technique modifications to ensure safe use in the clinical setting (OSHA, 1999). Preventing HCWs having to modify their catheterisation technique depending on the type of device used would be very difficult. One solution would be to ensure that all HCWs were trained using the same technique, however currently there are two

accepted techniques for inserting IV peripheral catheters. Moreover, the technique to insert ported catheters, for example SLP catheters or BD Venflon™ is different from inserting non-ported catheters, for example BD Insyte™ Autoguard™. It is therefore essential for new products to be similar to those currently used, to enable HCWs to alternate between products.

Blood leaked during the catheterisation procedure from the back of the catheter or along the tether concurring with Watters *et al.*, (1995) and Asai *et al.*, (2002). Reasons for blood leak may be due to modified insertion techniques, ability to successfully occlude the vein or may reflect the new technology of NPDs. The speed of the flashback observed with SLP catheters was improved and therefore reduced the time in which HCWs had to remove the needle and secure the device before blood flowed back from the vein into the catheter.

Blood splashed when the introducer needle was finally removed from the catheter and subsequently the clinical trial was suspended due to the potential for mucocutaneous exposure to blood. No other published trial of NPDs was suspended due to blood splash or blood leak, however, there was previous evidence of this issue. Asai *et al.*, (2002) documented blood splash when the safety mechanism was activated and the introducer needle retracted with BD Insyte™ Autoguard™. Similarly, Watters *et al.*, (1995) reported blood spillage on final separation of the introducer needle from the catheter with BD Safelon™. With reference to SLP and BD Safelon™ (products with similar activating safety mechanisms), the blood splash may have been caused if blood contaminated the needle guard. Subsequently, the substantial force to finally separate the introducer needle from the catheter may have caused blood to flick off the needle guard and splash. It would not be possible to ensure all HCWs utilised a catheterisation technique which prevented blood contaminating the needle guard,

indeed in certain situations, for example patients with oedematous arms or accessing antecubital fossa veins, it is not always possible to ensure complete vein occlusion. Therefore, to reduce blood splash, it was necessary to modify SLP's safety mechanism.

The needle guard did not consistently deploy. These findings concurred with Watters *et al.*, (1995), who documented 3 incidents where the safety mechanism did not activate. Previous studies also identified the failure of NPDs' safety mechanism (Department of Health Services, 2002; Short Life Working Group, 2001; CDC, 2000). Reasons for failed safety mechanism deployment may be that HCWs did not insert the catheter according to the technique demonstrated during the training session. If a finger was placed on the introducer needle and tether whilst removing the introducer needle, the needle guard would not deploy.

Needle guards that did deploy successfully all remained in place until disposal of the device. This was essential to reduce the risk of PIIs to ancillary staff and other HCWs who were not the original user of the device (Department of Health Services, 2002; May and Brewer, 2001; Puro *et al.*, 2001; Osborn *et al.*, 1999). Indeed, HCWs do not consistently dispose of sharp devices in the appropriate container as found in chapter 3. Therefore, if the safety mechanism remained over the needle tip, this may reduce the number of injuries sustained by ancillary staff or other HCWs who are injured by sharp devices found on floors, in bins and other surfaces in the clinical arena.

During the pilot study less than a quarter of SLP catheter insertions failed. However, the 21% failure rate was higher than 9% demonstrated by Asai *et al* (2002) and 5% by Watters *et al.*, (1995). This may reflect HCW's years of experience. In this study, senior doctors had a higher success rate compared with junior doctors. The participants in previous studies (Asai *et al.*, 2002; Watters *et al.*, 1995) were more

experienced and therefore may have achieved a higher insertion success rate. This may also have been due to an inadequate catheterisation technique. Currently, the majority of doctors learn how to catheterise in the clinical setting without adequate supervision or educational input, developing self-taught techniques, which may influence their success rate.

Other findings from the pilot study were that SLP catheters were inserted most frequently between 12.00 and 18.00 hours, which was suggestive of doctors' routine clinical practice. Doctors inserted IV peripheral catheters least often between 24.00 and 06.00 hours reflecting their change in working hours and the implementation of protected night rest. In addition, the quality of patients' veins did not influence the number of attempts taken to successfully insert SLP catheters, despite being identified as a cause of nearly half of all failed insertion attempts. The number of first attempt successful SLP insertions (84%) was lower than previously described by Asai *et al.*, (2002) (92 and 96%) and Watters *et al.*, (1995) (95%), however higher than described by Asai *et al.*, (1999) (72%). It is unclear why first attempt success varied. The two trials conducted by Asai *et al.*, (2002; 1999) had similar patient inclusion criteria (if a cephalic vein was not easily visible, the patient was excluded from the trial), inferring that patients with poor vein quality were not included which may have increased success rate. Alternatively, it may have been that number of years of experience influenced the number of attempts required to insert the NPD. However, it may also reflect the different features associated with each NPD or other influencing factors associated with clinical practice, for example the environment, fatigue, time of day, and pressure of workload.

5.4.1 Limitations

The study's methodology presented limitations with reference to distribution of SLP catheters during the pilot study. This method relied upon HCWs carrying IV peripheral catheters with them during their daily activity. Doctors frequently forgot to take SLP catheters with them, could not fit them in their pockets or did not have the appropriate gauge size catheter with them when patients required IV access, which may have reduced the number of insertions. This may be resolved if the catheter to be evaluated was kept in one location in the ward setting and all HCWs in that area who inserted IV peripheral catheters were involved with the study to prevent untrained HCWs using the product. Furthermore, the time in which to complete the pilot study was extended due to factors inherent in clinical settings. The number of SLP catheters inserted was dependent upon patient requirement and staff activities and therefore fluctuated accordingly.

It was not always possible for HCWs to complete the comprehensive evaluation form immediately following the catheter insertion due to pressure of workload or work priorities. Therefore, HCWs may have depended upon recall to complete questionnaires. This may have been resolved if the evaluation form had been slightly shorter in length, however this would have reduced the amount of information obtained from the study.

Healthcare workers willing to participate in studies evaluating NPDs may be those who are supportive of change. In the pilot study, one HCW withdrew from the study, which may have been due to their resistance to change. Indeed, the HCWs who participated in the pilot study may have felt pressurised into participation due to their Consultant's agreement with the study. Consequently, in the clinical trial, by choosing two wards, HCWs may have felt more able to refuse participation. When evaluating NPDs it is

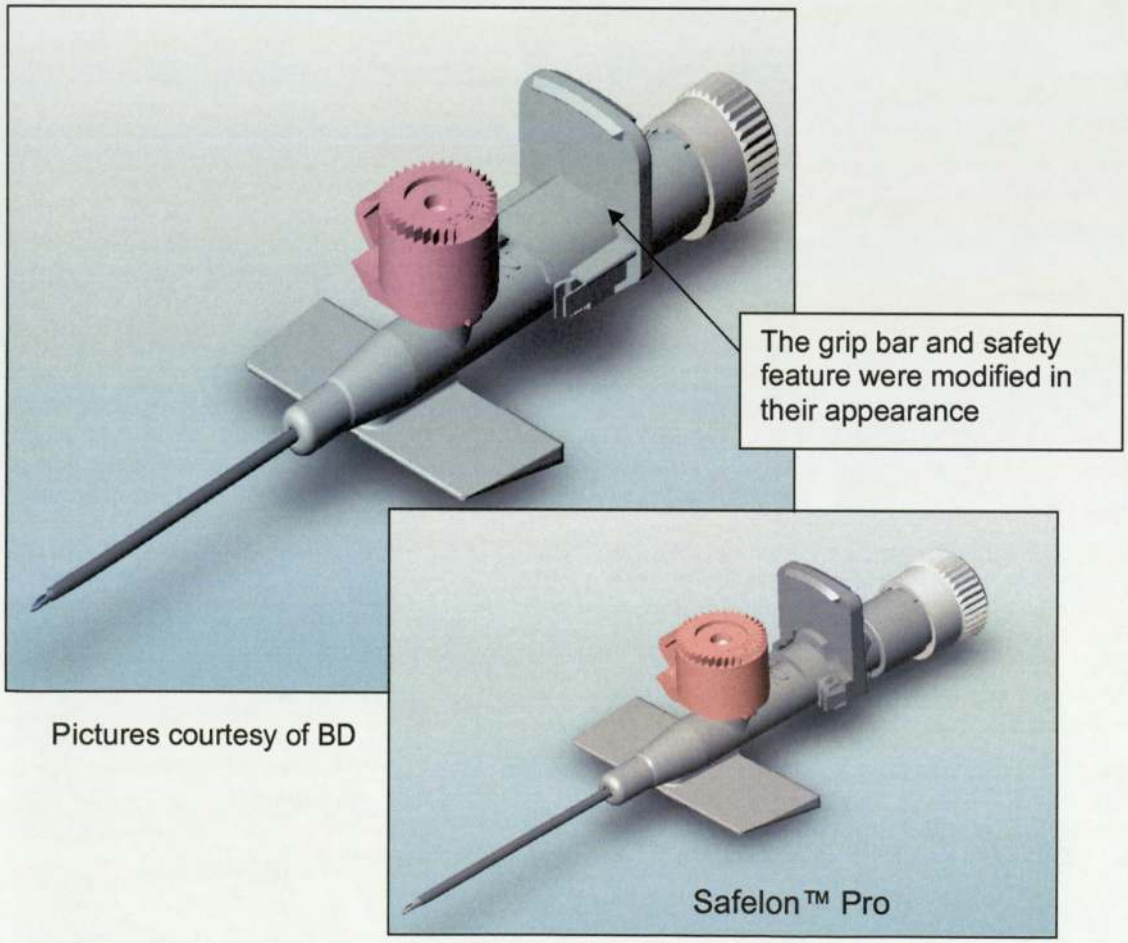
imperative to recruit a cross section of HCWs and not just a group of HCWs who are supportive of NPDs.

