An Evaluation of Three Strategies to Reduce Device Related Infection Associated with Hypodermic Needles and Peripheral Vascular Catheters.

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Summary

Medical devices are essential when providing healthcare in the 21st century. This study examined two key aspects of medical devices and their potential impact on infection control in the clinical environment; needlestick injuries (NSI) attributable to hypodermic needles and peripheral vascular catheter (PVC) associated phlebitis.

Needlestick injuries can result in healthcare workers being exposed to blood borne viruses. A four year, prospective evaluation of the impact a range of safety needle devices had on the number of reported needlestick injuries (NSI) was undertaken. Following a robust sharps awareness strategy and an evaluation of healthcare workers knowledge of risks associated with NSI in 2002, the number of NSI was reduced by 18%. The following year saw a return to increased numbers of NSI. However, following subsequent introduction of three safety needle devices, a significant 70% reduction in reported NSI was observed. In addition to the reduction in NSI, user satisfaction and acceptance of the safety needles was very favourable. These results suggest that safety needle devices can significantly reduce the number of NSI. However, a six to 15 fold increase in purchase costs would be associated with the implementation of safety needle devices compared with standard needles.

The efficacy of a new skin disinfectant, 2% (w/v) chlorhexidine gluconate (CHG) in 70% (v/v) isopropyl alcohol (IPA) (ChloraPrep®), was compared to five commonly used skin disinfectants *in vitro*. Overall, the most effective skin disinfectants tested against *S. epidermidis* RP62A, were ChloraPrep® and 10% (w/v) povidone iodine. Interim analysis of results comparing 70% (v/v) IPA (standard disinfectant) with ChloraPrep®, for the disinfection of skin prior to the insertion of a PVC *in vivo*, demonstrated that whilst there was no reduction in phlebitis in PVC which remained *in situ* less than three days, there was a significant reduction in microbial contamination of the cannula tip when ChloraPrep® was utilized, compared to 70% (v/v) IPA. This suggests that if PVC were to remain *in situ* longer, a reduction in phlebitis may be observed.

The potential for microbial contamination associated with a recently developed safety needle PVC (Nexiva™; Becton Dickinson, UK) which incorporates a needleless closed luer access device (CLAD. Q-Syte™) was evaluated *in vitro*. Findings suggest that the Q-Syte™ CLAD may be activated up to 70 times with no increased risk of microbial contamination within the fluid pathway. Therefore, in addition to offering the healthcare worker a needle safe device, it may also offer reduce the risk of PVC associated phlebitis.

No one single strategy will reduce the risk of either NSI or PVC associated phlebitis. However, these studies have demonstrated that novel approaches are being developed to address the unacceptable level of risk currently being observed. Further studies are required to evaluate these findings in a wider clinical arena.

Key Words: needlestick injuries, skin disinfection, catheter related infection, peripheral vascular catheters.

Dedication

To my family.

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Abbreviations.

A/E	Accident and Emergency
ABG	Arterial Blood Gas
ANOVA	A One Way Analysis Of Variance
ALT	Alanine Transaminase
ATCC	American Type Culture Collection
BD	Becton Dickinson
BHI	Brain Heart Infusion
BMA	British Medical Association
BNF	British National Formulary
BSI	Blood Stream Infection
CDC	Centre for Disease Control and Prevention
CFU	Colony Forming Units
CHG	Chlorhexidine Gluconate
CLAD	Closed Luer Access Device
CNS	Clinical Nurse Specialist
COSHH	Control of Substances Hazardous to Health
CVC	Central Venous Catheter
CRI	Catheter Related Infection
CRBSI	Catheter Related Blood Stream Infection
DNA	Deoxyribonucleic Acid
DOH/DH	Department of Health
E3LU	East Three Liver Unit
ECRI	Emergency Care Research Institute
ELISA	Enzyme Linked Immunosorbent Assay
EPIC	Evidence Based Guidelines for Preventing Healthcare Associated Infections In Primary and Community Care in England
EPINet	Exposure Prevention Information Network
EPP	Exposure Prone Procedure
ESS	Exocellular Slime Substance
FBC	Full Blood Count
FRCS	Fellowship of the Royal College of Surgeons
GERES	*Group d'Etude sur le Risque d'Exposition des Soignants*
g	gram
HAI	Hospital Acquired Infection
HaSaWA	Health and Safety at Work Act

HBeAg	Hepatitis B e Antigen
HBIG	Hepatitis B Immunoglobulin
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDV	Hepatitis D Virus
HGV	Hepatitis G Virus
HIV	Human Immunodeficiency Virus
HPA	Health Protection Agency
HSE	Health and Safety Executive
ICNA	Infection Control Nurses Association
IHCWSC	International Healthcare Worker Safety Centre
IM	Intramuscular
IPA	Isopropyl Alcohol
IV	Intravenous/Intravascular
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
l	litre
LOPD	Liver Out Patients Department
MDA	Medical Devices Agency
MLA	Medical Laboratory Assistant
MRSA	Methicillin Resistant *Staphylococcus aureus*
MSSA	Methicillin Sensitive *Staphylococcus aureus*
µl	microlitre
ml	millilitre
nm	nanometre
NCTC	National Collection Type of Cultures
NaSH	National Surveillance System for Hospital Healthcare Workers
NCTC	National Collection of Type Cultures
NHS	National Health Service
NPASA	NHS Purchasing and Supply Agency
NICE	National Institute for Clinical Excellence
NINSS	Nosocomial Infection National Surveillance System
NRTI	Nucleoside analogue Reverse Transcriptase Inhibitors
NNRTI	Non Nucleoside analogue Reverse Transcriptase Inhibitors
NSI	Needlestick Injury
OHD	Occupational Health Department
OD	Optical Density

ODA	Operating Department Assistant
ODO	Operating Department Orderly
ODP	Operating Department Personnel
OSHA	Occupational Health and Safety Administration
PBS	Phosphate Buffered Saline
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PFGE	Pulse Field Gel Electrophoresis
PI	Povidone Iodine
PRHO	Pre Registration House Officer
PVC	Peripheral Vascular Catheter/Peripheral Venous Cannula
QEH	Queen Elizabeth Hospital
RCN	Royal College of Nursing
RCN	Royal College of Nursing
RIDDOR	The Reporting of Incidents, Diseases and Dangerous Occurrences Regulations
RNA	Ribonucleic Acid
SC	Subcutaneous
SHO	Senior House Officer
SIROH	*Studio Italiano Rischio Occupazional da HIV*
TDICT	Training For Development of Innovative Control Projects
TFT	Thyroid Function Tests
U and E	Urea and Electrolytes
UHB	University Hospital Birmingham
UK	United Kingdom
UP	Universal Precautions
USA	United States of America
V/V	Volume per Volume
W/V	Weight per Volume
W2	West Two
W3LU	West Three Liver Unit
WTE	Whole Time Equivalent

Chapter One:

The Conceptual Phase.

1 Introduction.

Hypodermic medical devices such as hollow bore needles, vascular catheters; peripheral/central and phlebotomy equipment are now widely used in the healthcare setting to administer medications, heamodynamic monitoring and nutritional support. However, these devices continue to be associated with a relatively high risk of complications for both the healthcare worker and the patient. This review focuses on two main themes;

- The risk of needlestick injury (NSI) and potential blood borne virus transmission to the healthcare worker from hypodermic devices.
- The risk of transmission of infection to the patient, associated with practices and procedures related to peripheral vascular catheters (PVC).

1.1 The Risk to Healthcare Workers from Needlestick Injuries.

Healthcare workers are at risk from transmission of blood borne pathogens resulting from exposure to blood through NSI (Centre for Disease Control and Prevention: CDC, 1997). A NSI has been defined as "*the parenteral introduction into the body of a healthcare worker, during the performance of his or her duties, of blood or other potentially infectious material by a hollow bore needle or sharp instrument, including, but not limited to needles, lancets, scalpels, and contaminated broken glass*" (Bandolier, 2003). It has been estimated that there are approximately 100,000 NSI occurring annually in the United Kingdom (UK. Munro, 2001). Experiences both in the UK and in the United States of America (USA) indicate that even by adopting robust educational strategies it may not be sufficient to significantly reduce the number of NSI. Jagger *et al.* (1988) noted that no single solution exists for avoiding NSI and that a variety of different strategies must be incorporated in the healthcare setting. They include finding alternative methods for performing procedures which are not reliant upon needles and to design devices which have safety features incorporated. Several studies in the USA and the UK have proven that the implementation of needle protective devices such as intravenous/vascular (IV) access devices can reduce occupationally acquired NSI.

The device associated with the majority of NSI is the needle and syringe. It is therefore essential that clinical evaluations assessing the effectiveness of safer needle/syringe devices are undertaken to identify whether these protective devices can reduce NSI as shown in studies from the USA.

1.1.1 Inoculation Injuries.

Inoculation injuries may be sub-divided into two groups: percutaneous and mucutaneous. Percutaneous inoculation injuries occur when the skin of the healthcare worker is cut or penetrated by a needle or other sharp object (for example, scalpel blade, trochar, bone fragment, or tooth), which is contaminated by blood or other body fluid. Mucutaneous inoculation injuries occur when the eye(s), the inside of the nose or mouth, or an area of non-intact skin of the healthcare worker is contaminated by blood or other body fluid (Ramsay, 1999). This thesis focuses on significant percutaneous exposures from hollow bore needles related to NSI.

1.1.2 Epidemiology.

Epidemiological studies are being increasingly used to investigate and identify potential health and safety risks (Rushton and Betts, 1999). The epidemiology of NSI depends upon several factors; occupational groups, devices, specific work areas, procedures and reporting practices. In order to identify and risk assess the hazards identified with this problem, it is necessary to instigate surveillance studies.

1.1.2.1 Surveillance Systems.

There are several notable surveillance systems reviewing NSI throughout the world. These include GERES (*Group d'Etude sur le Risque d'Exposition des Soignants*) in France, NaSH (*National Surveillance System for Hospital Healthcare Workers*) in the USA and SIROH (*Studio Italiano Rischio Occupazional da HIV*) in Italy. However, probably the largest system being introduced worldwide is EPINet™ (Exposure Prevention Information Network). The EPINet™ system was developed by Professor Janine Jagger at The International Healthcare Workers safety Centre (IHCWSC) University of Virginia, 1992. The system provides a standardised method for recording percutaneous injuries and blood and body fluid contacts.

EPINet™ software enables data to be collected for any inoculation injury. In addition it allows the user to statistically analyze the data to produce pre-programmed and customized reports. This level of information permits healthcare facilities to focus their strategies on high risk areas of concern. The system has now been adopted by the USA, Canada, Australia, Italy, Spain, Brazil and Japan. Conducting epidemiological research within both a national and international framework provides robust data which can then be benchmarked.

The Royal College of Nursing (RCN) introduced the "Be Sharp, Be Safe" campaign during 2000, this is part of an on going "Working Well Initiative" (RCN, 2002). One of the activities of the campaign was to determine the burden of injury and exposure to blood borne viruses. The surveillance system chosen for the 14 pilot sites within the UK was EPINet (Exposure Prevention Information Network). Within the first six months of the study 455 incidents were reported (May and Churchill, 2001).

1.1.2.2 Estimating the Size of the Problem.

It remains difficult to estimate the total number of NSI occurring within the UK as there is a lack of adequate information and no co-ordinated national surveillance program exists. Since 1997, occupational health departments have been requested to complete a form outlining occupational exposure to blood borne viruses (Evans *et al.*, 2001). However, this only provides limited data and is reliant on the co-operation of the occupational health departments to report exposures.

Munro (2001) estimated that at least 100,000 NSI are reported in the UK by healthcare workers each year. The National Audit Office (Bourn, 1996) reported that one sixth of all accidents involving healthcare workers in English National Health Service (NHS) Trusts were related to sharps injuries. Data from NHS Trusts in Scotland demonstrated that there had been 2168 to 2439 injuries reported over three consecutive years 1997 to 1999 (NHS Scotland, 2001). In addition, in a survey carried out by the RCN (Ball and Pike, 2001) it was estimated that 37% of nurses had been received a NSI during their career.

1.1.2.3 Devices Associated with Needlestick Injuries.

Studies have shown that the device commonly identified with occupational acquired inoculation injuries is the hollow bore needle. Hollow bore needles are primarily used in association with a syringe, butterfly cannulae and peripheral vascular access catheters. and they have been responsible for up to 71% of all reported NSI (Mercier, 1994; May and Churchill, 2001; Tan *et al.*, 2001; Health Protection Agency (HPA), 2004). Therefore, it is unfortunate that the hollow bore needle has the greatest capacity for inoculating blood (Jeans, 1999) and is also associated with the transmission of blood borne pathogens (Collins and Kennedy, 1987; Jagger *et al.*, 1988; Cardo *et al.*, 1997). Napoli and McGowan (1987) demonstrated that the average volume of blood inoculated from a 22 gauge needle was approximately 1 micro litre (µl), which is a quantity sufficient to contain up to 100 infectious doses of hepatitis B virus (Shikata *et al.*, 1977).

Jagger *et al.* (1988) reviewed 326 NSI which occurred over 10 months in a University Hospital, Virginia, USA. Device characteristics which were commonly identified with NSI were noted, this was then corrected for the number of each device purchased. (Table 1.1).

Table 1.1: Rates of Needlestick Injuries Caused by Various Devices over a Ten Month Period: University Hospital, Virginia (Jagger *et al.*, 1988).

It is not surprising that the syringe and needle is most commonly associated with NSI. In English NHS Trusts over £20 million is spent on needles and syringes each year. During 2000 to 2001 over 168 million syringes, 123 million needles and two million needle/syringe combinations were purchased (NHS Purchasing and Supply Agency: http://www.pasa.doh.gov.uk/medicalandsurgical/needlestick/prod-needles.stm)

1.1.2.4 Health Care Workers; Who is at Risk?

Healthcare workers who are most at risk of acquiring a NSI are frontline workers which include; doctors, nurses and domestics. Data from four studies within the UK and the USA demonstrated that nurses account for almost 45 to 63% of reported NSI and medical staff 9 to 17%. (Mercier, 1994; Cone, 2000; Tan *et al.*, 2001; NHS Scotland, 2001). However, it is to be expected that nurses will have a greater number of reported NSI than medical staff, due to the large number of nurses employed in the healthcare setting compared to doctors.

A disturbing finding has been noted in several studies; in the UK almost 40% of NSI did not occur to the original user of the device, but to downstream workers such as hotel services staff (May and Churchill, 2001). In California, USA, a total of 1951 injuries were reported from 316 health care facilities between 1998 to 1999: of these 511 (26%) involved an employee who was not the original user. Downstream injured employees have been described as "innocent victims" and defined a person who "received a needlestick or puncture wound from an object that was not discarded after use, was improperly discarded, or handled carelessly by another employee" (Reed *et al.*, 1980). Injuries most frequently occurred from cleaning equipment, waste collection and environmental cleaning (Cone, 2000).