5.5 Product modification and non-clinical evaluation of Safelon™ Pro 3

Following suspension of the clinical trial of SLP, results were communicated to BD for review. Subsequently, modifications were made to the NPD in an attempt to resolve the usability issues.

The modifications focused on the separation forces associated with removing the introducer needle from the catheter and the speed of the secondary flashback (blood back flow from the vein into the catheter). Following modification, SLP 3 differed in appearance from SLP (figures 5.19, 5.20).

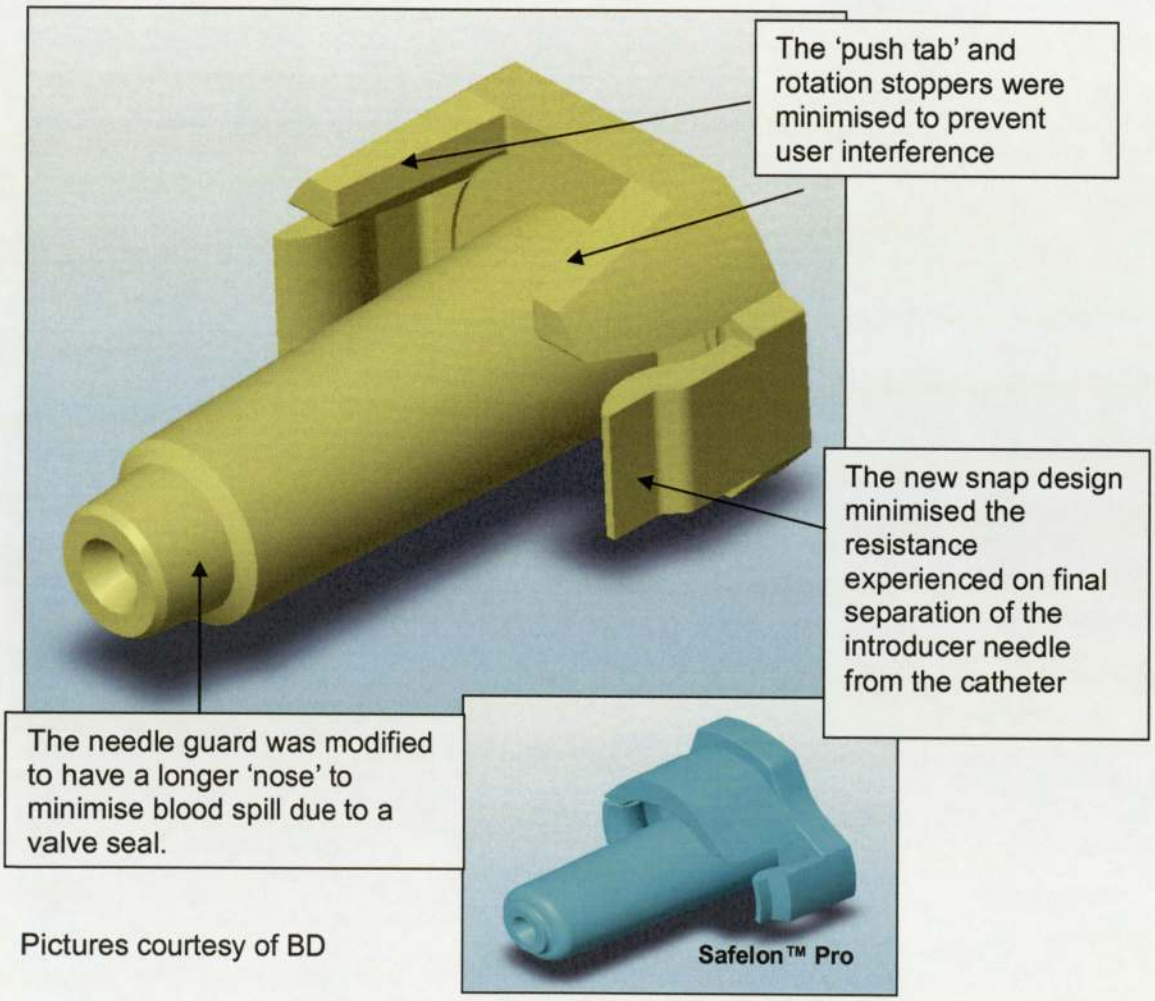
Figure 5.19: Modified appearance of Safelon™ Pro 3 and visual comparison with Safelon™ Pro.



Pictures courtesy of BD

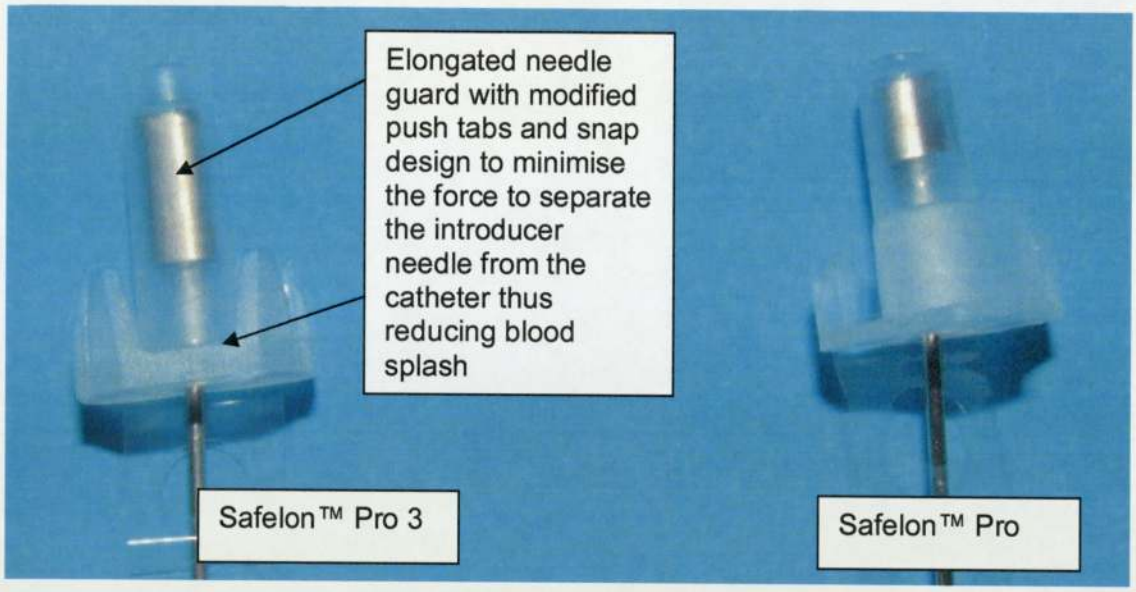
The needle guard was modified to minimise the final separation force of removing the introducer needle from the catheter. This was achieved with a new snap design; the push tab and rotation stoppers prevented the operator from interfering with the safety mechanism. Furthermore, the needle guard was elongated to minimise blood leak by incorporating a valve seal (figures 5.20, 5.21).

Figure 5.20: Needle guard modifications and visual comparison with Safelon™ Pro.



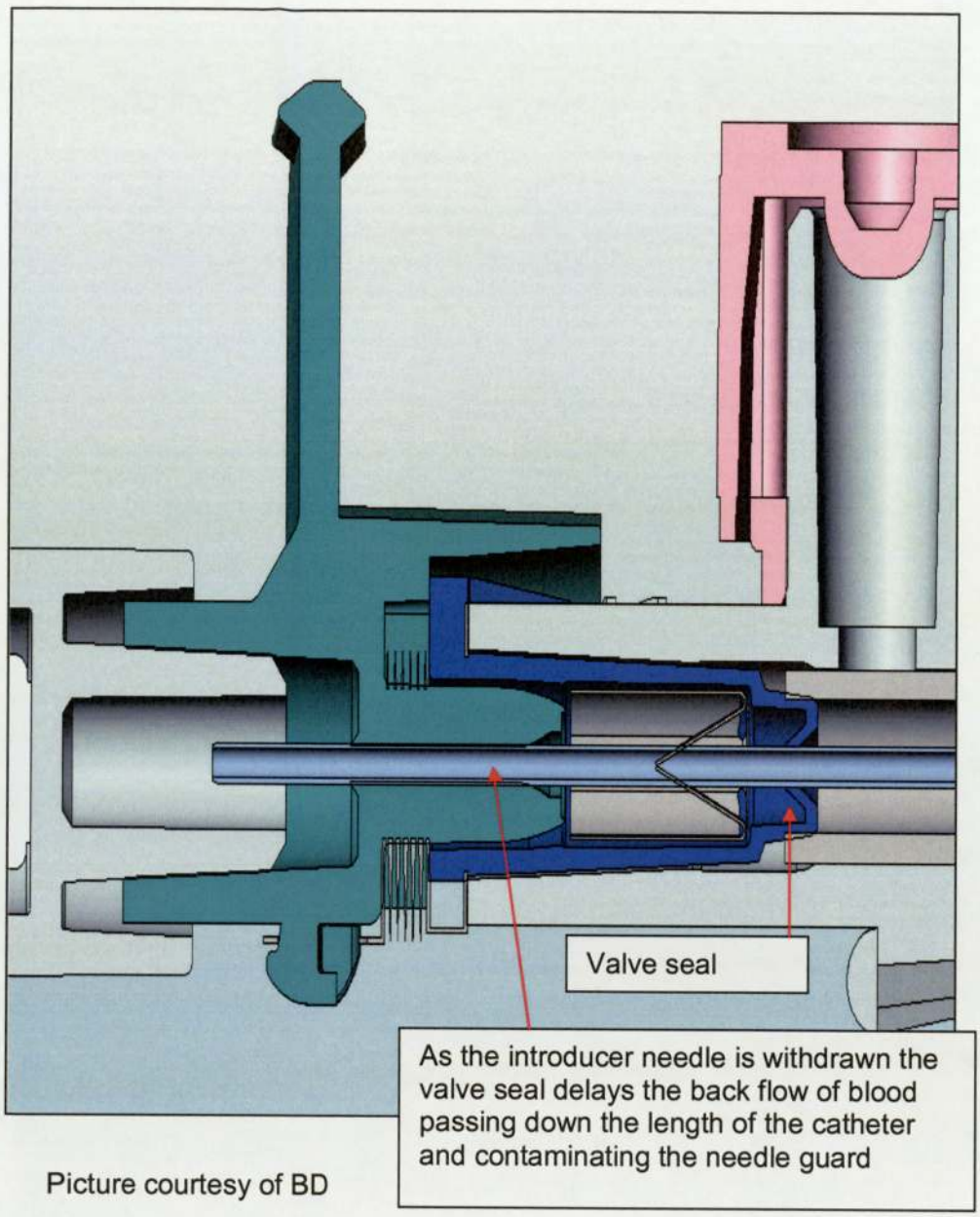
Pictures courtesy of BD

Figure 5.21: Comparison of Safelon™ Pro and Safelon™ Pro 3 needle guard.