Clinical waste has been categorised into five levels of risk, ranging from A; all human tissue to E; used bed pans (Health and Safety Commission, 1992). Used syringes and needles have been risk assessed as Group B and must be discarded as one unit into a puncture resistant, leak proof, yellow container, which complies with British Standard 7320. Weltman *et al.* (1995), studied disposal related sharps injuries, significant risk factors included; sharps boxes at a height greater than four foot off the floor and a distance less than five foot from the sharps container.

Another disturbing factor related to downstream NSI is the life span of blood borne viruses outside the body. Hepatitis C virus (HCV) can survive outside the body up to one month (Hughes, 1999) and possibly up to three months (Dolan, 1997). Hepatitis B has been reported to survive up to one week (Robinson, 1995). Human immunodeficiency virus (HIV) is thought to only remain viable for relatively short periods outside of the body. Therefore, a NSI even from an "old" needle may still be able to transfer blood borne viruses.

1.1.2.5 Procedures Linked to Needlestick Injuries.

Cone (2000) reported that the most common procedures associated with NSI were: injection 28%, venepuncture 25%, suturing 14%, manipulating IV injection ports 11%, inserting peripheral IV catheters 11%, and other medical procedures 11%. It has been reported that between 13 to 62% of all NSI have been related to blood collection (McCormick *et al.*, 1991; McGeer *et al.*, 1990). Venesection is one of the most commonly performed procedures and can be undertaken by phlebotomists, doctors or nurses. Gaffney *et al.*, (1992) noted that 72% of all interns had acquired a NSI whilst performing phlebotomy procedures during one six month period, less than 5% of these injuries had been reported.

In 1996, of the 51 documented cases of occupational transmission of HIV, 39% was associated with phlebotomy (CDC, 1997). A study by Howanitz and Sohlman (1994) of 683 healthcare facilities demonstrated that a NSI associated with a phlebotomy procedure was less than 1:10,000 venepunctures performed and the frequency varied greatly between facilities. Nonetheless, the incidence of NSI did not change over a three year period (1990 to 1992). This relatively low rate of injury has probably placed venepuncture low on the list of priorities in the healthcare setting when deciding on

which safety products to evaluate and implement. However the high incidence of seroconversion makes this an essential area of practice for review.

1.1.2.6 Where and When Do Needlestick Injuries Occur?

In a review over a three year period in 77 hospitals in the USA, over 5% (571) of reported NSI were related to conventional peripheral vascular catheter. Of these, 75% (428) were sustained by nurses located in the USA, who regularly cannulate. The majority of the injuries occurred in patient rooms (47%), the remainder in, Intensive Care (13%), the emergency department (11%), the operating room (7%) and the procedure room (7%) (Jagger *et al.*, 1999). Mercier (1994) analysed the sharps injuries reported in two UK hospitals. Two hundred and six injuries were reported with an underreporting rate of 41.7%. The majority of injuries in this review occurred in the ward/clinic (60.7%), operating rooms (22.4%), accident and emergency (4.9%), laboratories (4.4%) and unknown areas (9.7%). These studies demonstrate the difficulty in limiting safety devices to "high risk" areas.

Futhermore, Mercier (1994) noted that the majority of injuries occurred between 11am to midday. In comparison McKeown (1992) reported that most NSI occurred at night. In a study of NSI occurring to medical students in California, 13% occurred when they had been on duty for at least 16 hours and had had less than four hours sleep in the previous 24 hours (Josefson, 1999). Two clear issues can be noted; injuries occur when staff are at their busiest and when they are tired. Gershon *et al.*, (1995) noted that employees may be simply too tired to make the effort to comply with safety. Clarke *et al.* (2002) surveyed 2287 nurses from 22 hospitals in the USA regarding organisational climate, staffing and NSI. This study demonstrated that there was a 50%, to two fold increase in the likelihood of a NSI occurring in areas which had a poor organisational climate and high workload.

1.1.2.7 Under-reporting of Needlestick Injuries.

It is important to acknowledge that the number of NSI reported may not accurately indicate the size of the problem; it has been highlighted in several reports that the incidence of under-reporting is high. McCormick and Maki (1981) noted that only one in 500 doctors reported an inoculation injury, this tended to be only when the patient had a transmissible infection. More recent reports from the USA suggest that this continues to

be a problem. The Occupational Health and Safety Administration (OSHA, 1997) identified there may be up to 90% under reporting of NSI by physicians and the CDC (1997) indicated that there was a 32% under reporting by nurses. The experiences in the USA reflect those of the UK. Burke and Madan (1997) identified that only 9% of doctors and 46% of midwives questioned had reported a NSI. Several studies have highlighted the number of medical students reporting a NSI; these ranged from 11.7% to 48% (Choudry and Cleator, 1992; Gamester *et al.*, 1999; Tereskerz *et al.*, 1996; Osborn *et al.*, 1999; Sullivan *et al.*, 2000). In a smaller study undertaken in Birmingham, England, of 84 members of healthcare staff (including; doctors, nurses and phlebotomists), 65% of those questioned had not reported some or all of their occupational exposures (Dobie *et al.*, 2002). This was reaffirmed in a later study of 300 healthcare workers in Cambridge, England. Eighty percent of staff were aware that NSI should be reported, however, only 51% of those affected had reported such incidents (Elmiyeh *et al.*, 2004)

The under reporting of NSI may be due to several factors, Burke and Madan (1997) and Haiduven *et al.* (1999) both indicated that staff felt that the reporting procedure was time consuming, staff were too busy, the follow up procedures were poor and staff under estimated the risks associated with a contaminated NSI. Leliopoulou *et al.* (1999) found that nurses working in high and low risk areas thought that a needle contaminated with blood was an unlikely source of infection. This confirmed previous reports from Burke and Madan (1997) and Rabaud *et al.*, (2000) who identified both nursing and medical staff underestimated the risks of acquiring hepatitis B and HIV following contamination incidents. It is unfortunate that data from a decade ago identifies the same indications for not reporting: too time consuming and unaware of the correct procedures (Hammory, 1983). Povolny (1997) identified that staff who had received a NSI considered the risk of being "thought silly" and of "over reacting" before reporting a NSI.

There have been several studies analysing why doctors under-report:

- the fear of being judged (Rabaud *et al.*, 2000)
- personal carelessness philosophy, (Chiarello and Cardo 2000).

Junior surgeons were often treated with a lack of compassion and sensitivity after a sharps injury and that it may be seen as a lack of safe operative skill (Camilleri *et al.*, 1991.

Embarrassment; afraid to implicate another person as the cause of their injury and concerned that the injury would impact on their evaluation and grade (Shen *et al.*, 1999).

Hettiaratchy *et al.* (1998) in a study of 190 student doctors in London found that only 17.5% of NSI were reported and that surgeons were the least likely to report the incident. Wright (1998) also acknowledges that "on gaining their FRCS (Fellowship of the Royal College of Surgeons), surgeons somehow acquire immaculate lifelong immunity to hepatitis B as well as to any other pathogen that may breach their mucous membranes". There is obviously a clear lack of personal responsibility and liability which needs to be overcome. The question is how?

Only one study has analyzed the link between personality and behaviour associated with inoculation injuries (Rabaud *et al.*, 2000). Six nurse training schools in France were studied; four variables were significantly linked to having an increased risk of occupational exposure; staff that had a permanent position, those who were less inhibited, those who were easily bored and those with less nursing experience.

1.1.3 Initial Treatment and Risks Associated with a Needlestick Injury.

1.1.3.1 First Aid Treatment.

Health care workers are potentially at risk from acquiring a blood borne virus after receiving an inoculation injury. It is therefore essential that any occupational exposure to blood or body fluids is treated immediately.

The initial action advised for a sharps injury is to encourage the wound to bleed. However, sucking of the wound by mouth is strongly discouraged. If a mucutaneous injury has occurred the exposed mucous membranes e.g. eyes and mouth, should be copiously irrigated with water. If contact lenses are being worn then eyes should be irrigated both before and after their removal to ensure maximum effectiveness (UK Health Departments, 2000). The healthcare worker should then follow local guidelines regarding receiving expert advice on risk assessment of the injury.

1.1.3.2 Risks of Occupational Transmission of Infection.

The risk of occupational exposure to a blood borne pathogen is influenced by; the nature and frequency of the exposures and the prevalence of infection in the patient population. In comparison, the likelihood of becoming infected after an occupational exposure is related to the severity of the exposure (Chiarello and Cardo, 2000). There has been documented evidence of at least twenty different pathogens which have

been inoculated following a NSI (Table 1.2). The risk of occupational transmission of one of the blood borne viruses (hepatitis B, C, G and HIV) is relatively low. However, this should not lead to complacency.

Table 1.2: Documented Infections from Needlestick Injuries (adapted from Collins and Kennedy, 1987).

1.1.3.3 Healthcare Workers Knowledge and Perception of Risk.

A telephone survey which included 26 surgeons was conducted in the South and West region of England (Duff *et al.*, 1999) it demonstrated that there was only limited knowledge relating to; awareness of hospital polices relating to NSI and that post exposure prophylaxis (PEP) was required within one hour. None of the surgeons interviewed were aware of the risk of seroconversion after an NSI from a HIV positive patient.

Parks *et al.* (1998) noted that theatre staff judged their risk of acquiring a blood borne virus on two key factors: the patient's age and marital status. Less than 30% of staff knew the risk of acquiring HIV from an infected patient following an NSI and even fewer recognised the risks for hepatitis B virus (HBV) and hepatitis C virus (HCV). In 2000, two studies were published, evaluating the responses of a questionnaire sent to healthcare workers in Scotland (Scoular *et al.*, 2000) and anaesthetists in Southampton (Diprose *et*

al., 2000), both studies found that healthcare workers had insufficient awareness of the risks associated with NSI and the care that was required post injury. This attitude of immortality is summed up by Fasbinder (1992) in an article she wrote after acquiring HIV from an occupational exposure to a positive HIV patient, in an emergency room in the USA.

"If you happen to think nothing bad can happen to you, I'm living proof that can be a fatal attitude".

Ms Fasbinder died from HIV in 1992. It is clear that there is still a need for further educational initiatives.

1.1.3.4 Transmission of Blood Borne Viruses from Patients to Healthcare Workers in the United Kingdom.

According to the Public Health Laboratory Service (PHLS, 1999a) 291 out of 316 (92%) of occupationally acquired HIV infections have been reported from countries with surveillance systems and low prevalence of HIV within the general population. Between 1997 to 2000 in England, Wales and Northern Ireland there have been 827 reports of healthcare workers exposed to blood borne viruses. Seven hundred and thirty nine incidents were single exposures to: HCV: 396, HIV: 242, HBV: 101. Eighty three were to two blood borne viruses and five were triple exposures (PHLS, 2000). In a seven year study (1996 to 2004) by the HPA (2005), 1664 initial reports of exposures to blood borne viruses via percutaneous injury were received. During this period one healthcare worker seroconverted to HIV despite post exposure prophylaxis and nine converted to HCV (one of which occurred in 1996 but was retrospectively reported), six of which were in the twelve months between July 2003 to 2004. It is now known that prior to the initiation of this enhanced surveillance scheme that four healthcare workers occupationally acquired HIV (HPA, 2004). However, under-reporting is frequent and therefore this estimation may be higher.

1.1.3.5 Transmission of Blood Borne Viruses from Healthcare Workers to Patients.

There have been several reports of healthcare workers who have infected patients (Incident Investigation Team, 1997; Molyneaux *et al.*, 2000). From 1972 to 1994 there were 42 HBV infected healthcare workers with documented disease transmission to over 375 patients (Bell *et al.*, 1995).

There have been five reported cases of HCV transmission in the UK, the first reported case was in 1994 (PHLS, 1999b; PHLS, 1995; Cody *et al.*, 2002). One case has been reported in Spain (Esteban *et al.*, 1996), two cases in Germany (Ross *et al.*, 2002a and b) and a case in the USA is currently under investigation (DOH, 2002).

HIV infections from healthcare workers to patients have been documented in three cases. The first transmission was from a dentist to six patients in the USA (Ciesielski *et al.*, 1992). A further two cases have been reported in France; one from an orthopaedic surgeon (Lot *et al.*, 1999) and a nurse (Goujon *et al.*, 2000).

1.1.4 Blood Borne Viruses; hepatitis and Human Immunodeficiency Virus.

Hepatitis B, C, D, G and HIV are discussed as they are of particular concern to health care workers who may contract the viruses from occupational exposure.

1.1.4.1 Hepatitis.

Hepatitis B Virus (HBV).

Hepatitis B is the only occupationally acquired, blood borne virus which is preventable; due to immunization, and post exposure prophylaxis (PEP) being available. Vaccination consists of three injections of hepatitis B surface antigen (HBsAg) over a six month period; this confers protection in 80 to 90% of individuals who mount a response to the vaccine with serum anti-HBs levels >10miu/ml, an antibody level of below 10miu/ml is classified as a non-response to the vaccine. A poor response is indicated by a level of 10 to 100miu/ml, >100miu/ml is considered to be protective (DOH, 1996). A single booster dose is recommended after five years and is considered to be sufficient to retain immunity. In the event of a NSI occurring, specific hepatitis B immunoglobulin (HBIG) can be used to provide temporary, immediate protection against hepatitis B, however ideally it must be administered within 48 hours of exposure. All healthcare workers in the UK are offered the hepatitis B immunization. However, some staff do not respond to the vaccine and are therefore non immune, others do not wish to undertake the immunization program. It is mandatory in the UK that healthcare workers who perform exposure prone procedures (EPP) are immune to hepatitis B.

Alzahrani *et al.* (2000) demonstrated that in one centre in the UK, 10% of staff had not been vaccinated and 27% of those who had received vaccination had no anti-HBs. Gyawali *et al.* (1998) reported that the overall uptake of hepatitis B vaccine in one UK hospital was 78%, however this fell to 70% in paramedical staff and as low as 45% in domestic staff. To date vaccinations against hepatitis C and human immunodeficiency virus (HIV) are unavailable.

The risk of occupational transmission for Hepatitis B is affected by several factors:

- The type of body fluid.
- The HBeAg status of the patient.
- The type of transmission.
- The immune status of the healthcare workers.

Of all body fluids, blood contains the highest viral load of HBV. The most efficient mode of occupational spread of HBV is by NSI. A NSI occurring from a patient who is both HBsAg positive and HBeAg positive can result in a risk of 22% to 31% of acquiring clinical hepatitis, the risk of the developing serological evidence of HBV was 37% to 62%. However, if the patient was HBsAg positive but HBeAg negative, the risk of acquiring clinical hepatitis is reduced from 1% to 6% and 23% to 37% for developing serological evidence of the virus. These figures are for healthcare worker who are non-immune for HBV (Werner and Grady, 1982). Treatment of patients who develop chronic HBV infection is with Lamivudine; this drug reduces the viral replication by 100 to 1000 times (Gow and Mutimer, 2001).