A valve seal was incorporated to reduce the volume of blood leak and potential blood splash (figure 5.22).

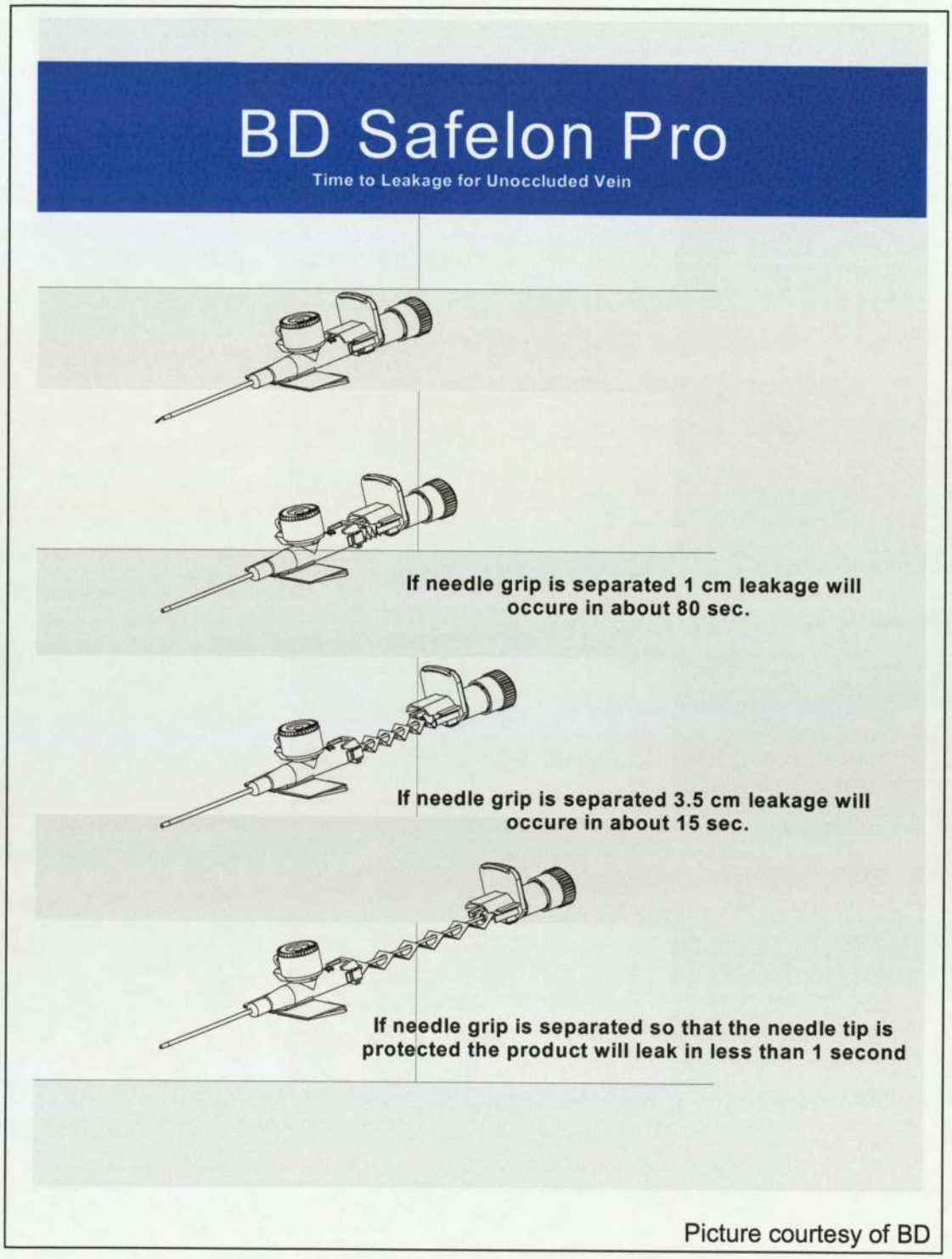
Figure 5.22: The valve seal incorporated in the needle guard.



Picture courtesy of BD

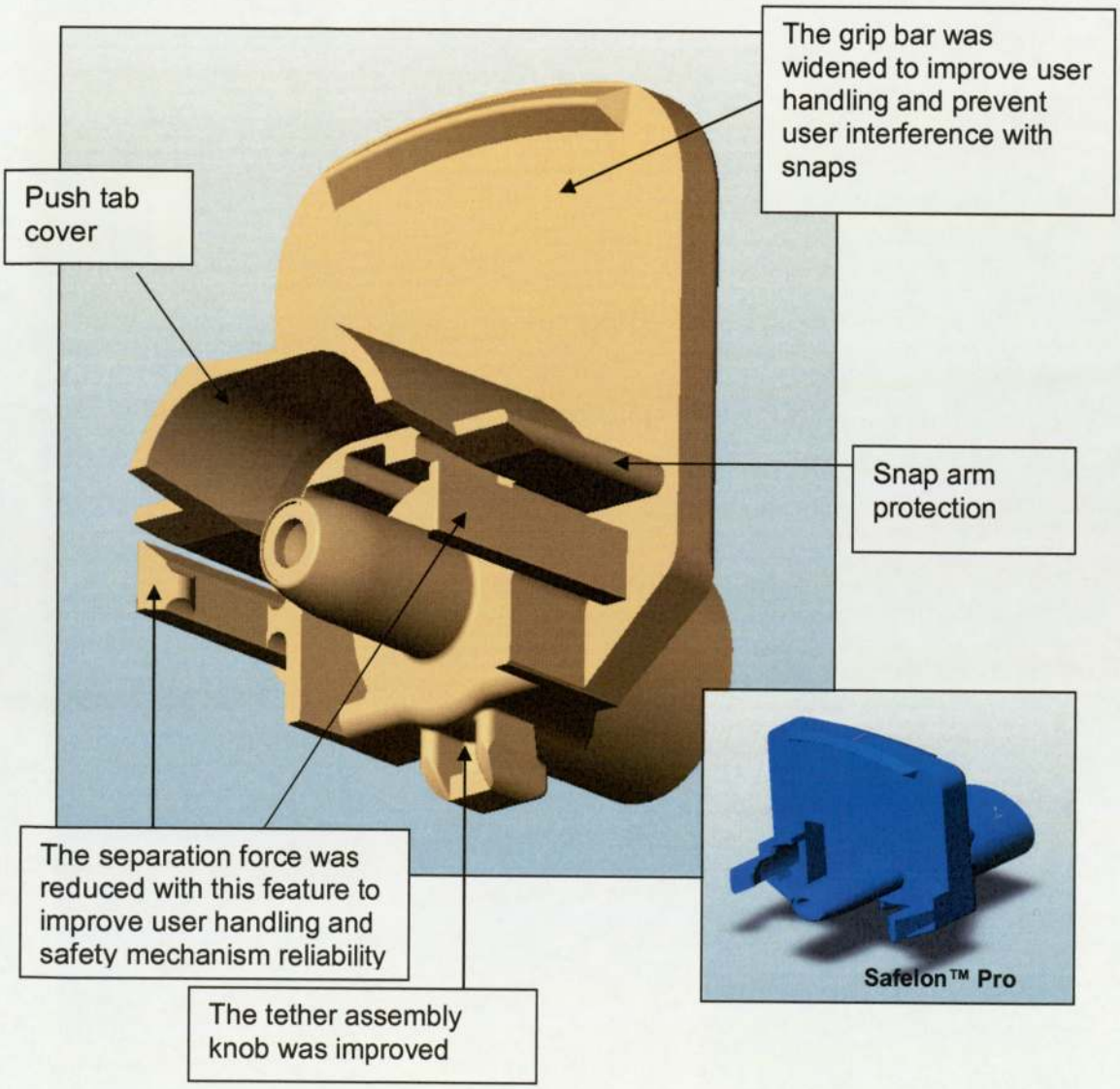
By incorporating the valve seal, the time lapse increased before blood flowed down the catheter (secondary flashback), contaminating the needle guard. This enabled the operator more time for vein occlusion prior to removing the introducer needle from the catheter (figure 5.23).

Figure 5.23: The effect of the valve seal on back flow of blood down the catheter following correct placement of Safelon™ Pro 3.