In order to limit the risk of transmission of infection to patients, healthcare workers who are HBeAg negative and perform EPP are required to undergo further testing to assess their viral load. If this exceeds 103 genomes equivalents/ml they are restricted from performing EPP. Those workers whose viral load is below 103 are followed up at twelve monthly intervals. Follow up is necessary as it is now known that some people who are infected carry a genetic variant of HBV, which does not have the e-antigen but is still capable of assembling the infectious viral particles (Health Service Circular, 2000).

Hepatitis C Virus (HCV).

The global prevalence of HCV is 0.1% to 5.0% (Hughes, 1999) with an estimated 170 million people affected world wide. The prevalence of HCV among UK healthcare workers remains low as demonstrated in two studies in Nottingham and then later in the West of Scotland (Neal *et al.*, 1997; Thorburn *et al.*, 2001). The studies also demonstrated that healthcare worker who perform EPP were not at any greater risk than other healthcare staff.

Hepatitis C virus is not as readily transmitted as HBV via a NSI. It has been estimated that seroconversion following an occupational acquired inoculation injury from a HCV positive source is between 0% to 7% (Alter, 1997; Puro *et al.*, 1995; Lanphear *et al.*, 1994; Mitsui *et al.*, 1992).

The long term consequences of HCV are:

- 15% spontaneously clear the virus.
- 85% may develop chronic infection.
- 30%-50%may develop cirrhosis.

(Gow and Mutimer, 2001).

If a healthcare worker has been exposed to HCV positive blood it is not currently recommended that antiviral agents (e.g. interferon) or immunoglobulin are used until a diagnosis of seroconversion has been made (UK Health Departments, 1998). The source patient should be tested for anti HCV after consent has been gained. The exposed healthcare worker should have baseline anti HCV and Alanine Transaminase (ALT) activity at the time of the injury; the serum should be stored for at least two years. Healthcare workers who have been exposed to HCV should be followed up at six weeks for HCV ribonucleic acid (RNA). At twelve weeks and twenty-four weeks serum should be taken for HCV RNA and anti-HCV. If the source is thought not to be positive then follow up is not required (Ramsay, 1999).

In October 2000 the UK National Institute for Clinical Excellence (www.nice.org.uk) supported the use of combination therapy: Interferon and ribavirin as opposed to monotherapy, for patients with substantial histological damage and cure rates of 80% to 90% have been achieved (Gow and Mutimer, 2001).

In a recently published study by Jaeckel *et al.* (2001) the effect of Interferon Alfa-2b on 44 acute HCV infected patients was monitored (14 of whom acquired it through a NSI). At the end of the treatment 98% had undetectable levels of HCV RNA in serum within 3.2 weeks and normal serum ALT. However, further studies are required to demonstrate this effect on a larger scale.

The risk of transmission of HCV from an infected healthcare worker to a patient is very low (Beltrami *et al.*, 2000). However, the Department of Health (DH, 2002) has now stated that health care workers who are found to be HCV RNA positive should not now be allowed to perform EPP.

Hepatitis D Virus (HDV).

Hepatitis D (delta agent) is a defective incomplete virus which can only replicate in cells occupied by the HBV. If co-infection exists it is likely to be more severe than a single hepatitis B infection.

Hepatitis G Virus (HGV).

Approximately 10 to 15% of patients who have chronic hepatitis C are co-infected with HGV (Bisceglie, 1996). Hepatitis G is spread by the blood borne route, however it remains unclear whether it causes severe hepatitis or any other clinically significant diseases. The risk of occupational exposure to HGV is low, nevertheless HGV is transmissible by NSI (Shibuya *et al.*, 1998).

1.1.4.2 Human Immunodeficiency Virus.

HIV can be spread via the blood borne route; infected blood, sexual contact or vertical transmission (mother to newborn). The average risk of occupational transmission of HIV following NSI from a HIV infected source patient has been reported to be 0.3% (Bell, 1997; Tokars *et al.*, 1993; Henderson *et al.*, 1990; Gerberding, 1994; Ippolito *et al.*, 1993). There is currently no immunization available for HIV.

Ciesielski and Metler (1997) noted that among healthcare workers with a documented seroconversion to HIV, 5% tested negative to HIV antibodies at over six months following occupational exposure but were sero-positive within 12 months.

The criteria set by the CDC, (1985) defining occupational transmission of HIV includes: a worker with no identifiable risk factors whose serum was negative for HIV antibodies within a few days of exposure but who then develops for HIV antibodies at a later date with no interim exposure.

The risk of seroconversion to HIV increases if one or more key factors are associated with the NSI (CDC, 1995; Cardo *et al.*, 1997):

- Depth of injury.
- The device was visibly contaminated with the source patient's blood.
- The device had previously been placed inside the source patient's vein or artery.
- Larger diameter hollow bore needles.

- The volume of blood transferred.
- If the source patient was in the terminal stages of the disease.

Post exposure prophylaxis should be considered after an inoculation injury which carries the risk of transmitting HIV. If the source patient is known then an assessment should be made to ascertain the degree of risk. If the source patient consents, serum should be taken and tested for HIV antibodies.

If the source is not known and a significant exposure has occurred consideration of the circumstances should be given. However it has been noted that in the vast majority of cases it would be difficult to justify the use of PEP (DH, 2004).

Post exposure prophylaxis consists of three classes of antiretroviral drugs: protease inhibitors, nucleoside analogue reverse transcriptase inhibitors (NRTIs) and non nucleoside analogue reverse transcriptase inhibitors (NNRTIs). They should be commenced within one hour of the inoculation injury for optimal efficacy; however it may still be worth considering starting PEP even up to two weeks after the injury (DH, 2004). Patel *et al.* (2002) noted in a review of 177 occupational blood and body fluid exposures which occurred "out of hours" at a London teaching hospital, that the prescribing of PEP was inconsistent within hours practice.

Since 2004, the recommended drugs for PEP are; zidovudine (NRTI), lamivudine (NRTI) and Nelfinavir (protease inhibitor), which are taken for four weeks (DH, 2004). However, if the source patient has any anti-retroviral drug resistance this should be taken into account when choosing PEP. Poor tolerance of these drugs has been noted by Wang *et al.* (2000). In a study of 492 healthcare workers exposed to HIV in the USA, 449 healthcare workers were followed up after six weeks; only 195 (43%) completed the course of PEP; the most common reason for non completion was due to symptoms associated with the therapy. This is also the experience in the UK where in a study of 138 exposures to HIV only 43 (31%) completed PEP (Evans *et al.*, 2001). Commonly reported symptoms in both studies were; nausea, emotional distress, headache, fatigue and loss of appetite.

Grime *et al.* (2001) reviewed the management of occupational exposure to HIV following the introduction of the UK DOH (2000) guidelines on the use of PEP in 71 English NHS Trusts around the Pan-Thames region. They identified that although most Trusts had implemented the guidelines, data collection on individual exposures was proving

difficult. Only half of the staff who had been exposed to HIV over six months ago were known to have had a follow up HIV test.

HIV infected healthcare workers must remain under regular medical/occupational supervision. Working practices will vary between individuals and therefore each individual will require assessment by a specialist occupational health physician, taking into account the working practices concerned (DH, 2005).

1.1.5 Universal Precautions.

With the emergence of HIV, the CDC, (1987) based in Atlanta, USA outlined the framework of Universal Precautions (UP). Universal Precautions acknowledge that many patients with blood borne infections are not recognised. Universal Precautions were originally applied to all body fluids, however in 1988 the CDC updated these guidelines as blood borne viruses are not transmitted by certain body fluids including urine, sputum, faeces and tears unless they contain visible blood. In addition to the 1987 guidelines emphasis was placed upon:

- Blood being the single most important source of HIV, HBV and other blood borne pathogens in an occupational setting.
- The risk of mucutaneous spread; the need for eye protection and masks was highlighted.

Universal Precautions consist of: hand hygiene, protective clothing, safe handling of sharp instruments, safe disposal of waste and linen, decontamination of equipment and the treatment of blood and body fluid spills. These guidelines were then updated in 1989 to include more specific recommendations; including, hand washing after glove removal and phlebotomy precautions. The DOH (UK Health Departments, 1990) endorsed the same level of precautions with all patients.

In 1996 UP (designed to reduce the risk from blood borne pathogens) and Body Substance Isolation (designed to reduce the risk from moist body substances) were combined to form Standard Precautions (Garner *et al.*, 1996). Standard Precautions apply to: blood, all body fluid secretions and excretions except sweat regardless of whether they contain visible blood, non intact skin and mucous membranes. Therefore, reducing the risk from both recognized and unrecognised sources of infection. The revised guidelines contain two tiers of precautions. The primary tier are those precautions designed to care for all patients regardless of their diagnosis or presumed

infective state. The secondary tier are transmission-based precautions designed for patients with known or suspected with epidemiologically important pathogens which may be transmitted by airborne droplet or contact route of spread. These precautions have yet to be accepted into practices adopted by the UK.

McCoy *et al.* (2001) monitored healthcare professional training and compliance with Standard Precautions within 149 healthcare institutions in Iowa and Virginia, USA. It was noted that nurses and laboratory workers were adequately trained in the correct practices, whilst physicians were less so. Monthly induction programmes for new staff which included Standard Precautions guidelines were provided in only 36% of the institutions. Only 23% offered monthly training opportunities for current staff. The common format for this training was either by lecture or interactive training. Although this study measured perception of Infection Control Practitioners and therefore has limitations, it is suggested that healthcare workers who have received adequate information on UP are more likely to comply with them. This is supported by studies by Wong *et al.* (1991), Fahy *et al.* (1991), Stotka *et al.* (1991), Gershon *et al.* (1995) and Godin *et al.* (2000).

It is clear that although guidelines have been available since 1987 compliance is low. It has been recommended that by providing adequate education (Nelsing *et al.*, 1997) with consideration given to independent strategies for different occupational groups (McCoy, 2001) that this may improve. Calabro *et al.* (1998) studied the effectiveness of a customized infection control education plan for second year medical students. The intervention demonstrated a significant increase in post test knowledge. However, the study did not demonstrate whether this knowledge improved practice in the clinical setting. Snowden (1997) investigated whether nursing students understood the term UP and whether they practiced its principles after their three years of nurse training in the UK. Only 35% of third year students felt confident in implementing UP and only 24% claimed to always follow the correct procedures. Therefore, it is clear that education plays an important role but is not exclusive. McCoy (2001) suggests that education coupled with greater supervision and monitoring of practices and positive reinforcement of compliance is required.

In a survey of Sheffield medical students (Moscrop, 2001) it was shown that no training was provided in the prevention and management of inoculation injuries. Students blamed "haphazard and random" education in traditional ward "firms".

It is apparent that the body of evidence demonstrates that whilst healthcare workers may understand what UP are, their compliance with them is low. It is important to understand what "drives" people to comply with safer practices as primary intervention is crucial in maintaining a safer working environment. Bermingham and Kippax (1998) studied 451 Australian General Practitioners during 1993 to 1994. They noted that glove wearing during venepuncture was related to discriminatory attitudes and anxiety about HIV, rather than compliance with UP. This confirms the findings of Gershon *et al.* (1995) who carried out a survey of 1716 healthcare workers in the USA and found that compliance with UP was statistically associated with a fear of occupational transmission of HIV. In a later study Gershon *et al.* (2000a) also concluded that the perception that senior management was supportive of strategies to reduce workplace exposure incidents enhanced compliance and reduced incidents. Confirming that all members of the healthcare team need to have effective communication and clear goals on the actions required to address this issue.

1.1.5.1 Gloves.

In order to evaluate the effectiveness of gloves in reducing the risk of percutaneous exposure from NSI Mast *et al.* (1993) studied the efficacy of gloves in reducing blood volumes transferred during a simulated NSI. They demonstrated that gloves reduce the transferred blood volume by up to 46% to 86% from a NSI and recommended that gloves are worn whenever needles are handled. This is supported by the EPIC (Evidence Based Guidelines for Preventing Healthcare Associated Infections in Primary and Community Care in England) Project guidelines (Pratt *et al.*, 2001) which states that "Gloves must be worn for handling sharp or contaminated instruments".

1.1.6 Legislation.

1.1.6.1 American Legislation.

The OSHA Blood Borne Pathogens Standard (OSHA 29 CFR Part 1910.1030) was introduced into the USA in 1991, which was then mandated on November 6th when President Clinton signed into law the "Needle Stick Safety and Prevention Act" (2001). This act requires that all health care facilities in the USA purchase and provide needle protective devices in order to reduce the risk of staff acquiring a blood borne virus. Failure of facilities to implement the protective measures indicated could lead to civil penalties. Four major requirements were emphasised in the Act:

1. The use of safer medical devices.
2. Annual review of the exposure control plan.
3. The involvement of non-managerial employees in the review process.
4. Maintenance of a sharps injury log.

In the USA the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) announced in August 2001 that by 2003 it would be monitoring healthcare facilities compliance with the Act as part of its accreditation process.

1.1.6.2 United Kingdom Legislation.

In the UK, prescriptive legislation on safer devices has not yet been formulated; rather it centres on risk assessment and control.

The legislation which addresses the issues of protecting healthcare workers from NSI is:

- The Health and Safety at Work Act (HaSaWA), 1974, which requires employers to ensure the health and safety of both employees and the public as far as reasonably practical to do so.
- The Management of Health and Safety at Work Regulations, 1999 requires employees to carry out risk assessments and to take the necessary measures to remove, or reduce and control that risk. In relation to NSI the assessment should include both reducing the risk of an injury occurring and setting up procedures should the incident occur. Once the assessment has been completed a detailed policy and procedure must be developed.
- Control of Substances Hazardous to Health (COSHH), 1999, regulations require a safe system of work, a safe place to work, safe equipment, appropriate training, supervision and storage facilities. They also require the employer to carry out a risk assessment where hazardous substances are utilized; this includes the risk from NSI and surveillance where employees are exposed to dangerous viruses.
- The Occupiers Liability Act, 1957, imposes a common duty of care to safeguard the public. It states that (Trusts) should take "such care as in all circumstances is reasonable to see that the visitor will be reasonably safe in using the premises...."
- Reporting of Injuries Diseases and Dangerous Occurrences (RIDDOR), 1995 does not automatically cover NSI unless the injury causes the injured person to be absent from work for greater than three days or transmission of infection occurs. However all NSI should be reported to management.

1.1.6.2.1 Safe Practice Initiatives.

Royal College of Nursing (RCN): During 2000 the RCN introduced EPINet (Exposure Prevention Information Network) into the UK to investigate the reporting, monitoring and tracking of NSI. This is part of the Working Well Initiative.

UNISON (Public services union): an extensive publicity campaign has been mounted to highlight the number of occupationally acquired NSI. In addition, they have also called for changes in the UK Legislation to address the introduction of safer devices.

British Medical Association (BMA): In 1995 the BMA published a Code of Practice for the Safe Use and Disposal of Sharps.

In addition, these strategies are supported by; the UK Health Departments (1998) which recommends a reduction in the use of sharp items wherever possible and "to consider the benefits of introducing new safety devices", the NICE (2003) and the EPIC Guidelines (Pratt *et al.*, 2003) which state that "needle safe devices must be used where there are clear indications that they will provide safe systems of working". In 2005 the NHS Employers Guidelines on "The Management of Health, Safety and Welfare Issues for NHS Staff" highlighted that a number of safety devices are now available, however they must be thoroughly evaluated for fitness for purpose, as within the UK there is a deficiency of evidence to support their use.