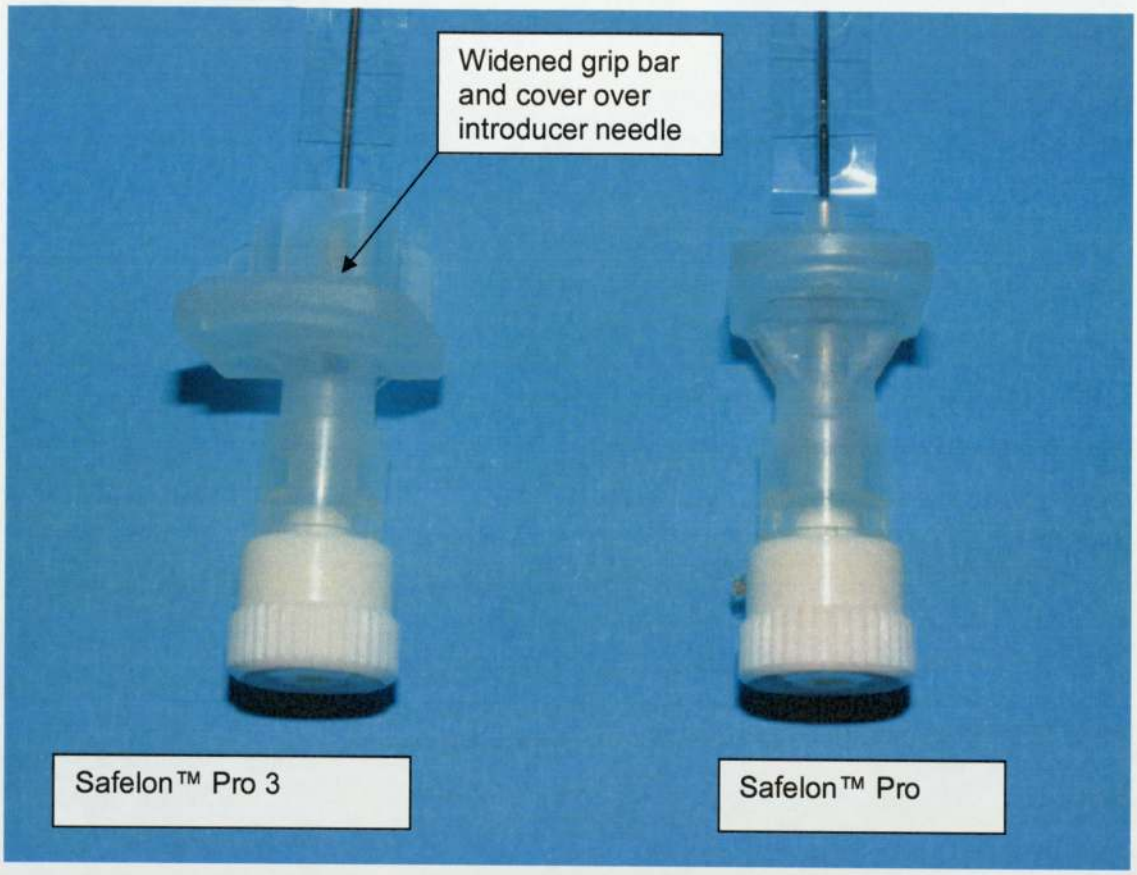
The needle hub was substantially modified (figures 5.24, 5.25). The push tab cover minimised the operator placing their finger on the introducer needle and tether, which prevented the safety mechanism deploying. The grip bar was widened to improve operator handling and minimise interference with the safety mechanism. Furthermore, the initial separation force was minimised by modifying the needle hub.

Figure 5.24: Needle hub modifications and visual comparison with Safelon™ Pro.



Pictures courtesy of BD

Figure 5.25: Comparison of the needle hub and grip bar with Safelon™ Pro and Safelon™ Pro 3.



5.5.1 Methods and materials

Prior to commencing this non-clinical study, Local Research Ethics Committee and the Trust's Research and Development and Clinical Governance departments' approval was sought and granted. SLP 3 was not available for clinical use immediately post modification, therefore, the product was evaluated utilising a simulator arm (Ambu I.V. Trainer®). The solution in the simulator arm was used to reproduce the effect of blood in patients' veins. It was prepared by dissolving 9 grams of reagent grade sodium chloride in distilled water to make a 1litre solution. This solution was then mixed with 450 millilitres of glycerol (BDH Ltd). A red colouring was added to simulate the colour of blood. This solution was then injected into the simulator arm veins according to manufacturers' instructions.

Eighteen HCWs were approached to participate in the non-clinical evaluation of SLP 3. Participant inclusion criteria were at least 6 months experience inserting IV peripheral catheters in the clinical setting and insertion of a minimum of 3 IV peripheral catheters per week. Two evaluation days were organised; 1 in the Trust's Clinical Skills Centre and the other in the cardiac surgical theatres' training room. The locations were determined by room availability. The sample was chosen from HCWs, who met the inclusion criteria and who were working in surgical theatres on the given evaluation day. In addition, HCWs who participated on the second evaluation day were nurses and medical officers who met the inclusion criteria and who were available on the day, determined by workload pressure. Although the sample was not randomly selected, the product evaluators had no influence over HCW availability and therefore the sample was unbiased. All participants received an information sheet, consent form (appendix 5G) and initial demographic questionnaire (appendix 5H) prior to device evaluation.

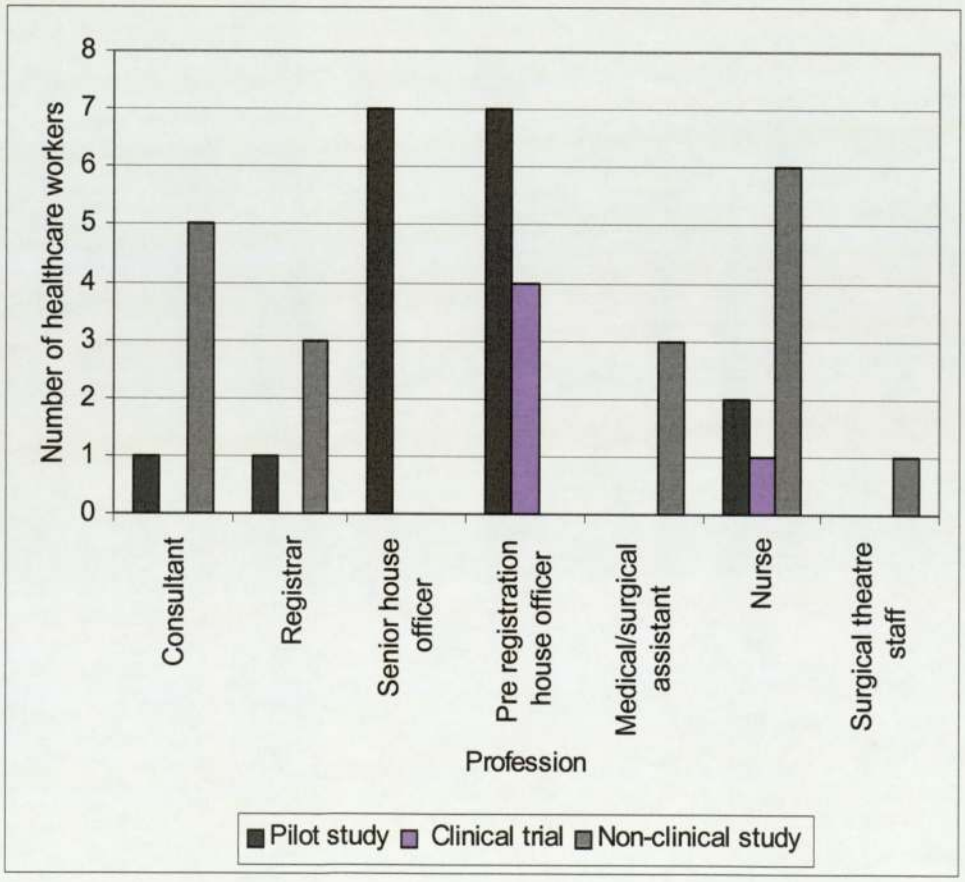
The evaluation process included:

- Explanation of the product and its modifications by a BD company representative.
- At least 5 practice insertions with SLP 3 using a simulator arm.
- Ten sequential SLP 3 insertions. The participant completed an evaluation form (appendix 5I) following each insertion.
- Each insertion was observed by the Clinical Research Nurse (J Trim) or a BD representative, to document insertion technique, safety mechanism activation and evidence of blood leak or splash (appendix 5J). In addition, each insertion was filmed to capture any potential blood splash for which permission was sought prior to commencing the evaluation.
- Healthcare workers completed a summative questionnaire on completing the 10 sequential insertions (appendix 5K).

5.5.2 Results

The 18 HCWs comprised 5 consultants, 3 registrars, 2 medical assistants, 1 surgical assistant, 1 surgical theatre staff, 1 E grade nurse, 2 F grade nurses and 3 G grade nurses. These HCWs were compared with those who participated in the pilot study and clinical trial (figure 5.26). A higher number of senior medical staff participated in the non-clinical trial of SLP 3 than in the pilot study and clinical trial, whereas more senior house officers and pre registration house officers participated in the pilot study and clinical trial of SLP 3.

Figure 5.26: Comparison of participating healthcare workers from each study of Safelon™ Pro and Safelon™ Pro 3.