It is also important that there is a culture of safety adopted by the workplace. Gershon *et al.* (2000a) noted that "when employee safety is considered and valued, employees feel valued". The DOH (2000) reinforced this ethos in its document "An Organisation With A Memory", where it states where open reporting and balanced analysis are encouraged by both principle and by example, a positive and quantifiable impact can be observed on the performance of the organisation. Therefore, it is not sufficient to just collect data on NSI, it is obligatory to take action, in order to reduce risk to staff. The process also falls within the agenda for Clinical Governance (DOH, 2001), of providing an environment which is safe and healthy for patients, visitors and staff.

1.1.7 Safety Devices.

Between 1984 and 1995 in the USA there were over 1,000 patents issued for devices to prevent NSI (Kelly, 1995). There are two main types of safety feature used in the design of safety devices:

- Passive safety devices: no additional steps are needed by the user to activate the safer feature.
- Active safety devices: these devices require the user to activate the safety feature in some way.

Recently in the UK, engineered safety needle protective devices have been introduced. Several studies have evaluated the effect that "safety devices" have made on the incidence of NSI. Many of these studies have attributed the reduction in NSI to the device and have not evaluated the external influences which may have played an important role. There is increasing pressure from health care professionals, union representatives and health and safety to reduce occupational acquired inoculation injuries by introducing safety engineered designs. It is therefore essential to critically evaluate published studies to ensure the device is suitable and will not exchange one problem for another.

Sohn *et al.* (2004) examined whether safety devices had an effect on the rate of reporting NSI by healthcare workers. If reporting rates decreased/increased following the introduction of safety devices then this would introduce bias to the estimates of interventional effectiveness. Their study demonstrated no statistically significant variability in the reporting rates.

One resource which healthcare workers can utilize to evaluate protective devices is the ECRI (Emergency Care Research Institute) Report (2003). ECRI is an independent, non profit health service research agency, whose aims are to improve the safety, efficacy and cost effectiveness of health technology utilizing evidence based practice. It is a Collaborating Centre of The World Health Organization.

ECRI provides a Ratings Rationale for all protective devices reviewed, based on four levels.

Preferred: the product meets all, or most of the desired criteria required for a protective device.

Acceptable: the product meets most of the criteria; any disadvantages do not outweigh the protection afforded in most cases.

Not Recommended: at least one disadvantage may limit the protection afforded.

Unacceptable: although the product may offer more protection against traditional devices it does not offer the level of protection expected from a protective device.

In the following section clinical trails of protective devices will be reviewed. In cases where the products have been evaluated by ECRI this will be included and their Rating Rationale will be given.

1.1.7.1 Safety Device Design.

Three key functions should be examined when evaluating a protective device: safety, human factors and compatibility with need. In order to assess product safety features several evaluation sheets have been designed. Two of the many standard tools are: ECRI (2003) and TDICT (Training for Development of Innovative Control Project, 1998). The main features of a safety device are:

- The device can be activated using a one handed technique.
- The device is easy to handle whilst wearing gloves.
- During the use of the device the hands remain behind the sharp until activation is complete.
- There is a clear, unmistakeable change which occurs when the safety feature has been activated.
- The device operation is obvious.
- The device is compatible with a variety of products and situations.

1.1.7.2 Safety Devices and their Features.

Safety devices are only as good as the operator using them. It is therefore essential that frontline workers are included in any decision to purchase these devices. OSHA (1997)and Fahey and Henderson (1999) reported that one reason these devices failed to reduce NSI was that they were not accepted by healthcare staff because they had not received a comprehensive training programme and that poor implementation of the change process had been incorporated. Ihrig *et al.* (1997) evaluated the acceptability of a needleless vascular access catheter in an Indiana University Medical Centre. They identified that staff that were adequately trained before devices were implemented were more likely to correctly use and maintain the system. This was supported by Alvarado–Ramy *et al.* (2003), Rivers *et al.* (2003) Marini *et al.* (2004).

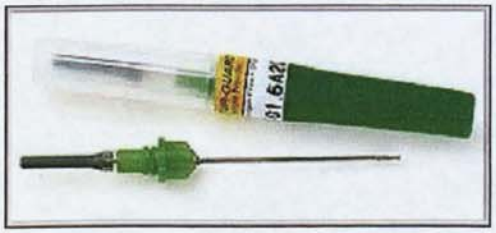
In order to demonstrate that the safety device alone can reduce occupational acquired inoculation injuries clinical trials need to be undertaken. As Jagger (1996) noted this is becoming increasingly more difficult to statistically prove due to:

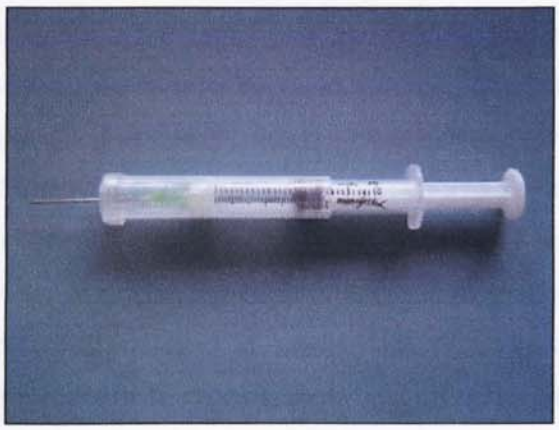
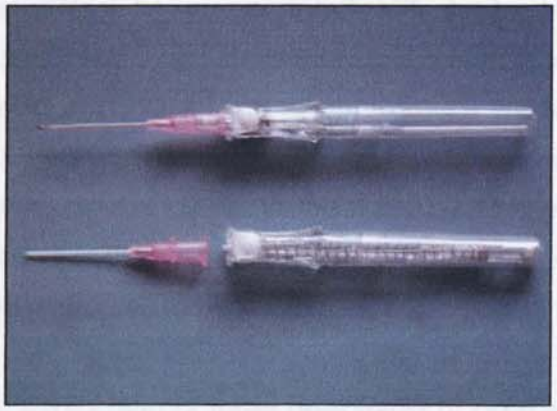
- At introduction the safety device is subject to the "honeymoon period"; praise and enthusiasm followed by critical assessment.
- Searching for problems often highlights them.
- Needlestick injuries are rare events ranging from one to 40 injuries/ 100,000 units used. Therefore, large trials are required to produce statistically significant data.

- Safety devices may themselves cause injuries yet to be identified. This has been identified in a study by Asai *et al.* (2002) where a review of two safety IV cannula were examined; Insyte™ Autoguard™ (Becton Dickinson; BD. Figure 1.4) and Protective Acuvance™ (Ethicon Endo-surgery). Insertion of the devices was found to be significantly more difficult and splashing was noted during needle withdrawal, potentially causing mucutaneous inoculation injuries.

A variety of safety devices are now available within the UK (Table 1.3).

Table1.3: Safety Devices and their Features.

Device	Features
IV Access Device.	
Figure 1.1: Connecta Clave™ (BBraun). 	This is a Luer activated device. The product can be used in most syringe applications. ECRI has evaluated the product as ACCEPTABLE (2003) as it offers good protection against NSI.
Phlebotomy Devices.	
Figure 1.2: Puncture Guard™ (Bio-Plexus Inc). 	This is a self blunting needle used to collect blood. The safety feature is activated before it is withdrawn from the patient. ECRI has evaluated the product as PREFERED (2001) as it offers excellent protection against NSI.

Safety Needles/Syringes.	
Figure 1.3: Monoject Safety Syringe™ (Sherwood Medical). 	This is a safety syringe. The product requires a two handed technique to push the protective sleeve over the needle in order to active the safety feature. The device can be used without the safety feature being activated. The product can be used in most syringe applications. ECRI has evaluated the product as NOT RECOMMENDED (2001, 2003) as it does not offer adequate protection against NSI.
Safety IV Catheters.	
Figure 1.4: Insyte Autoguard™ (BD). 	This is a safety peripheral IV catheter. The user activates the safety feature by pushing a button once the catheter is positioned in the vein; this causes the needle to retract into the plastic housing. However it is possible to use the device without activating the safety feature. ECRI has evaluated the product as ACCEPTABLE (2001, 2003) as it offers good protection against NSI.

1.1.7.3 Intravenous Access Devices.

Several studies have reviewed the introduction of needleless IV systems. In 1991, a 394 bed hospital in Wisconsin USA introduced a needle-free IV system for all inpatients. A 68% reduction in NSI was shown for 1992. The increase in education also had an impact on NSI associated with IM injections; these were reduced by 31% (Wolfrum, 1994). This is supported by DeBaun *et al.* (1995a) who implemented Safsite™; a 50% reduction in NSI was noted over a two year period. Yassi *et al.* (1995) introduced a needleless IV access system (Interlink™; Baxter Healthcare) into a 1,100 tertiary care hospital in Canada. There was a 78% reduction in reported IV related NSI during the study period. However, no control group was used in this study. Mendleson *et al.* (1998) carried out a six month cross over clinical trial, which evaluated a randomly allocated conventional heparin lock system and a needleless IV access system. The introduction of a needleless intermittent IV access system with reflux valve was effective in reducing occupational acquired inoculation injuries, with no associated increase in insertion site complications or nosocomial bactereamias. In addition, 95.2% of nursing staff preferred the trial device. However, this coincided with an increased educational campaign on UP. Orenstein *et al.* (1995) also demonstrated a reduction in occupational acquired inoculation injuries after a shielded 3ml safety syringe (Safety-Lok™; BD) and a needleless IV system (Interlink™; Baxter Healthcare) were introduced. However, the control ward also demonstrated a reduction in NSI. In the studies by Wolfrum (1995) and DeBaun (1995ab), no control groups were used, therefore the results may have been derived from the increase input from the researchers into the trial area, rather than the safety device alone. In the study by Yassi *et al.*(1995), both the control and study group had a reduced number of incidents reported, demonstrating the effect educational strategies alone may have on NSI.

An evaluation of three needleless IV devices (a metal blunt cannulae, a two way valve and a plastic blunt cannulae) was carried out in three areas by L'Ecuyer *et al.* (1996). No reduction in NSI compared to the control units was noted. The authors noted that the products were not readily accepted or correctly used by the healthcare workers and traditional products continued to be used.

It is important that consideration is given to providing the most suitable strategy to address NSI. Bryce *et al.* (1999) reviewed the prevention priorities associated with sharps injuries, including those of needleless IV sets. They concluded that "resources were best allocated to protective devices at source (e.g., safety syringes) and on a comprehensive, multidisciplinary and sustained education program. Needleless IV sets

would mainly prevent low-risk injuries at significant cost". This was reinforced by Shields (1998) who concluded that conventional IV systems were safe, cost effective and that the risk to healthcare workers from blood borne pathogens from conventional IV delivery systems was small.

1.1.7.4 Phlebotomy Devices.

The CDC (1997) reviewed three types of "safety devices" designed to reduce risks for phlebotomy associated occupational acquired inoculation injuries in a multi-centre study: Safety-Lok™, a re-sheathable, winged steel needle. Puncture-Guard™ (Bio-Plexus Inc, Figure 1.2), a bluntable, vacuum tube blood collection needle, activated whilst in the patient's vein and Venepuncture Needle-Pro™ (Portex), a vacuum tube, blood collection needle, with a hinged recapping sheath. A 23 to 76% reduction in NSI was noted when safety devices were used, compared with routine products. In addition healthcare workers found them relatively easy to use and judged their use acceptable.

Chen *et al.* (2000) evaluated a safety winged steel needle blood collection set at a 1,100 bed hospital in New York, which had already reported a 50% reduction in NSI by using a safety device. During a 16 month period between 1998 to 1999 SafetyLok™ (BD) was introduced. Prior to this device being trialled there was a reported NSI rate of 13.4/100,000 winged steel needles used. The post study rate fell to 5.5/100,000 devices used; a 59% reduction on there baseline data. The safety feature of the device had been activated in 71% of the 627 units observed.

Mendelson *et al.* (2003) compared the effect on NSI when a safety re-sheathable winged steel butterfly needle was introduced compared with a standard butterfly needle in an acute hospital in the USA. Needlestick injuries were substantially reduced after the implementation of the safety device and 63% of staff preferred the device to the standard one. Needle stick injuries associated with the safety device were commonly associated with non activation of the device. When sharps containers were audited 83% of the safety devices had been activated.

1.1.7.5 Safety Needles and Syringes.

Four published studies have demonstrated the effect of introducing safety needles/syringes into clinical areas:

In Australia 1993, Wright and Farrer (1993) identified that their major cause of NSI was from recapping hypodermic needles. Together with a local manufacturer they developed "NECON"; a box of upright needle covers, which is supported by a holder, which reduces the hazard of re-capping needles by hand. A significant reduction in NSI was noted in this study. Compared to today's more sophisticated designs, this was very basic and relied on staff completing another action prior to disposal. It is now recommended that sharps boxes are taken to the patients' bedside and needles disposed of at source (Wilson, 2001), therefore negating the need for needle covers.

A study evaluating the impact of a safety syringe on NSI amongst healthcare workers was carried out at three USA medical centres (Younger *et al.*, 1992). The study demonstrated the effectiveness of the 3ml safety syringe (Monoject Safety Syringe™; Sherwood Medical. Figure 1.3) in significantly reducing NSI involving a 3ml syringe. However, it was noted that healthcare workers also had the opportunity to use the conventional product; this therefore might have lead to distortion of the results.

In comparison, a study evaluating the efficacy of a safety syringe requiring "one stop" activation was carried out in an emergency department in California. No corresponding reduction in NSI was attributed to the introduction of the device. Healthcare workers also found the product unsatisfactory and in over 40% of the syringes observed had not had the safety feature activated (Mulherin *et al.*, 1996).

Siddharta *et al.* (2001) assessed the effect of introducing hospital wide, a safety syringe and a needleless IV system. The study was carried out at an 800 bed hospital in Texas, USA. A significant reduction in the incidence of NSI was reported when, comparing data from three years prior to the introduction to three years post implementation. Again however, confounding variables such as traditional needles and systems were still available and a comprehensive education programme was introduced part way through the study which may also have influenced the outcome.

1.1.7.6 Safety Peripheral Vascular Catheters.

A study carried out at the University of Virginia Hospital in 1986 demonstrated that the injury rate from peripheral vascular catheters (PVC) was 18.4/100,000 units purchased (Jagger *et al.*, 1988). During 1992 a safety PVC was introduced into three hospitals which used the same database (EPINet) network for collecting inoculation injury data. The injury rate associated with these catheters was 1.2/100,000 units compared with

7.5/100,000 units for the conventional catheter. When this data was compared with the 1986 data it demonstrated a reduction from 18.4/100,000 to 7.5/100,000 without the introduction of a safety device. Effective education on the handling and disposal of sharps can therefore reduce inoculation injuries up to 59%. Comparing this with the safety device data where an 84% reduction in needlestick injuries was noted (Jagger, 1996).

Mendelson *et al.* (2000) evaluated a safety IV catheter (Insyte Autoguard™; BD. Figure 1.4) at a 1,100 University Hospital in New York. The safety feature had been activated in 85% of the units studied. The study found that there was a significant reduction in stylet related injuries.

In another study undertaken by Mendelson *et al.* (BBraun, 2003) the Introcan Safety IV catheter (BBraun) was evaluated. No needlestick were sustained whilst the product was in use, compared to a baseline rate of 5.08/100,000 devices when traditional catheters were used. In addition, this catheter has the benefit of being passive compared to other devices which require activation by the user.

1.1.8 Costs Associated with Needlestick Injuries.

When different healthcare interventions are not expected to generate the same results the costs and the consequences associated with the differences need to be examined (Robinson, 1993).

1.1.8.1 Costs Related To Needlestick Injuries.

The costs associated with NSI are difficult to comprehensively calculate. Jagger *et al.* (1990) estimated the cost to be $390.45/NSI (based upon US dollars 1988). This included treatment, prophylaxis and occupational health department time. In a study comparing two hospitals from 1995 to 1997 (Jagger *et al.*, 1998); one in a high HIV prevalence region and the other in a low HIV prevalence region, the costs for high risk NSI were compared. Four categories were included: laboratory tests, HIV chemoprophylaxis/HBV vaccine, occupational health charges and other costs which did not fall into the above categories. The costs were $691 in the high HIV prevalence area compared with $532 in the low prevalence area.

1.1.8.2 Costs Related to the Psychological Trauma Associated With Needlestick Injuries.

Several studies have reported the issue of emotional trauma associated with an NSI which have included problems associated with concentration, sleep, anger and a decrease in sexual desire (Armstrong *et al.*, 1995; Povolny, 1997; David and David, 1997; Algie *et al.*, 1999; Ames, 1999). In addition, many nurses felt abandoned by their managers and peers following a NSI (Gershon *et al.*, 2000b).

1.1.8.3 Costs Related to Litigation.

In addition to the costs of providing PEP, laboratory tests and counselling, there is also the potential cost of litigation. In a five year period one NHS Trust alone had 942 reported NSI. If they had all realised into claims, the associated payout would have been costly (Ellington, 2000). There is very little documented on the compensation payouts individuals receive in the UK following a NSI; however three cases have been well documented. A doctor received £465,000 compensation for mental health problems suffered following an occupationally acquired NSI (Ellington, 2000). However on closer examination of the award it was felt that the high amount was awarded because the Trust in question was unable to defend a case of negligence regarding; failure to implement the health and safety policy, failure to ensure the safe disposal of sharps and failure of management and occupational health to rehabilitate and redeploy (Kearns, 1999). It has been argued that this will set a precedent for staff to sue the NHS (Hayes, 1999). In comparison to the £465,000 paid to a doctor, an auxiliary worker who received a NSI from inappropriately discarded scalpels and needles left in a rubbish bag was awarded only £750 which is apparently the average payout for such cases (Sarfas, 2000). Finally, in 2002 a senior operating department assistant sustained a contaminated NSI following displacement of an instrument tray in an operating theatre. He was awarded £58,000 in compensation for severe shock and trauma (NAO, 2003).

The increasing number of recent claims in the UK demonstrates that healthcare staff are reluctant to accept the risks associated with the most basic of healthcare equipment. UNISON have negotiated an immediate settlement of £2,000 for healthcare workers who make a claim against NHS Trusts for certain NSI (NAO, 2003).

1.1.8.4 Costs Related to the Implementation of Safety Devices.

The implementation of safety devices is not inexpensive. Mendelson *et al.* (1998) noted that the introduction of needleless intermittent IV access device would add an additional $230/1000 bed days. However, this has to be weighed against the costs of staff being injured and potentially infected following an occupational exposure.

Before safer devices are introduced widespread through the NHS it is important to evaluate the costs and benefits associated with their introduction. A tool designed to facilitate this, has been designed by the NHS Scotland, Short Life Working Group (2001). It helps evaluate the total benefit; financial and human, of introducing safer devices.

Costs associated with providing a safer working environment for staff are not a new phenomenon. With the implementation of UP in the USA in 1989 it was estimated to have cost $336 million; 64% of this was due to the introduction of rubber gloves and 25% due to the introduction of isolation gowns (Doebbeling and Wenzel, 1990). There is no reason not to believe that there was a similar increase in expenditure in the UK. It is inconceivable in the 21st Century not to wear protective clothing when dealing with blood and body fluids, hopefully soon this will be the same when discussing needle protective devices.

1.2 Preventing Patient Acquired Infection Associated with Peripheral Vascular Catheters.

The first synthetic IV catheter was introduced in 1945 (Meyers, 1945). Administration of fluids and medicines via the IV route is now routine practice within the healthcare setting and it has been identified that 40% of patients in the UK who require surgery will have an IV cannula inserted (Nyström *et al.*, 1983). In 2000, NHS logistics sold over 18.6 million PVC to the UK market (NPASA, 2003) and in 2002 the University Hospital Birmingham (UHB) NHS Trust, UK used a total of 122,943 cannulas (unreported data). Although infections associated with these devices remains relatively low they have the potential to become life threatening, especially in the critically ill and immunocompromised.

1.2.1 Cannula Material.

The type of material the PVC is made from can affect the incidence of catheter related infections (CRI). Subsequently, devices made from materials which do not encourage the adherence of microorganisms to their surfaces are of less risk for associated BSI and phlebitis. Studies have demonstrated that IV catheters made from Teflon™ are more resistant to microbial adhesion than those made from polyvinylchloride (PVC) or polyethylene (Sheth *et al.*, 1983; Maki and Ringer, 1991). However, a more recent development in catheter material, Vialon™ (BD; New Jersey, USA) which is a polyetherurethane, has been developed. This has several advantageous properties which include; a smooth surface to allow easy insertion and once inside the vein Vialon™ becomes soft and pliable which ensures the catheter floats in the vein rather than lying against the intima (McKee *et al.*, 1989). Maki and Ringer (1991) carried out a randomized clinical trial with 1054 PVC, evaluating the risk of infections associated with Vialon™ and Teflon™ designed cannulas. They identified that the catheter related bacteraemia risks associated with Vialon™ cannulas were comparable to those designed from Teflon™. However, the risk of phlebitis was substantially reduced (30%) when evaluating Vialon cannulas compared to Teflon™. This supported studies undertaken by McKee *et al.* (1989) and Gaukroger *et al.* (1988) and in a later study by Kerrison and Woodhill (1994).

1.2.2 Types of Intravascular Catheters.

Until recently there has not been a recommended format for describing the different types of IV catheters. They have previously been identified by various methods including; the catheters intended life span, the type of vessel it is to occupy and the site of insertion. However, the CDC (2002) has recommended that a standard format should be used to identify a specific catheter (Table 1. 4).

Table 1.4: Identification of Catheters Used For Venous and Arterial Access. (Amended from CDC, 2002)

1.2.3 Infections Associated with Peripheral Vascular Catheters.

Patients who require a PVC as part of their clinical management are at risk of developing a device related infection. Complications associated with infection have been reported since the first IV plastic catheter was introduced in 1945 (Meyers, 1945). Microorganisms most frequently associated with catheter related bloodstream infections (CRBSI) include *Staphylococcus aureus*, aerobic Gram-negative bacilli, *Candida albicans* and coagulase negative staphylococci; (Elliott *et al.*, 1994; Mermel *et al.*, 2001; Graninger *et al.*, 2002; Parker, 2002).

Intravascular catheter related infections (CRI) can be classified in a variety of ways; phlebitis, thrombophlebitis, site infection, bacteraemia and septicaemia. Consequently there is a wide variation in reported infection rates from 0% to 50% (Elliott, 1993; Collignon, 1994; Waghorn, 1994; Curran *et al.*, 2000; Cornely *et al.*, 2002; Creamer *et al.*, 2003; Vandenbos *et al.*, 2003).

However, indications are that CRBSI are rare in relation to PVCs (Maki and Ringer, 1991; Pearson, 1996; Mermel *et al.*, 2001; Cornely *et al.*, 2002; Grüne *et al.* 2004). In the UK only two studies have reported the incidence which ranged from 3.3% (Waghorn, 1994) to 6.2% (Nosocomial Infection National Surveillance Service; NINSS, 2002). Nevertheless, due to the frequency with which PVC are used, infection can produce considerable annual morbidity (CDC, 2002).

1.2.4 Pathogenesis of Infection.

Following insertion of an IV catheter into a vein, a sheath of fibrin, thrombin, fibronectin and other plasma proteins develops (Fletcher and Bodenham, 1999) which can then act as a target for microbial colonisation. The surface of the cannula can influence bacterial adhesion; PVC, polyethelene and silicone are more susceptible to colonization than Teflon and polyurethane (Sheth *et al.*, 1983). In addition, cannulae which have smooth surfaces and are absent of defects may reduce the risk of bacterial colonization (Tebbs *et al.*, 1994).

The next stage of colonization is the development of a biofilm. With the addition of certain microorganisms, such as *Staphylococcus (S.) aureus* to the plasma proteins a

biofilm can be secreted as early as 24 hours of an IV catheter being inserted (Anaissie *et al.*, 1995).

Advances in microelectrode technology have shown that bacterial biofilms consist of microcolonies adhered to an inert or living surface which survive in organised communities enclosed in a self produced polymeric matrix (Costerton *et al.*, 1999). The biofilm constitutes a protected mode of growth which allows aids the adhesion of bacteria on the cannula and resists the effects of antibiotics circulating in the blood. Several hypothesis exist to explain antibiotic resistance; one mechanism of resistance is the inability of the antibiotic to penetrate to the full depth of the biofilm. This is caused by their reduced ability to diffuse caused by the polymeric matrix (Costerton *et al.*, 1999). Another hypothesis is that some of the cells in the biofilm survive in a slow growing or starved state (Brown *et al.*, 1988).

Some organisms such as *S. epidermidis* secrete a glycocalyx biofilm or exocellular slime substance (ESS). The function of ESS is to promote the colonisation of medical devices by binding the bacterial cells to each other within the developing biofilm. In addition, it can also impedes the immune response and therefore the host defence mechanisms and contributes to the antimicrobial resistance by blocking the path of antibiotics (Kloos and Bannerman, 1994)

1.2.4.1 Sources of Microorganisms Causing Catheter Related Infections.

There are four main routes from which micro-organisms can gain access to intravascular catheters: extraluminal, intraluminal, haematogenous seeding or contaminated infusates (Figure 1.5).

Figure 1.5: Access Routes for Microorganisms to Invade Intravascular Catheters.
(Modified with permission from Elliott, 1988).

The routes most frequently associated with transmission of microorganisms are the extra and intraluminal ones (Elliott, 1993). It has been demonstrated that cutaneous microorganisms can contaminate the IV catheter during insertion or can migrate along the catheter post insertion (Bjornson *et al.*, 1982). However, it is believed that the most common cause of CRBSI is due to contamination of the catheter hub. When manipulated, this can cause intraluminal migration (Sitges-Serra *et al.*, 1985. Linares *et al.*, 1985). Contaminated infusates and haematogenous seeding of the catheter are rare (Elliott, 1993).

1.2.5 Diagnosis of Catheter Related Infection.

1.2.5.1 Clinical Diagnosis.

Systemic infections associated with IV devices are not easy to diagnose clinically because of their poor specificity and sensitivity (Mermel *et al.*, 2001). The patient often has low grade pyrexia which has not responded to broad spectrum antibiotics and no other focus of infection (Elliott *et al.*, 1994). In a recent UK study by Coello *et al.* (2003) it was reported that 3.9% of all hospital acquired bactereamias reported in the teaching hospitals reviewed were due to PVC. The criteria for the diagnosis of CRI can be seen in Table 1.5.

1.2.5.2 Laboratory Diagnosis of Peripheral Vascular Device Sepsis.

The recommended microbiological approaches to diagnosing a CRI associated with PVC are; tip culture by use of a semi-quantitative method and two separate blood samples (Mermel *et al.*, 2001).

Tip Analysis: The most commonly used semi-quantitative method of determining tip colonization is one introduced by Maki *et al.* (1977). A section of the catheter is rolled at least four times across the surface of an agar plate. The plate is then incubated in air at 37°C for 24 hours. Quantiative culture requires the catheter segment to be flushed with broth, or vortexing or sonicating in broth, followed by serial dilutions and then surface plating onto blood agar (Brun-Buisson *et al.*, 1987). A colony count of ≥15 colony forming units (cfu) obtained from a catheter by means of the Maki *et al.* (1977) method or a colony count of $\geq 10^3$ by means of the Brun-Buisson *et al.*, (1987) method, with accompanying signs of local or systemic infection is indicative of CRI.

Blood Cultures: Two separate blood samples should be obtained prior to starting antibiotic therapy, one of which should be percutaneous (Mermel *et al.*, 2001). Blood culture results which are positive for *S. aureus*, coagulase negative staphylococci or *Candida* species, without an other identified source of infection should raise suspicion of a CRBSI (Kiehn and Armstrong, 1990; Mayhall, 1992; Pearson, 1996).

Table 1.5: Clinical Criteria for the Diagnosis of Catheter Related Infections. Adapted from Mermel *et al.* (2001).

1.2.5.3 Typing of Microorganisms.

Traditional methods of microbial identification rely on phenotypes; morphology, growth variables and biochemical utilization of organic substrates. The biological profile is termed a biogram. Strains of bacterial species can be typed according to biochemical or cultural differences between the strains (biotyping). Some examples include; antibiotic sensitivity patterns and phage analysis. Biograms which are identical have been used to infer relatedness between the strains. However, several isotypes may exist from a single isolate and therefore biotyping is often used with other methods to accurately profile organisms (Tang *et al.*, 1997).

Molecular methods of microbial identification have now been developed. They are extremely sensitive and can detect very small numbers of organisms in much shorter time periods than phenotypical methods. Methods include polymerase chain reaction (PCR) which is used to amplify nucleic acid. PCR is based on the capability of deoxyribonucleic acid (DNA) polymerase to copy a strand by elongation of complementary strands initiated from a pair of closely spaced chemically synthesized oligonucleotide primers. The final nucleic acid can then be identified by several methods, including pulse field gel electrophoresis (PFGE). PFGE uses a specialized electrophoresis device to separate chromosomal fragments produced by enzymatic digestion of intact bacterial genomic DNA. Due to the large DNA fragments produced effective resolution requires the use of a pulsed field (Sahm, 1996).

1.2.6 Management of Peripheral Vascular Catheter Infections

Routine application of prophylactic antibiotic cream to the insertion sites of PVC is not recommended (CDC, 2002). The management of CRI depends upon several factors; the microorganism, the patients underlying condition and the type and position of the catheter (Elliott, 1993). Local infections usually respond to treatment with appropriate antibiotics (Elliott and Faroqui, 1992). In addition, it is recommended that the PVC is removed if signs of phlebitis develop (CDC, 2002).