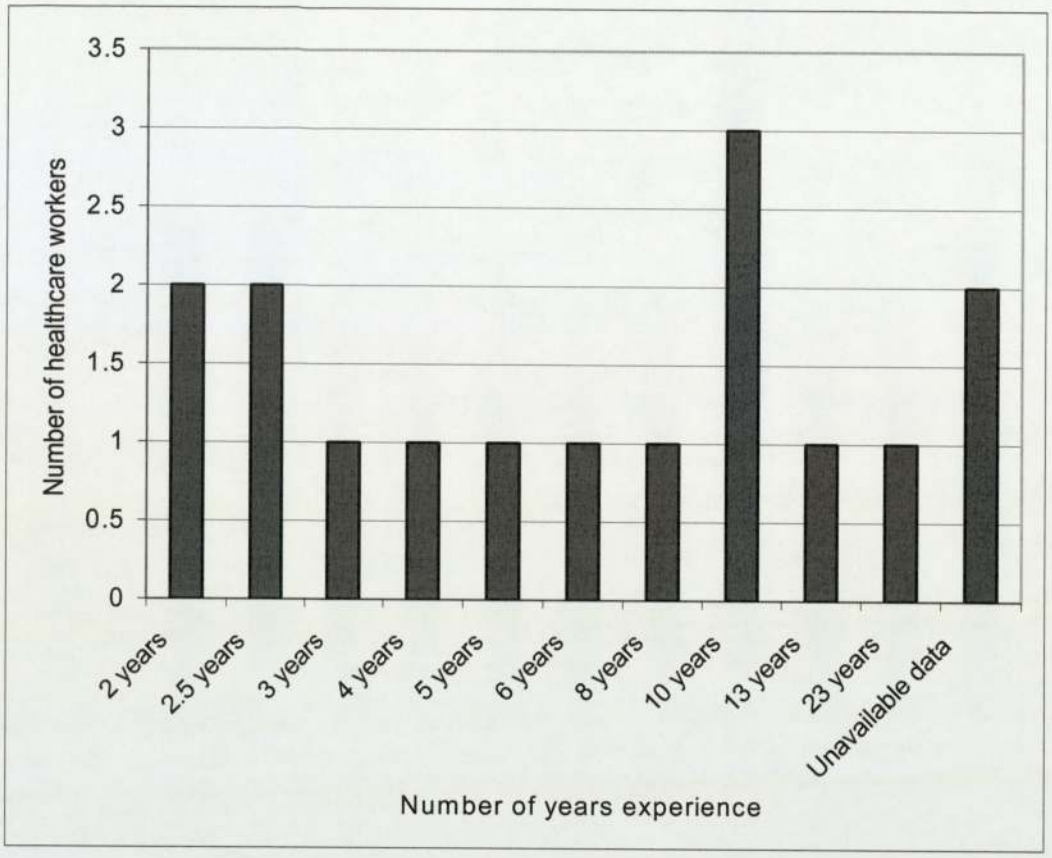
Conventional IV peripheral catheters most frequently used by HCWs included BD Venflon™ (5 out of 18, 28%), Johnson and Johnson Optiva™ (6 out of 18, 33%) and a variety of other ported and non-ported IV peripheral catheters including BD Insyte™ (7 out of 18, 33%). These results were similar to those found in the pilot study (table 5.7). The gauge size of catheters used in the clinical setting varied from 14 to 24 gauge.

Table 5.7: Comparison of conventional products used by healthcare workers who participated in the pilot study and non-clinical study.

Type of conventional catheter	Number of healthcare workers in the pilot study (n=18)	Number of healthcare workers in the non-clinical study (n=18)
BD Venflon™	9	5
Johnson and Johnson Optiva™	3	6
Variable catheters	5	7
Unavailable data	1	0

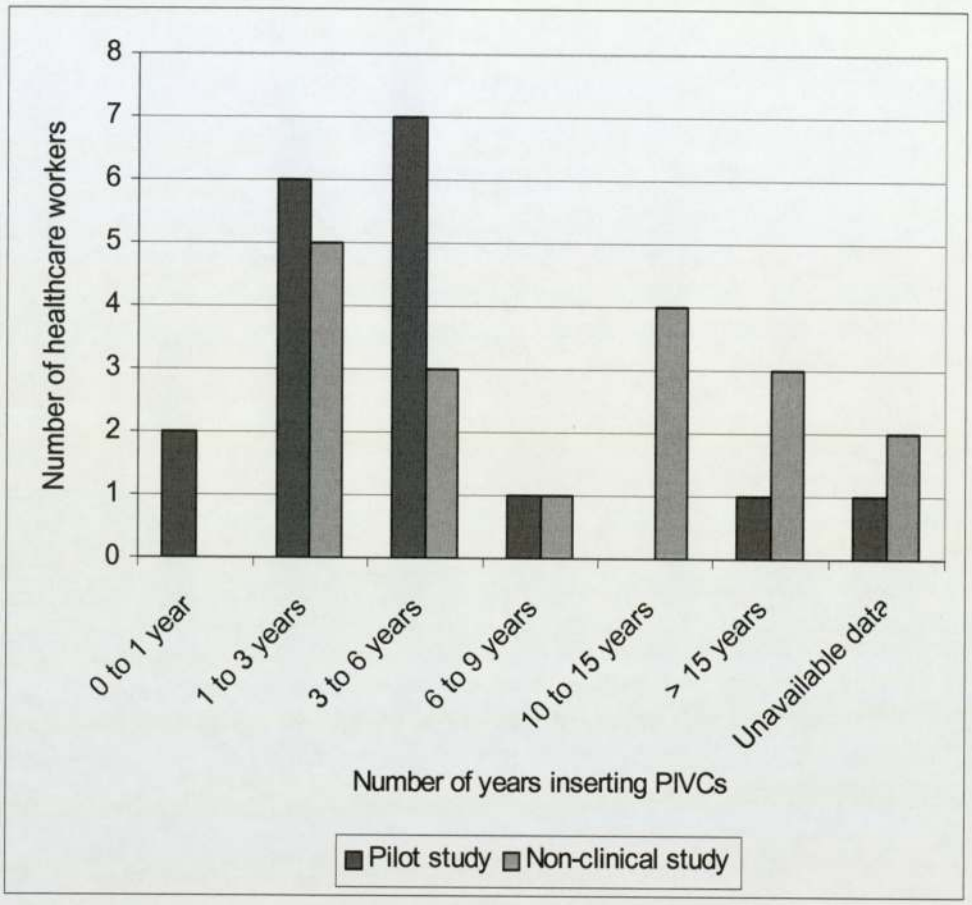
All participants had more than 6 months experience inserting IV peripheral catheters in the clinical setting (figure 5.27).

Figure 5.27: Healthcare workers' number of years of experience inserting intravenous peripheral catheters in the clinical setting.



The length of time HCWs had been inserting IV peripheral catheters who participated in the pilot study and non-clinical study were compared. It was not possible to compare HCWs who participated in the clinical trial because this data were not gathered (figure 5.28). Healthcare workers who participated in the non-clinical study had been inserting IV peripheral catheters for longer when compared with those who participated in the pilot study.

Figure 5.28: Comparison of the length of time healthcare workers had been inserting intravenous peripheral catheters at the time of the pilot study and non-clinical study.



Key: PIVCs = peripheral intravenous catheters

Blood splashed on removal of the introducer needle in 17 out of 180 (9%, 95% CI 6-15%) insertions. Of the 17 blood splash incidents, 3 out of 17 (18%, 95% CI 4-43%) were perceived as more than with conventional catheters. Of these, blood splashed 5 times for 1 HCW, once for 9 HCWs and 3 times for 1 HCW. This concurred with the observer evaluation. The severity of blood splash was documented by the observer (table 5.8).

Table 5.8: Observers' evaluation of the severity of blood splash following removal of Safelon™ Pro 3 introducer needle.

Severity of blood splash	Number of Safelon™ Pro 3 insertions
Mild (1 – 2 drops within 5 cm of the catheter)	7
Moderate (several drops 5-20 cm from the catheter)	7
Severe (on patient, user and wall)	1
Unavailable data	2

The rate of blood splash reported in the pilot study, clinical trial and non-clinical study was compared (table 5.9). The same rate of blood splash was reported in the pilot study and non-clinical study. When the clinical trial (SLP) and non-clinical study (SLP 3) results were compared, blood splash was reduced by 62% following product modification.

Table 5.9: Comparison of blood splash experienced in the pilot study, clinical trial and non-clinical study.

Pilot study	Clinical trial	Non-clinical study
18 out of 211 insertions 9%	5 out of 7 reports 71%	17 out of 180 insertions 9%

The level of blood splash associated with inserting SLP 3 catheters was evaluated as acceptable to 14 out of 18 (78%) HCWs and unacceptable to 2 out of 18 (11%) HCWs. Two HCWs did not complete the question. Indeed no HCW reported that the level of blood splash would prevent them using the NPD, however 2 HCWs did not complete the question. The unacceptability of blood splash decreased from 56% in the pilot study, 80% in the clinical trial to 11% in the non-clinical study of SLP 3.

The needle guard deployed and remained until disposal in 175 out of 180 SLP 3 insertions (98%, 95% CI, 94-99%). No data were available for the remaining 5 SLP 3 insertions. These findings concurred with those documented by the observer. In the pilot study of SLP, the needle guard deployed in 204 out of 211 (97%) insertions. In the clinical trial only 1 out of 112 needle guards failed to deploy (<1%).

Blood leaked during 26 out of 180 (14%, 95% CI 9-21%) SLP 3 catheter insertions, from the back of the catheter each time (20 out of 26, 77%), however data were not available for 6 insertions. The cause of blood leak was documented as procedure related (15 out of 26, 58%), however 11 evaluations were not completed. In comparison, 31 out of 211 insertions (15%) during the pilot study resulted in blood leak and in 6 out of 7 reports (86%) in the clinical trial, HCWs experienced blood leak.

Healthcare workers' technique to insert SLP 3 catheters was observed during the evaluation. One hundred and three out of one hundred and eighty (57%) HCWs adopted a hooded technique (following successful catheter placement, the introducer needle is withdrawn until the needle tip is located within the catheter whilst advancing the catheter. The catheter and 'hooded' introducer needle is advanced into the vein). In comparison, 73 out of 180 (41%) used a guidewire technique (following successful catheter placement, the introducer needle was stabilised and the catheter advanced over the introducer needle into the vein).