1.2.7 Prevention of Peripheral Vascular Catheter Related Sepsis.

Several factors influence the prevention of PVC related sepsis (Table 1.6).

Table 1.6: Factors Influencing the Prevention of Peripheral Vascular Catheter Related Sepsis.

Healthcare Worker	Device
Experience of inserter.	Cannula material
Hand decontamination	Duration of cannulation
Aseptic technique	Site of insertion
Skin decontamination	Associated devices
Dressing	

1.2.7.1 Duration of Cannulation and Replacement.

Peripheral vascular catheters should be removed if there is any sign of associated phlebitis; pain, warmth and erythema (CDC, 2002) or as soon as their purpose is completed (Lederle, 1992). However, several studies have recommended the routine replacement of PVC at 72 to 96 hours (Collin *et al.*, 1975; Maki and Ringer, 1991; Waghorn, 1994; Lai, 1998) due to the increasing incidence of phlebitis and bacterial colonisation when they are left *in situ* for longer. However, Nyström *et al.* (1983) found no correlation between the duration of cannulation and bacteraemia and this was supported by Bregenzer (1998) and Curran *et al.* (2000) who recommend that routine replacement of PVC should be re-evaluated, considering the cost and discomfort for the patient.

The CDC (2002) and RCN (2003) recommend that the devices should be replaced at least every 72 to 96 hours to reduce the risk of phlebitis. However, if there are limited venous access sites or there are no signs of associated infection, PVC may be left *in situ* for longer with continued monitoring of the insertion site. Current recommendations from the Chief Medical Officer; Department of Health (2003), however, still recommend that PVC should be replaced every 48 to 72 hours. These guidelines need to be updated in line with recent research findings and recommendations from other expert bodies.

1.2.7.2 Site of Insertion.

Site selection for suitable venous access for PVC should include an assessment of the patients vascular access. The veins which are recommended for consideration for use with these devices are those in the upper limbs, preferably in the hand (CDC, 2002. Figure 1.6); metacarpal, cephalic and basilic (Dougherty, 2001).

Figure 1.6: Diagrammatic Representation of the Veins of the Hand. (http://www.harmreduction.org/idu/images/hand.gif).

1.2.7.3 Care of Insertion Site.

1.2.7.3.1 Principles of Asepsis.

Hand decontamination is required prior to the insertion of a PVC (CDC, 2002). Sterile gloves are not required. However, disposable non sterile gloves are recommended as a measure to protect the healthcare worker from blood borne virus transmission.

1.2.7.3.2 Skin Antisepsis.

Antisepsis is the application of a microbiocidal or microbiostatic antimicrobial agent to the skin (Crabtree *et al.*, 2000). Prior to the insertion of an IV device, the intended site should be cleansed with an antimicrobial solution (RCN, 2003) in order to reduce the risk of colonisation of the tip on insertion. Pratt *et al.*, (2003) recommend the use of 2% (w/v) chlorhexidine prior to line insertion, NICE (2003) recommend the use of an alcoholic chlorhexidine preparation.

Maki *et al.* (1991) in a large clinical trial using 668 catheters, evaluated the efficacy of three skin disinfectants (10% w/v povidone iodine: PI; 70% v/v isopropyl alcohol: IPA and 2% w/v aqueous chlorhexidine gluconate: CHG) in preventing infections associated with IV devices. Two percent (w/v) CHG was associated with the lowest incidence of catheter related infection (2.3% compared to 7.1% and 9.3% for 70% v/v IPA and iodine respectively.

In a meta analysis of eight studies involving 4143 catheters by Chaiyakunapruk *et al.* (2002) they identified that CHG significantly reduced the risk of blood stream infections compared to PI by approximately 50% in hospitalised patients requiring short term IV cannulation. Several potential explanations were given for their findings; protein rich biomaterials such as blood can deactivate the microbial effect of povidone iodine, but not CHG. Chlorhexidine has a long-term antimicrobial suppressive action (Carret *et al.*, 1997) and also has a superior bactericidal effect against Gram positive cocci; a common bacterium associated with IV infections, unlike PI.

<u>Isopropyl Alcohol.</u>

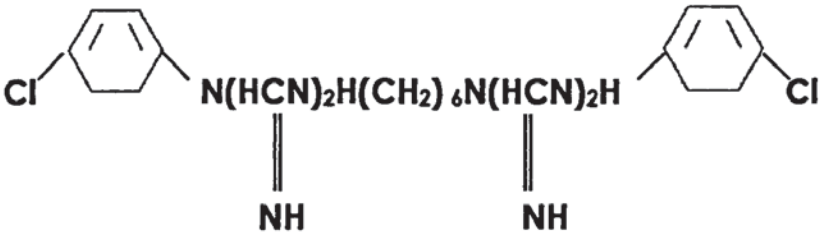
Chemical structure: isopropanol

Alcohols are rapid effective non-specific antimicrobial agents for both antisepsis and disinfection. They are both bacteriostatic and bactericidal, but not sporicidal depending upon the conditions and concentrations in which they are used. Cellular death occurs from protein coagulation and denaturisation at the microbial cell wall. Proteins are not denatured in the absence of water; therefore explaining why absolute alcohols such as ethanol and isopropanol are less bactericidal than dilutions of alcohol with water (Ali *et al.*, 2000). The most effective concentration for alcohol ranges from

60% (v/v) to 70% (v/v), concentrations below 30% (v/v) have little effect (Hugo and Russell, 1999). They should only be used on physically clean skin as they do not penetrate well into organic matter (Ayliffe *et al.*, 1993).

Chlorhexidine Gluconate.

Chemical structure: chlorhexidine



Chlorhexidine has a wide spectrum of antimicrobial activity. Gram positive bacteria are more susceptible to chlorhexidine than Gram negative bacteria but it has no effect on spores, tubercle bacilli and little effect on viruses (Wilson, 2001). Chlorhexidine gluconate is rapidly taken up by bacterial and fungal cells. Death of the cell is thought to be achieved by a series of processes: it is first attracted to the bacterial cell and is then adsorbed to certain phosphate-containing compounds on the surface. The exclusion mechanisms on the wall are overcome and then attraction towards the cytoplasmic membrane occurs. This results in leakage of low molecular weight cytoplasmic components such as potassium ions and precipitation of the cytoplasm which culminates in cell death (Denton, 2000). The antimicrobial activity of CHG is reduced in the presence of organic matter (Hugo and Russell, 1999).

Povidone Iodine.

Povidone iodine has a wide range of antimicrobial activity, including some activity against spores. Depending upon the concentration used they may be inactivated by organic matter (Ayliffe *et al.*, 1993). The majority of iodine preparations contain 7.5% to 10% PI. Preparations which have lower concentrations have good antimicrobial properties because the dilution increases the free iodine concentration. However, as the free iodine concentration increases the likelihood of skin irritation also increases (Berkelman *et al.*, 1982). Cellular death is caused when the iodine molecule penetrates the cell wall of the microorganism and forms complexes with amino acids and unsaturated fatty acids which results in impaired protein synthesis, alteration of the cell membrane and finally inactivation of the cell (Gottardi, 2000).

1.2.7.3.3 Dressings.

In the UK, most PVCs were stabilised by the use of non sterile tape until transparent, semi-permeable polyurethane sterile film dressings were manufactured (Curran *et al.*, 2002). Currently there is no evidence to suggest that sterile dressings result in a lower incidence of phlebitis than non sterile tape (Curran *et al.*, 2000). In a large, controlled study evaluating the dressing regimens used with 2000 PVC by Maki and Ringer (1987) there was no significant difference in the phlebitis rates between sterile transparent dressings and gauze. In addition, it was shown that dressings for PVCs can safely be left on for the duration of the cannula insertion without increasing the risk of thrombophlebitis. Subsequently, the type of dressing used to stabilise the PVC is often a matter of individual choice. However, the RCN (2003) recommends that the dressing chosen should not interfere with the assessment or monitoring of the insertion site.

1.2.7.3.4 Intravascular Filter Devices.

It has been suggested that IV filters can be used to reduce the incidence of infusion related phlebitis associated with IV devices. However, there is very little evidence to support this and therefore no recommendations for their use have been made (DOH, 2001).

1.2.7.3.5 Clinical Experience.

There have not been any large scale studies within the UK evaluating the effect of different staff groups inserting PVCs (Curran *et al.*, 2000). However, it is evident that the experience of the person inserting the catheter can clearly influence the risk of phlebitis (Armstrong *et al., 1986;*. Maki and Ringer, 1991; Eggimann *et al.*, 2000). In the USA, Maki and Ringer (1991) identified that PVCs placed by experienced nurses in the intensive care unit were less likely to develop phlebitis than those sited by nurses in general wards.

Specialist IV teams have demonstrated a reduction in the incidence of CRI and complications. Soifer *et al.* (1998) demonstrated a significant reduction in bactereamic complications from PVC following the introduction of a specialist IV team. This supports findings by Nehme (1980) and Tomford and Hershey (1984).

1.2.7.3.6 Infusate.

Evidence has demonstrated that the nature of the infusate via a PVC can have a profound effect on the incidence of phlebitis (Maki *et al.*, 1973; Turnidge, 1984; Lewis and Hecker, 1985). For example, administration of antibiotics via a PVC can substantially increase the risk of phlebitis (Maki et al., 1991).

In addition, it has been demonstrated that infusions prepared in the clinical area, as opposed to a sterile environment are more likely to increase the risk of phlebitis three fold (Curran *et al.*, 2000).

1.2.7.3.7 Needleless Intravascular Devices.

In studies based in specific locations Cookson *et al.* (1998) found a significant increase in blood stream infection (BSI) rates on a surgical intensive therapy unit (ITU), and a Transplant Unit associated with the introduction of a needleless IV device. This was attributed to unfamiliarity with the device and practices differing from the manufacturer's recommendations.

Arduino *et al.* (1997) found no statistically significant difference in the rate of fluid pathway contamination when comparing standard devices and needleless access devices. This is also supported by Rodriguez (1993), Larson *et al.* (1993), DeBaun *et al.* (1995b), Steinberg (1995), Roger *et al.* (1996), Luebke *et al.* (1998) and Seymour *et al.* (2000). These studies suggest that breaks in correct aseptic technique including; poor device surface decontamination and poor hand hygiene have a crucial part to play in the potential for microbial contamination of medical devices associated with IV access.

Brown *et al.* (1997) and Casey *et al.* (2003) studied two needleless connectors; "Connecta Clave™" (BBraun. Figure 1.1) and Posiflow™ (BD). It was found that the systems not only had the potential for reducing NSI but when decontaminated effectively had the likelihood of reducing microbial contamination of the catheters via the internal lumen.

1.2.8 Costs Associated with Peripheral Vascular Catheter Related Sepsis.

The NAO (2000) reported that 9% of all inpatients in England will have a hospital acquired infection (HAI) at any one time. This is equivalent to 100,000 infections a year at a cost of £1,000 million per year.

Emmerson *et al.* (1996) estimated that 6.2% of HAI were BSI. Therefore, approximately 6,200 BSI infections occur each year. Plowman (2000) evaluated the socio-economic burden this placed up on hospitals. They found that treating patients who had one or more infections cost 2.8 times more than non-infected patients, with an estimated cost of £6209 attributable to each BSI. Patients who developed a HAI received an extra 11 days hospital treatment.

No studies have reported the expenditure associated specifically with PVC infection. However, Moss and Elliott (1997) determined the costs associated with drug therapy, antibiotic prescription and delivery and in-patient stay related to patients who developed a CVC infection. The mean cost reported was £1781 per episode, which exponentially may be attributing a burden of £2.5 million pounds to the UK healthcare budget.

1.3 Aims of the Study.

Medical devices such as hollow bore needles and PVC are widely used in the healthcare setting. However, these devices continue to be associated with a relatively high risk of complications for both the healthcare worker and the patient. This study focuses on three main themes (Figure 1.7);

1.3.1 The Risk of Needle Stick Injury and Potential Blood Borne Virus Transmission to the Healthcare Worker from Hypodermic Devices.

The aims of this study are to:

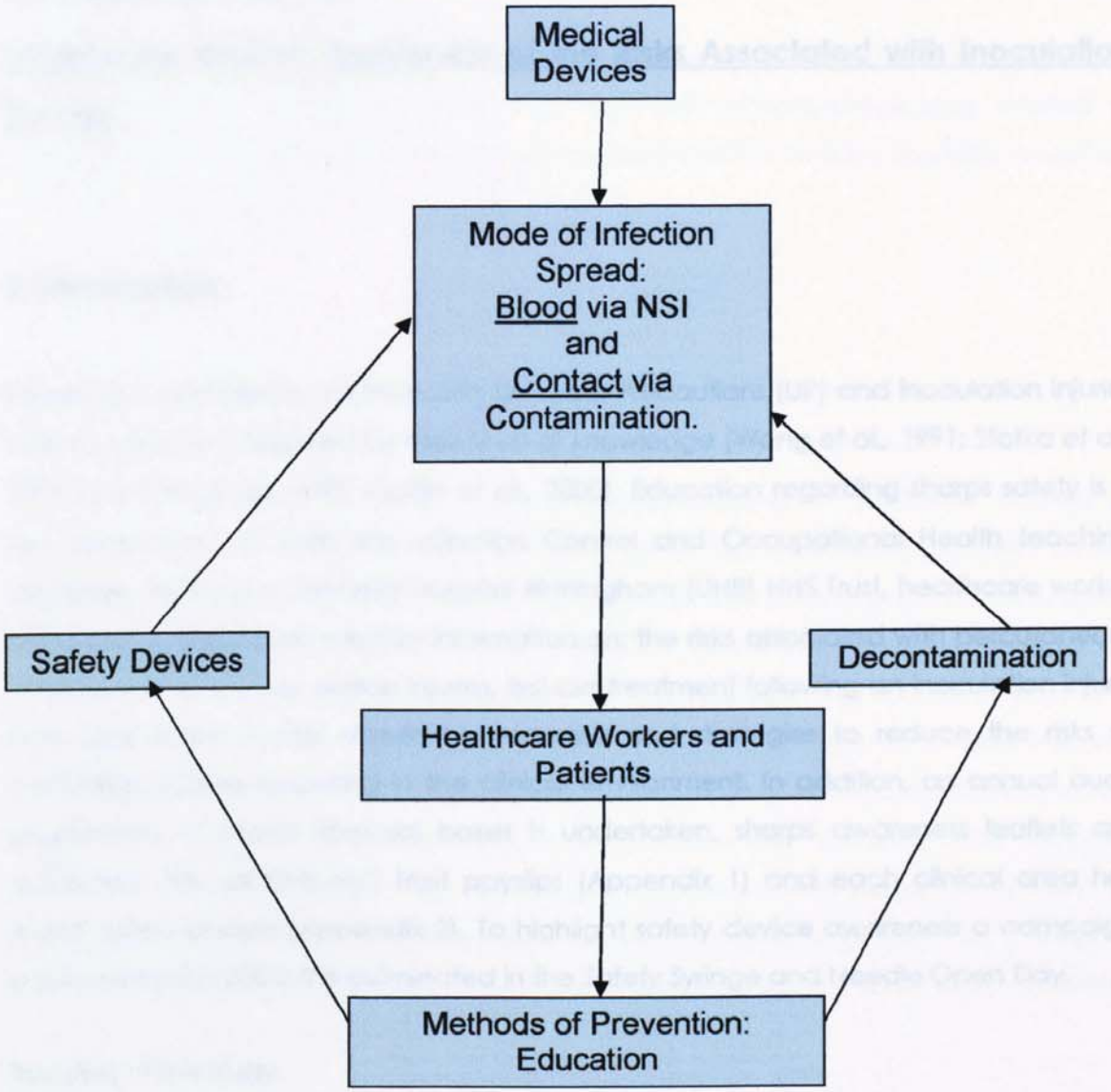
- To determine staff knowledge of risks associated with occupational acquired inoculation injuries, reporting patterns post injury and compliance with UP.
- To determine the usability and acceptability needle protective devices in the clinical area.
- To determine the baseline level of NSI associated with traditional syringe and needles within the UHB NHS Foundation Trust, UK.
- To evaluate the effectiveness of needle protective device in shielding healthcare workers from NSI.
- To perform a cost analysis comparing the costs attributable to NSI with the costs of introducing needle protective devices.

1.3.2 The Risk of Transmission of Infection to the Patient, Associated with Practices and Procedures Related to Peripheral Vascular Catheters.

The aims of this study are to:

- To evaluate the antimicrobial efficacy of IPA, CHG and PI, *in vitro*.
- To evaluate the rate of phlebitis associated with two skin disinfection regimes: 2% (w/v) CHG in 70% (v/v) IPA compared with 70% (v/v) IPA.
- To determine the potential infection risk associated with a needleless connector.

Figure 1.7: An Overview of the Thesis Contents.



Chapter Two:

Healthcare Workers Awareness of the Risks Associated with Inoculation Injuries.

2 Introduction.

Healthcare workers compliance with Universal Precautions (UP) and inoculation injuries may be directly influenced by their level of knowledge (Wong *et al.*, 1991; Stotka *et al.*, 1991; Gershon *et al.*, 1995; Godin *et al.*, 2000). Education regarding sharps safety is a key component of both the Infection Control and Occupational Health teaching strategies. Within the University Hospital Birmingham (UHB) NHS Trust, healthcare worker education programmes provide information on; the risks associated with percutaneous and mucutaneous inoculation injuries, first aid treatment following an inoculation injury, how and which injuries should be reported and strategies to reduce the risks of inoculation injuries occurring in the clinical environment. In addition, an annual audit programme of sharps disposal boxes is undertaken, sharps awareness leaflets are distributed with all UHB NHS Trust payslips (Appendix 1) and each clinical area has sharps safety posters (Appendix 2). To highlight safety device awareness a campaign was launched in 2001; this culminated in the Safety Syringe and Needle Open Day.

The aims of the study.

To assess the effectiveness of the education program provided, a survey evaluating healthcare workers knowledge of risks associated with inoculation injuries within the UHB NHS Trust, was undertaken.

2.1 Materials and Methods.

In 2002, 200 healthcare workers at the UHB NHS Trust were invited to participate in a study to determine their knowledge of; the risks, policies/procedures related to undertaking percutaneous inoculation procedures and the actions required should an inoculation injury occur.

2.1.1 Data Collection.

In order to evaluate healthcare workers understanding of practices related to inoculation injuries and knowledge of blood borne virus transmission, a series of key questions were developed which would demonstrate their level of understanding of the issues concerned. Two methods of data collection tools were reviewed to enable the researchers to obtain the best responses to the questions set; questionnaires and personal interviews, both options have very strong advantages (Polit and Hungler, 1991). The advantages associated with using questionnaires as the data collection tool were; less time consuming, less costly, interview bias was removed and complete anonymity could be offered. The advantages associated with personal interviews as the data collection tool were; interviews reduce the potential problem of ambiguity, the data obtained are often very detailed and respondents very rarely leave questions blank or state "don't know".

The questionnaire was the method chosen, as the advantages of it being less time consuming and anonymous outweighed the benefits of the depth of data the personal interview would produce. Firstly, clinical healthcare staff have limited spare time; therefore the questionnaire which was designed to be completed in five to 10 minutes was more acceptable than detailed personal interviews which would take considerably longer. Secondly, the interviewees may have felt intimidated by the researchers interviewing them about their level of clinical knowledge.

a). Structure of the Questionnaire.

The structure of the questionnaire was designed in order that the majority of questions were either; closed ended, fixed alternative or rank order. The advantage of limiting the range of possible responses was to allow quantification of the data given. The data in this particular aspect of the study was to be quantitative compared to qualitative; therefore the outcomes have to be measurable.

b). The Questionnaire.

The questionnaire consisted of 12 questions related to the risks and practices associated with needle stick injuries (NSI) (Table 2.1). Three areas of inoculation injuries were examined:

- Risk of transmission: Question four and five.
- Occupational Health and Safety: Question three, six, seven, eight and 10.
- Clinical practice: Question nine, 11 and 12.

Table 2.1: Clinical Healthcare Workers Awareness of Risks Associated With a Needlestick Injury Questionnaire.

1. Are you a:
   Doctor Nurse Phlebotomist ODA Other: .....**(Circle as appropriate)**
   Ward/Speciality:.....

2. What is your grade:
   PRHO SHO Registrar Consultant D grade E grade F grade G grade
   H grade Other.....**(Circle as appropriate)**

3. What is meant by an *inoculation injury*? **(Tick >1 if required)**
   An injury from a:
   Scratch☐ Blade☐ Bite☐ Scalpel☐
   A spicule of bone or teeth ☐ Splash of body fluid to eyes or mouth ☐
   A clean needle☐ A used needle

4. What is the incidence of transmission of Hepatitis B, Hepatitis C, and HIV from a positive patient to a negative person through a percutaneous inoculation injury?
   (Circle as appropriate)

Hepatitis B	1:0.3	1:3	1:30	1:300	1:3000
Hepatitis C	1:0.3	1:3	1:30	1:300	1:3000
HIV	1:0.3	1:3	1:30	1:300	1:3000

5. Which of these devices has the greatest risk of transmitting a blood-borne virus through a percutaneous inoculation injury? **(Number 1 to 8, 1 being the highest risk)**

Peripheral IV cannula; Venflon/butterfly	☐	Needle & Syringe	☐
Blood glucose lancet	☐	Suture needle	☐
Vaccutainer system (with needle)	☐	Subcutaneous butterfly cannula	☐
Stitch cutter	☐	Blade	☐

6. What is the first 'First Aid' action you should take if you get a percutaneous inoculation injury?

7. How do you report a percutaneous inoculation injury?

8. Should the source patient have blood taken for testing? YES☐ NO☐

   If Yes, who should take the blood sample?

   Yourself ☐
   Medical team ☐
   Occupational Health ☐
   Ward Manager ☐
   Other:_____

9. Is it **your** routine practice to wear gloves whilst:

	YES	NO	N/A
Giving a: subcutaneous injection	☐	☐	☐
intramuscular injection	☐	☐	☐
intravenous injection	☐	☐	☐
Inserting a peripheral IV cannula	☐	☐	☐
Inserting a central venous catheter	☐	☐	☐
Using a blood glucose lancet	☐	☐	☐
Taking blood (venesection)	☐	☐	☐
Carrying out an arterial stab	☐	☐	☐
Inserting a butterfly needle - subcutaneous	☐	☐	☐
- IV	☐	☐	☐
Acupuncture	☐	☐	☐

10. Is it **your** routine practice to report percutaneous inoculation injuries?

YES ☐
Why:.....

Sometimes ☐
Why:.....

NO ☐
Why:.....

Comments:

11. Are you aware of any safer devices to reduce the risk of percutaneous inoculation injuries? (Please indicate the name if known).

12. Is your ward/unit using any safer devices?

c). Distribution of the Questionnaire.

The options available for distributing the questionnaires were; mailing, self administration and group distribution. Questionnaires which are mailed are associated with a poor response rate (Polit and Hungler, 1991). This may cause bias if only a small representative sample was returned and this information was then used to represent the views of the majority.

Two methods were chosen to distribute the questionnaire; random self administration and group distribution prior to mandatory Infection Control update sessions. These distribution methods have been shown to have a positive effect on the response rate and have the advantage of clarifying the reasons for the study and answering any questions the interviewee may have (Polit and Hungler, 1991).

d). Sample Size and Population.

A total of 200 questionnaires were distributed to nurses, doctors, theatre staff and phlebotomists, to ensure a confidence interval of 95% with a range of <15% was achieved. This was calculated on the assumption that 50% of the respondents were correct in their responses and 50% were incorrect. These four groups of healthcare staff were identified as they are most at risk of acquiring a NSI though their clinical work (Mercier, 1994; Cone, 2000; Tan *et al.*, 2001; NHS Scotland, 2001).

e). Pilot Study.

To ensure the questionnaire design was suitable, a pilot study was undertaken to identify any inherent problems in either the design or the distribution plan. A total of 10 questionnaires were distributed to the chosen population, on review it was decided that no further amendments to the design were required.

f). Ethics Committee Approval.

In order to assess healthcare workers knowledge, access to the chosen population was required. Permission to undertake the questionnaire was obtained from Research and Development at the UHB NHS Trust and the South Birmingham Research Ethics Committee prior to commencing the study (Appendix 3).

2.2 Results.

A total of 200 healthcare workers at the UHB NHS Trust, completed the questionnaire (Table 2.2); this represents 10% of all doctors, 12% of all nurses and 100% of the phlebotomists working within the UHB NHS Trust during 2002. It was not possible to quantify the number of theatre staff.

Table 2.2: Analysis of the Professions/Grades of the 200 Healthcare Workers Who Completed the Questionnaire Related to Knowledge of Risks Associated with Needlestick Injuries Within the UHB NHS Trust.

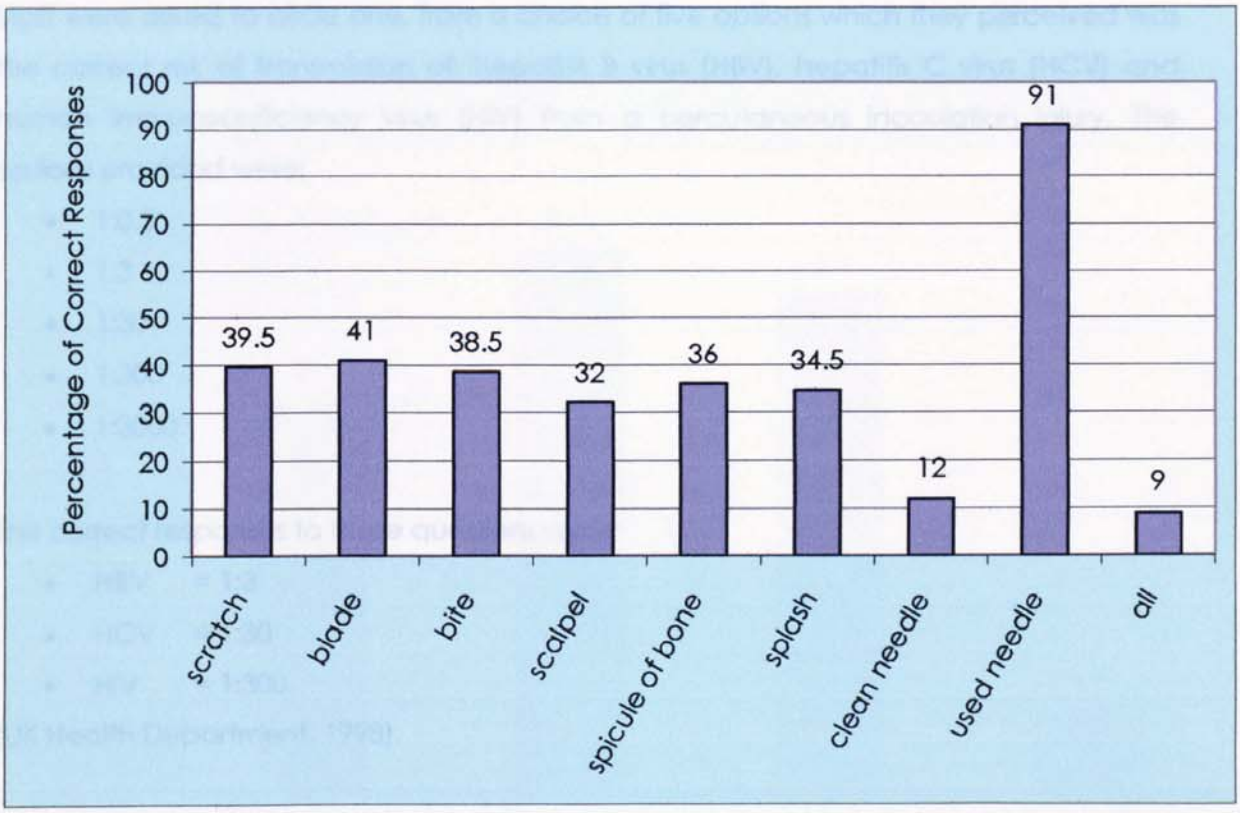
Doctors: n=35 (17.5%)		Nurses: n=139 (69.5%)		Theatre Staff: n=10 (5%)		Phlebotomists: n=13 (6.5%)		Other: n=3 (1.5%)
Grade	No	Grade	No	Grade	No	Grade	No	
clinical fellow	3	A	6	ODO	2	MLA	8	
clinical lecturer	1	B	3	ODA	6	B grade	1	
consultant	2	C	3	ODP	1	blank	1	
PRHO	12	D	39	orderly	1	other	3	
registrar	13	E	53					
SHO	4	F	17					
		G	6					
		H	2					
		I	1					
		military	1					
		student	5					
		supervised practice	1					
		unknown	2					

Legend: PRHO=Pre-Registration House Officer, SHO=Senior House Officer, ODO=Operating Department Orderly, ODA=Operating Department Assistant, ODP=Operating Department Personnel, MLA=Medical Laboratory Assistant.

2.2.1 What is an Inoculation Injury?

Staff were asked to select from eight listed incidents which they felt would be defined as an inoculation injury. These included an injury from; scratch blade, bite, scalpel, spicule of bone or teeth, splash of body fluid to eyes or mouth, clean needle and/or used needle (Figure 2.1). One or more of the options could be selected. The correct response was that all of the incidents listed were inoculation injuries.

Figure 2.1: Correct Identification of an Inoculation Injury from a Defined List by Healthcare Workers at the UHB NHS Trust (n=200).



One hundred and eighty two out of 200 (91%) of healthcare workers sampled correctly identified that an injury with a used needle was an inoculation injury; however less than 82 out of 200 (41%) identified that a scratch, blade, bite, scalpel, bone, splash or clean needle were also inoculation incidents. Out of the 200 staff questioned only 18 out of 200 (9%) identified all eight incidents listed were inoculation incidents.