One hundred and seventy seven out of one hundred and eighty (98%) HCWs attempted vein occlusion. Of these, 17 out of 177 (10%, 95% CI 6-15%) experienced blood splash on final separation of the introducer needle from the catheter. Furthermore, a hooded and guidewire insertion technique were both associated with 8 out of 17 (47%, 95% CI 23-72%) blood splash incidents (1 incident was associated with a technique described as 'other'). No statistical significance was reached when

incidence of blood splash was compared with insertion technique (p=1.00, Fisher's Exact Test).

5.5.2.1 Summative evaluation

Sixteen out of eighteen HCWs took less than 6 insertions to become familiar with SLP 3 catheters. Of these 10 out of 16 (63%) were confident with the product after 1 to 3 insertions, compared with 6 out of 16 (37%) after 4 to 6 insertions. The remaining HCWs took 7 to 9 insertions and more than 9 insertions to become confident with using the product. These results were compared with those from the pilot study (table 5.10). Results from the clinical trial could not be included because this question was not asked.

Table 5.10: Comparison of results determining the number of insertions required before healthcare workers were familiar with Safelon™ Pro and Safelon Pro 3.

Number of catheter insertions	Safelon™ Pro	Safelon™ Pro 3
1 to 3	7	10
4 to 6	9	6
7 to 9	0	1
> 9	0	1
Never	1	0
Unavailable data	1	0

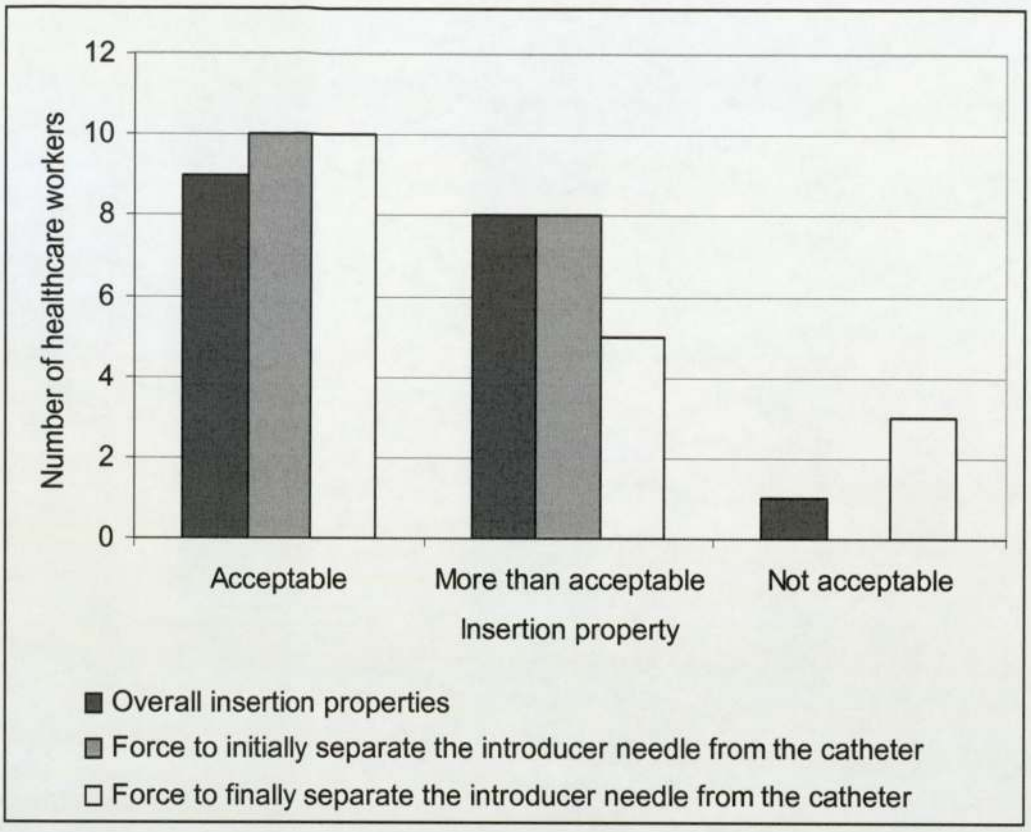
A higher number of HCWs found SLP 3 acceptable after 1 to 3 insertions (10) when compared with those inserting SLP (7), indeed more HCWs required 4 to 6 insertions with SLP (9) than with SLP 3 (6).

Ten out of eighteen HCWs reported having to change their catheterisation technique to insert SLP 3 catheters. Five out of ten (50%) modified their technique to stabilise the

catheter on removal of the introducer needle, 2 out of 10 (20%) had not previously supported the catheter whilst occluding the vein using one hand, 1 HCW was previously used to inserting non-ported catheters and 1 HCW modified their technique to the hooded technique. When these results were compared with those from the pilot study of SLP, the same number of HCWs modified their technique to insert SLP catheters (10, 56%).

The insertion properties of SLP 3 were evaluated (figure 5.29). From a total of 54 evaluations, only 4 (7%) were perceived to be unacceptable. Of these, 3 were related to the final force required to separate the introducer needle from the catheter and 1 to overall insertion properties. Indeed, 21 out of 54 (39%) evaluations were perceived to be more than acceptable. Of these, 8 were related to both overall insertion properties and the initial force required to separate the introducer needle from the catheter and 5 to the final separation force.

Figure 5.29: Evaluation of insertion properties associated with Safelon™ Pro 3.



The acceptable and more than acceptable insertion forces were compared for each study undertaken (table 5.11). All SLP 3 insertion forces were more acceptable to HCWs in the non-clinical study than in either the pilot study or the clinical trial. The force to finally separate the introducer needle from the catheter was significantly more acceptable with SLP 3 catheters when compared with SLP catheters in the pilot study ($p=0.0381$, Fisher's Exact Test).

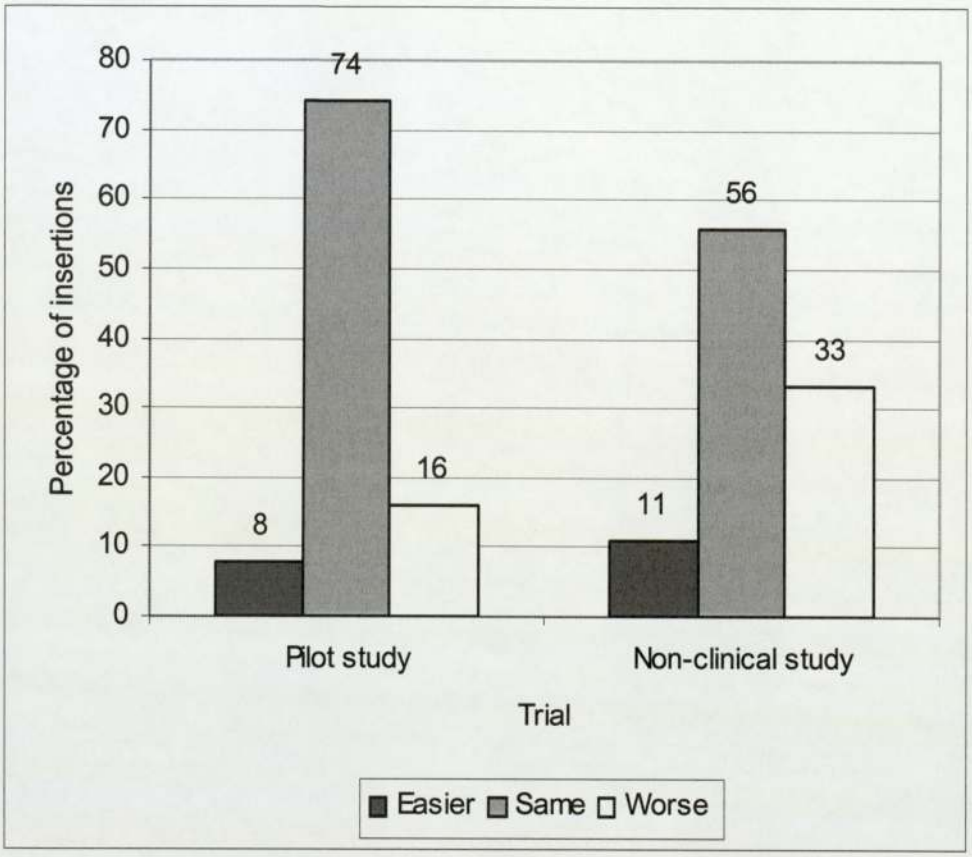
Table 5.11: Comparison of the insertion forces of Safelon™ Pro and Safelon™ Pro 3 documented in each trial.

Key: A = acceptable and more than acceptable
NA = Not acceptable

Insertion properties	Pilot study		Clinical trial		Non-clinical study	
	A	NA	A	NA	A	NA
Overall insertion	205	4	4	1	17	1
Force to initially separate the introducer needle from the catheter	205	5	4	2	18	0
Force to finally separate the introducer needle from the catheter	172	37	2	4	15	3

Healthcare workers were asked to compare the ability to prevent blood leak during insertion of SLP 3 catheters with conventional catheters. Two out of eighteen (11%) HCWs found preventing blood leak easier, 10 out of 18 (56%) the same and 6 out of 18 (33%) more difficult. These results were compared with those from the pilot study and clinical trial (figure 5.30). Preventing blood leak was easier with SLP 3 than with SLP in the pilot study, however statistical significance was not reached ($p=0.1161$, Fisher's Exact Test). Indeed, in the clinical trial 100% of HCWs reported blood leak to be worse than with conventional catheters.

Figure 5.30: Comparison of the ability to prevent blood leak with Safelon™ Pro and Safelon™ Pro 3 in the pilot study and non-clinical study, illustrated in percentages.



Sixteen out of eighteen (89%) HCWs described SLP 3 as a safe product. Reasons for this are illustrated in table 5.12. One HCW did not perceive the NPD to be safe due to the blood splash and 1 HCW did not complete the question. When these results were compared with the pilot study results, an additional HCW perceived SLP to be a safe product when compared with SLP (17 out of 18, 94%).

Table 5.12: Healthcare workers' reasons that Safelon™ Pro 3 was a safe product.

Reason	Number of healthcare workers
Ease of insertion	2
Reduced blood leak	2
Percutaneous inoculation injury prevention and safety feature	12
Unavailable data	2

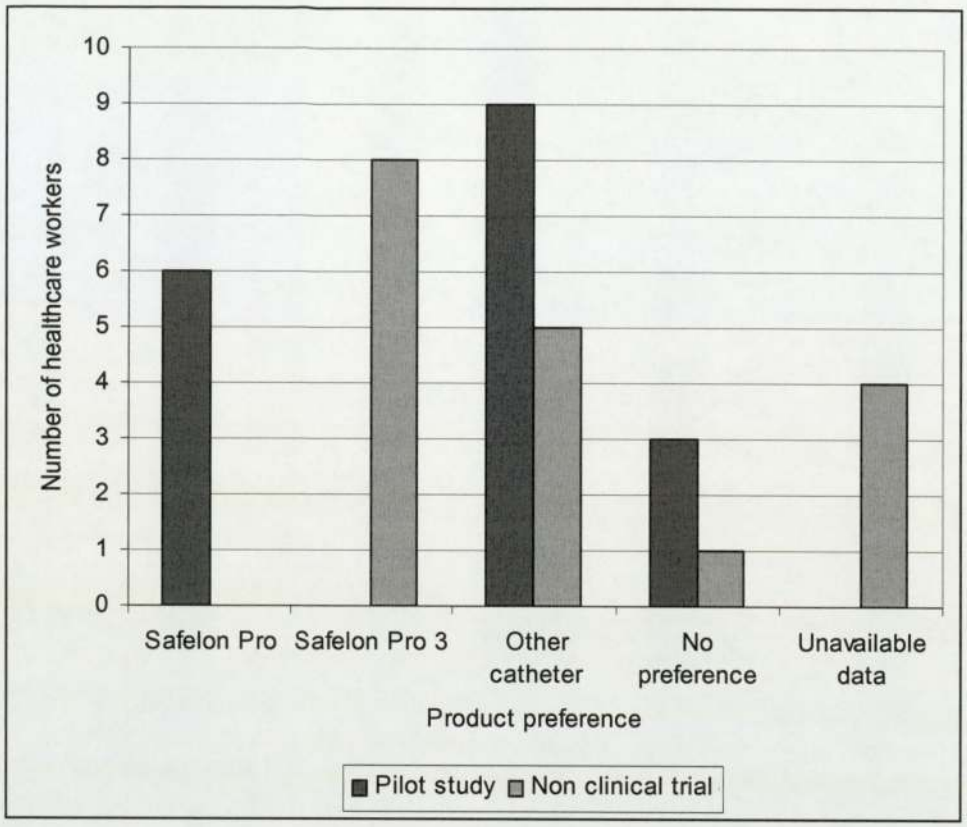
Healthcare workers were asked to compare SLP 3 catheters with conventional catheters used in the clinical setting (table 5.13).

Table 5.13: Healthcare workers' comparison of Safelon™ Pro 3 with conventional intravenous peripheral catheters.

Comparison	Number of healthcare workers
Better	3
Same	4
Good	2
Not as good	1
Safety feature	6
Unavailable data	2

Only 1 HCW perceived SLP 3 catheters as not as good as conventional catheters. All other HCWs gave positive comparative responses. Indeed, when HCWs were asked to document their product preference, between conventional products or SLP 3, 8 out of 18 (44%) preferred SLP 3 catheters, 5 out of 18 (28%) preferred conventional catheters, 1 HCW had no preference and 4 HCWs did not complete the question. These results were compared with those from the pilot study (data were not available for the clinical trial) (figure 5.31). The preference for SLP 3 catheters increased by 11% when compared with those who preferred SLP to a conventional catheter (6 out of 18), however statistical significance was not reached (p=0.512, Fisher's Exact Test).

Figure 5.31: Comparison of healthcare workers' product preference reported in the pilot study of Safelon™ Pro and the non-clinical trial of Safelon™ Pro 3.



5.6 Discussion of evaluation of Safelon™ Pro 3

SLP 3 was evaluated in a non-clinical study using simulator arms. Insertion properties, needle guard deployment and modifications were assessed to establish whether SLP 3 addressed the problems of blood splash, blood leak and the final separation force identified in the clinical trial of SLP.

The valve seal in SLP 3 reduced blood leak by 72% compared with the clinical trial of SLP and 1% compared with the pilot study. Both the valve seal and the minimised force required to separate the introducer needle from the catheter reduced blood splash by 62%. The improved force to finally separate the introducer needle from the catheter with SLP 3 catheters was significantly more acceptable to HCWs than the SLP catheter ($p=0.0381$, Fisher's Exact Test). To assess whether the incidents of blood leak and splash were product related, procedure related or an effect of using simulator arms, a clinical trial would need to be undertaken. It is inherently difficult to attain complete vein occlusion on simulator arms because of the rigid vein material and thick rubber used to imitate skin.

Prior to evaluating SLP 3, it was theorised that insertion technique may affect the degree of blood splash experienced. When SLP 3 was evaluated, both insertion techniques were associated with equal incidents of blood splash. Therefore, it could be concluded that insertion technique had no influence over degree of blood splash.

The rate of blood splash did not improve when compared with the pilot study results, however SLP 3 improved blood splash by 62% when compared with the clinical trial findings. This may be due to the use of the simulator arms. Healthcare workers were more accepting of the level of blood splash reported with SLP 3 than with SLP. Despite this, one less HCW perceived SLP 3 to be a safe product when compared with

SLP. However, HCW preference for SLP 3 catheters increased by 11% when compared with those who preferred SLP catheters. This may reflect the product modifications.

5.6.1 Limitations

These preliminary findings suggested that the issues of blood splash, blood leak and final separation force during the pilot study and clinical trial had been resolved and the NPD was safe and reliable. To confirm these findings, a clinical trial would need to be undertaken.

The use of simulator arms may have influenced the results due to the inherent difficulty of occluding the vein. It may be, therefore, the degree of blood leak and splash found in the non-clinical trial may have been further reduced if the product was trialled in the clinical area with patients.

The level of experience of HCWs is important when considering NPD evaluations. It is important to identify the professional group who inserts the majority of IV peripheral catheters. In the clinical setting, this is most frequently junior doctors and anaesthetists. Further trials should include these two professional groups, in addition to nurses and other HCWs who insert IV peripheral catheter.

5.6.2 Recommendations

The patient group with which the NPD is evaluated may influence the study findings. It is important to identify patient groups with varying vein quality to ensure the NPD is acceptable and reliable for patients who inherently have poor vein quality.

Healthcare workers willing to participate in studies evaluating NPDs may be those who are supportive of change. In the pilot study, one HCW withdrew from the study

because they were resistant to change and wanted to maintain their level of confidence of inserting conventional IV peripheral catheters. It would be beneficial to recruit a random sample of HCWs in further trials of NPD products.

It is essential to evaluate these NPDs prior to universal implementation. Therefore, SLP 3 should be implemented in specific clinical areas for evaluation.

5.7 Summary

SLP was evaluated utilising a cross section of patients and clinical specialties. During the pilot study, the insertion properties of the NPD were acceptable, however, participants did not favour the final force required to separate the introducer needle from the catheter, particularly for difficult insertion procedures. Blood leak was identified, however was not perceived to be more difficult to prevent than with conventional products. Although blood splash was documented whilst inserting SLP catheters, a number of participants would have continued using the product in the clinical setting and did not perceive the blood splash to be worse than with conventional products. The needle guard was reliable, with a 3% failure rate. Indeed, the majority of failed safety mechanisms were due to operator error, rather than device error. This study evaluated SLP to be acceptable to HCWs and reliable for routine clinical practice to potentially reduce PIIs.

The subsequent clinical trial identified blood splash and blood leak, due to the final separation force required to remove the introducer needle from the catheter, as a hazard to both the operator and patient. The degree of blood splash was perceived to be too great and therefore evaluation was suspended. The product company BD, Principal Investigator and Clinical Research Nurse reviewed the available results and agreed product retraction. Although previous NPD studies highlighted issues relating to blood leak and splash, no published study was suspended following further product modification. These results emphasise the importance of evaluating NPDs prior to implementation into the clinical setting. Indeed, it is imperative to comprehensively evaluate NPDs during their development and following commercial launch to ensure their reliability.

The main findings from evaluating the modified SLP 3 catheter were that the force required to finally separate the introducer needle from the catheter was substantially reduced. In addition, the valve seal delayed the back flow of blood from entering the catheter and contaminating the needle guard. This resulted in a marked decrease in the incidence of blood leak and splash when compared with the findings of SLP clinical trial. Following this preliminary evaluation, the technique used to insert the SLP 3 catheter did not affect whether blood leak or blood splash was observed. This may however, reflect the ability to successfully occlude the vein, which on the simulator arm is inherently difficult. To fully evaluate the success of the modifications made to SLP 3 a clinical trial is essential. This would not only provide a clinical evaluation of the usability and reliability of the modified product, but would establish its efficacy in reducing PIIs.

Chapter 6 Conclusion

The risk of occupational exposure to blood borne pathogens, in particular HBV, HCV and HIV has been recognised since the first documented transmission of HIV from a patient to a HCW in 1984 (McCreaddie, 2001). However, following USA legislation in 2001, mandating the implementation of NPDs and sharps injury data collection, the profile of occupational exposure to blood borne pathogens was raised. In addition, awareness campaigns led by the RCN and UNISON, the review of sharps injuries undertaken in Scotland (Short Life Working Group, 2001), the development of the UK Safer Needles Network group, PII discussion in the House of Commons, the emergence of published evaluative NPD studies and the National Audit Office report on health and safety issues in hospitals (2003), all contributed to placing PIIs as a priority on the risk management agenda.

The number of reported PIIs was evaluated at local and national levels, in the UK, across Europe and internationally. Comparisons were limited, however, due to varying study methodologies, sample groups and data collection strategies. At UHB NHS Trust, over the two year study period, the number of reported PIIs were similar, with 430 and 333 PIIs reported amongst an estimated 2000 clinical staff on 2001 and 2002. Previously, Dobie *et al.*, (2002) documented 195 inoculation injuries within the same Trust over one year. However, because the method of data collection was not described, it was not possible to make comparisons with this study.

Similarly, despite awareness of the importance of reporting PIIs, this study found an under reporting rate for PIIs of 23% amongst clinical staff and 29% amongst ancillary staff. Previous research literature documented under reporting rates between 26 and 91%, predominantly amongst clinical staff (table 1.3). There was a paucity of research evidence of ancillary staff under reporting PIIs, however, one study in Taiwan found a

similar rate of 25.4% (Shiao *et al.*, 2001) and the RCN pilot surveillance study identified that downstream injuries were sustained, where the injured person was not the original user of the device, which included ancillary staff (RCN, 2002; RCN, 2001). When the number of reported PIIs and non reported incidents are combined, the actual number of PIIs sustained per year may be as high as 529 (2001) and 409 (2002) for clinical staff and 555 (2001) to 429 (2002) for ancillary staff. Furthermore, the rate of non reported PIIs amongst clinical staff in chapter 3 (23%) and chapter 4 (13%) was similar. This may infer that within UHB NHS Trust the rate of under reporting was between 13 and 23%.

Ancillary staff experienced near miss incidents due to inappropriately disposed sharp devices in the clinical setting. The under reporting rate of near miss incidents was 50%. Reasons for these findings are similar to those highlighted for inadequate knowledge base and non compliance with Trust policy. In chapter 4, HCWs who did not report PIIs identified that pressure of workload as well as knowing the patient's serological status, dealing with the incident at a local level and being up to date with vaccinations, deterred them from utilising the Trust policy.

The device most frequently associated with PIIs was hollow bore needles, which concurred with previous research evidence (Tomkins *et* al., 2003; RCN, 2002, Whitby and McLaws, 2002; Rabaud, 2000). This was most likely due to the high number of hollow bore needles used per year within UHB NHS Trust when compared with other sharp devices. In addition, nurses reported the majority of PIIs (Gillen *et al.*, 2003; Whitby and McLaws, 2002; O'Dowd, 1999), a professional group who use the majority of hollow bore needles during their daily routine, for example in the administration of medication and re-constituting medication for administration. However, despite being the third (2002) and fourth (2001) most common device to cause a PII, injuries sustained via IV peripheral catheters presented a greater risk to HCWs not only due to

the hollow bore needle but because these devices directly access a vein (Goldmann, 2002; Culver, 1997, Cardo *et al.*, 1997). Therefore, although the number of PIIs sustained via IV peripheral catheters were lower than those caused by hollow bore needles, the potential risk of exposure and subsequent transmission of blood borne pathogens was greater with IV peripheral catheters.

The methods utilised to report PIIs were not consistent with UHB NHS Trust policy with only 10% able to correctly cite how to report such an incident. HCWs frequently either only completed a Risk Management incident form or sent their own blood for serological analysis. Most importantly, HCWs did not routinely contact the Occupational Health and Safety or Accident and Emergency departments for appropriate advice and guidance for treatment (areas allocated to manage such incidents). In chapter 4, 62% of HCWs documented that they would report a PII to a clinical area allocated to manage PIIs irrespective of Trust policy compliance. However, when compared with actual reported PIIs, in 2001 only 41% and in 2002 58% of HCWs reported to one of these allocated areas. There was some discrepancy, therefore, between theoretical knowledge and actual behaviour.

One reason for this may be the organisational climate. With increased pressure of workload and staff shortages, HCWs may have perceived the reporting process as laborious and impractical. Moreover, regardless of knowledge of reporting inoculation injuries, the feasibility of leaving a pressurised clinical area, to visit Occupational Health and Safety or Accident and Emergency departments, may be limited following a PII. Previous research literature indicated that organisational factors may increase the risk of PII (Infection Control Nurses Association, 2003; Doebbeling, 2003) and that lack of awareness of procedures prevented reporting (Connington, 2002; Rabaud *et al.*, 2000), however, there was a paucity of evidence correlating organisational pressures and non reporting despite awareness of the reporting procedure. These findings may also

reflect the complexity of factors contributing to the issue of PIIs. It may be that despite training, education and raising awareness, HCWs continued to place themselves at risk due to habitual behaviour. HCWs may attempt to save time by not implementing safe work practices and not adhering to Trust policy. This was demonstrated by HCWs not routinely wearing gloves when handling sharp devices (chapter 4). The reasons for this were not studied, however, anecdotally, HCWs commented that wearing gloves increased the time taken to complete procedures, not wearing gloves was habitual and it reduced their perceived dexterity. Indeed, encouraging HCWs to change their habitual practice may be met with resistance (Doebbeling, 2003). Interestingly however, Clarke *et al.*, (2002) commented, nurses working in clinical areas with staff shortages and poor organisational climates, were more likely to report risk factors, PIIs and near miss incidents. This may infer, therefore, that reporting would increase, however, despondence with the current clinical environment or the perceived inevitability of PIIs when handling sharp devices may influence HCWs' reporting behaviour (Jeanes, 1999).

HCWs self assessed incidents to determine the risk of exposure to blood borne pathogens based on the cause of injury and patient risk factors, subsequently deciding whether a formal report should be completed. It was concerning that HCWs self assessed PIIs based on patient and incident risk factors because they demonstrated an inadequate knowledge base of inoculation injuries, the risk of transmission of HBV, HCV and HIV, the risk of exposure related to individual sharp devices and were even unable to conclusively describe first aid actions following a PII (chapter 4). This inadequate knowledge base was previously described in numerous studies (Stein *et* al., 2003; May and Brewer, 2001; Scoular *et* al., 2000; Diprose *et al.*, 2000; Leliopoulou *et al.*, 1999).

Reasons for HCWs' inadequate knowledge were unclear because the Trust had a comprehensive training and education programme to highlight the risks associated with PIIs, which was continually reviewed by the inoculation review group. It may have been that PII information was not perceived to be important to the individual's clinical practice (Connington, 2002) because either their patient group were deemed low risk or HCWs' defined their clinical practice as safe. Alternatively, the teaching methods utilised and training environment, for example Trust induction may not have been conducive to information retention (Doig, 2000).

The most recent strategy to reduce the risk of PIIs is NPDs. The first IV peripheral catheter NPD study in the UK was published in 1995, with no subsequent work published until 2002. The introduction of NPDs may further reduce the risk of exposure to blood borne pathogens. In particular, BD Insyte™ Autoguard™ was found to reduce associated PIIs by 89% (Mendelson *et al.*, 2000). However, it is essential to evaluate these products for usability and acceptability prior to implementation (Adams & Elliott, 2003).

Safelon™ Pro was a new NPD, similar to BD's conventional counterpart, Venflon™, which incorporated a safety mechanism that covered the introducer needle tip on removal from the catheter. The studies found that SLP demonstrated a good flashback, with adequate blood volume. The insertion properties were acceptable to HCWs, however blood splash associated with separating the introducer needle from the catheter was unacceptable for HCWs due to the risk of mucocutaneous contamination. This finding emphasised the importance of conducting robust clinical trials prior to product implementation, to highlight any potential adverse issues.

Following product modification and the development of SLP 3, the final separation force was minimised in addition to reducing the incidence of blood splash by increasing

occlusion time prior to back flow of blood down the catheter due to a valve seal. HCWs perceived these modifications as an improvement and evaluated the product as safe and acceptable to use in the clinical arena. Interestingly, previous studies identified blood splash during the catheterisation procedure (Asai *et* al., 2002; Watters *et al.*, 1995), however, unlike this study, products were not suspended from trial.

This study confirmed that despite previous research studies, advances in technology and the implementation of preventative strategies, occupational exposure to blood borne pathogens via PIIs remains a considerable risk amongst staff in the healthcare setting. With the potentially increasing influence of organisational factors, including staff shortages and workload pressures, which may put HCWs at greater risk of PIIs, the importance of introducing NPDs, following evaluation, is never greater.

Recommendations

Percutaneous inoculation injury data collection systems

Review the data collection system and implement a single system, for example EPINet™, to evaluate its efficacy in collating and analysing data. Collect data to document and analyse the recipient's professional group compared with cause of injury and method of reporting.

Training and education

Review teaching methods, course content and training environments to ensure maximum information retention. Ensure all HCWs, including ancillary and medical staff complete an annual or biannual update session.

Undertake a study to evaluate reasons for HCWs' poor knowledge base regarding the Trust inoculation reporting procedure, risk of transmission of blood borne pathogens and associated issues, to evaluate any associated reduction in PIIs.

Needle protective devices

Implement SLP 3 into the clinical arena, particularly in high risk clinical environments, for example renal and liver services.

Further work

Complete a cost benefit analysis of NPDs currently available to identify the financial implication of introducing these products.

Evaluate other NPDs, including other IV peripheral catheters to identify usability and acceptability amongst HCWs. By introducing NPDs in this way, it may reduce resistance to change and encourage support for their implementation.

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