2.2.2 What is the Risk of Transmission of a Blood Borne Virus from a NSI?

Staff were asked to circle one, from a choice of five options which they perceived was the correct risk of transmission of: hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) from a percutaneous inoculation injury. The options provided were;

- 1:0.3
- 1:3
- 1:30
- 1:300
- 1:3000.

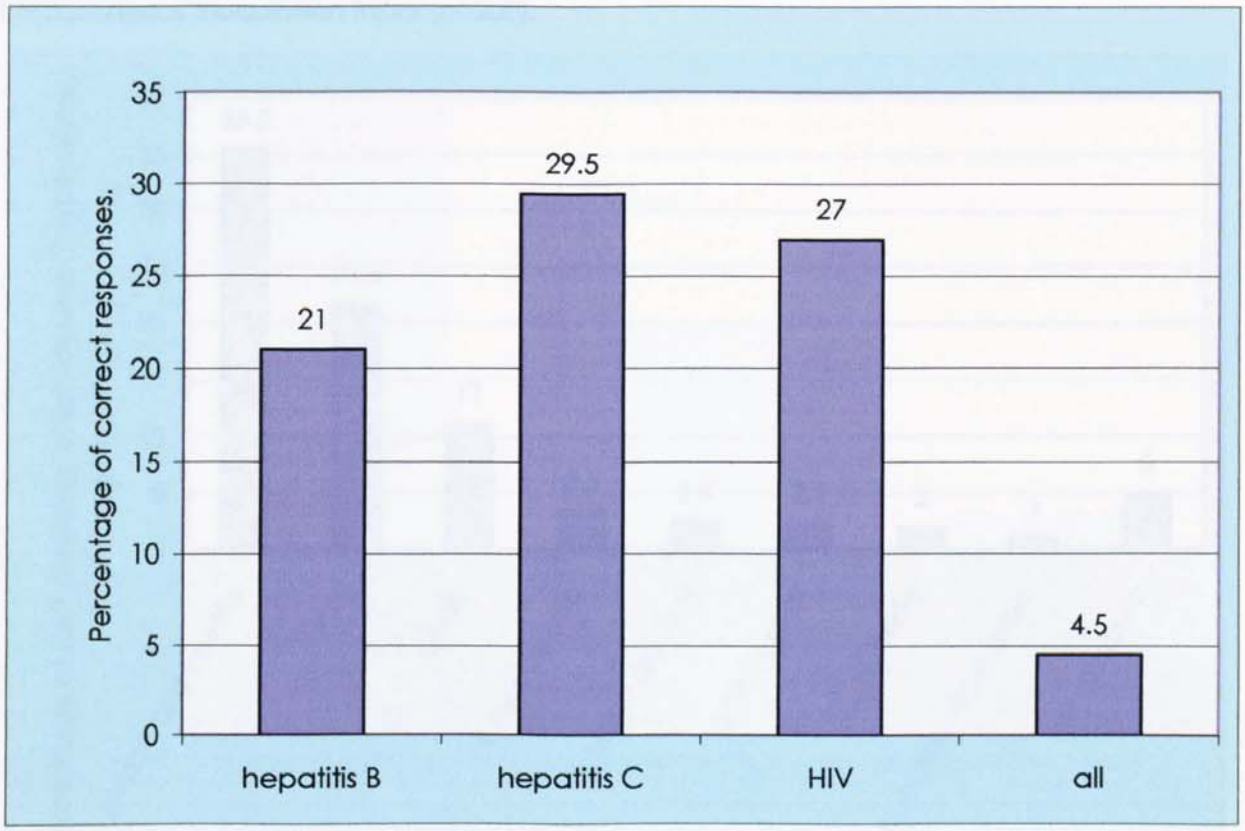
The correct responses to these questions were:

- HBV = 1:3
- HCV = 1:30
- HIV = 1:300.

(UK Health Department, 1998).

Figure 2.2 shows the percentage of staff who were able to correctly identify transmission risks of blood borne viruses from a percutaneous inoculation. Of the 200 healthcare workers questioned only nine out of 200 (4.5%) answered all three questions correctly; eight out of 200 (4%) nurses and one out of 200 (0.5%) doctors. When this was analysed per professional group it equated to only eight out of 139 (6%) of nurses and one out of 35 (3%) of doctors were able to identify the risks associated with a percutaneous inoculation injury from a source patient who has a known blood borne virus.

Figure 2.2: Correct Identification, by Healthcare Workers at the UHB NHS Trust, of the Risk Associated With Transmission of a Blood Borne Virus from a Percutaneous Inoculation Injury (n=200).

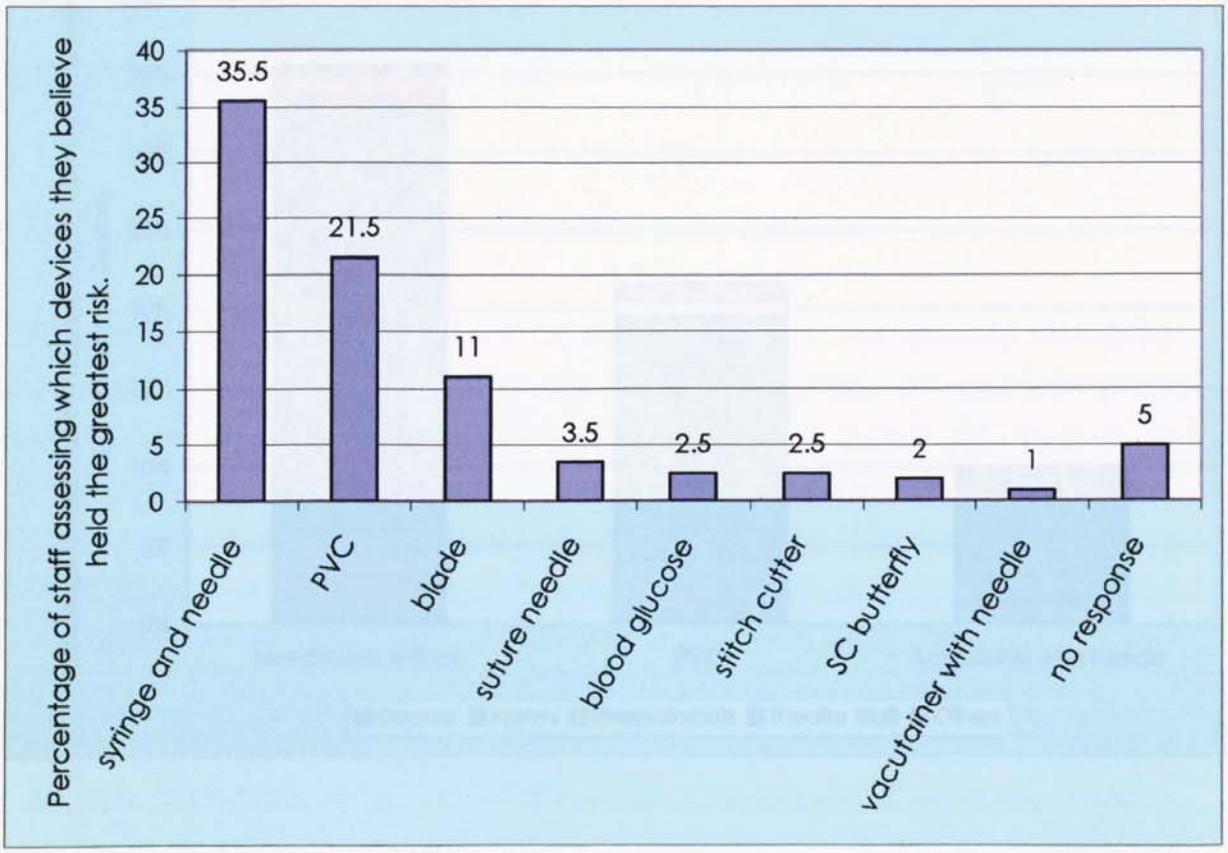


The majority of staff (104 out of 200; 57%) overestimated the risks of viral transmission from a Hepatitis BeAg positive inoculation, compared with 60 out of 200 (30%) from a HCV inoculation injury and 54 out of 200 (27%) from a HIV inoculation injury.

2.2.3 Identification of Which Devices Have the Greatest Risk of Transmission of a Blood Borne Virus.

In order that healthcare workers could evaluate which percutaneous devices had the highest risk of blood borne virus transmission associated with an injury, eight commonly used inoculation devices were listed. The devices were; peripheral venous cannula (PVC), needle and syringe, blade, suture needle, blood glucose lancet, vacutainer system with needle, subcutaneous (SC) butterfly cannula and a stitch cutter. Staff were asked to rate them from one to eight depending on which they felt had the greatest capacity for transmitting a blood borne virus following an inoculation injury; one being the highest risk (Figure 2.3).

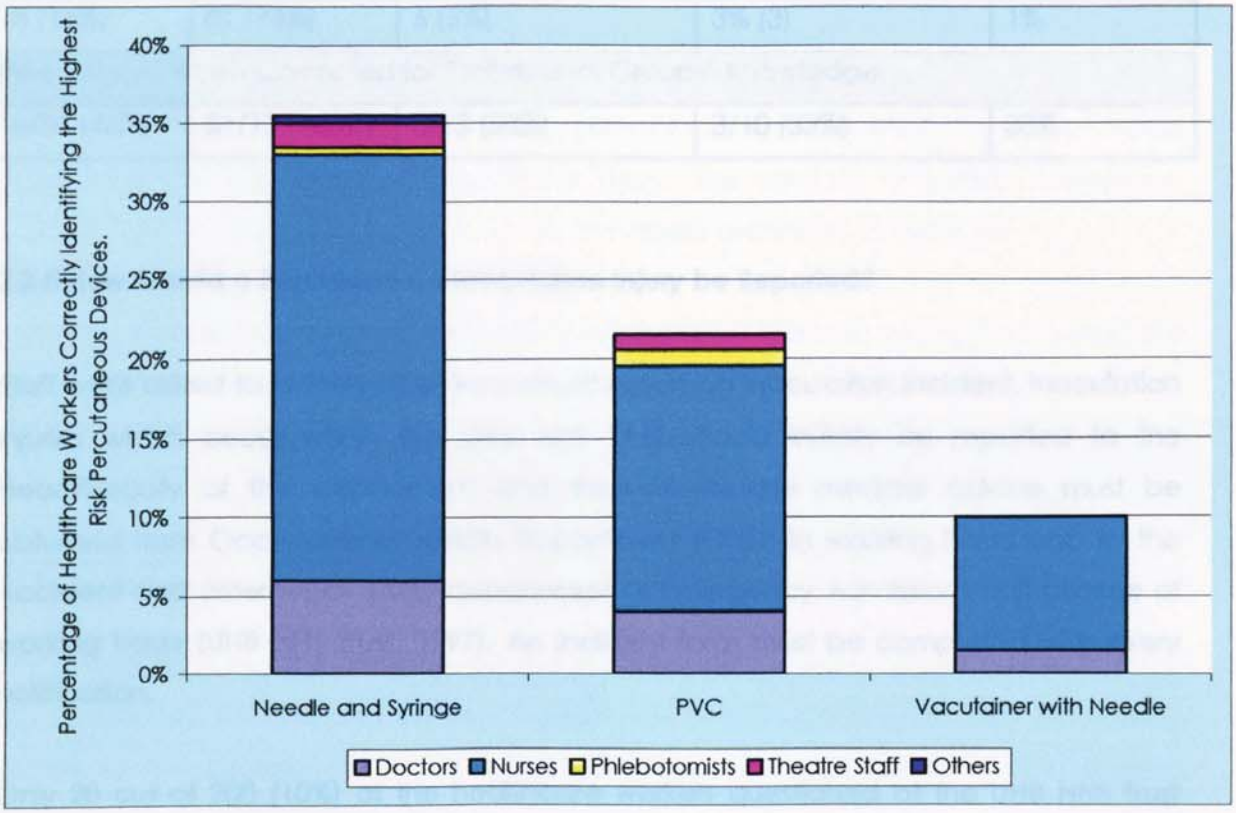
Figure 2.3: The Device Risk Assessed by Healthcare Workers at the UHB NHS Trust as Having the Greatest Risk Associated with Transmission of a Blood Borne Virus via Percutaneous Inoculation Injury (n=200).



The devices associated with the greatest risk for transmission of blood borne viruses are hollow bore needles (Collins and Kennedy, 1987; Jagger *et al.*, 1988; Cardo *et al.*, 1997, Jeans, 1999). When the results were reviewed in order to identify if staff had identified these devices (PVC, vacutainer with needle and/or syringe and needle) it was noted that only 104 out of 200 (57%) healthcare workers gave the correct answer.

Of the three hollow bore devices identified, the PVC and the vacutainer system hold the greatest risk, as these are generally more likely to be filled with blood. However, the syringe and needle was most frequently identified by healthcare staff as the device associated with the greatest risk (70 out of 200; 36%) (Figure 2.3). A review of which professional groups identified these three devices can be seen in figure 2.4.

Figure 2.4: Professional Groups at the UHB NHS Trust, Who Correctly Identified the Three Devices Associated with Having the Greatest Risk of Blood Borne Virus Transmission Following a Percutaneous Inoculation Injury (n=200)



2.2.4 What First Aid Action should be taken Following a Percutaneous Inoculation Injury?

Healthcare workers were asked what first aid action should be taken following a percutaneous inoculation injury; the correct response is to make the injury bleed and wash under running water (UHB NHS Trust, 1997). Only 109 out of 200 (55%) of healthcare workers correctly identified what action was needed (Table 2.3).

Table 2.3: Healthcare Workers at the UHB NHS Trust Who Correctly Identified the First Aid Action Required Following a Percutaneous Inoculation Injury (n=109).

Doctors	Nurses	Phlebotomists	Theatre staff	Others
18 (16%)	81 (74%)	6 (5%)	3% (3)	1%
Percentage When Corrected for Professional Groups' Knowledge.				
18/35 (46%)	81/139 (53%)	6/13 (38%)	3/10 (33%)	33%

2.2.5 How Should a Percutaneous Inoculation Injury be Reported?

Staff were asked to identify how they would report an inoculation incident. Inoculation injuries which occur within the UHB NHS Trust should initially be reported to the Head/Deputy of the department and then immediate medical advice must be obtained from Occupational Health Department (OHD) in working hours and to the Accident and Emergency (A/E) department or Emergency Admissions Unit outside of working hours (UHB NHS Trust, 1997). An Incident form must be completed with every notification.

Only 20 out of 200 (10%) of the healthcare workers questioned at the UHB NHS Trust were able to correctly state how an inoculation injury should be reported. Nineteen were nurses (grades B-G) and one "other". No doctors, theatre staff or phlebotomists were identified.

Probably the most important aspect of this question was whether "managers" were aware of the policy and procedure relating to the reporting of inoculation injuries. After the healthcare worker has performed first aid the manager is responsible for co-ordinating the next step of the reporting process. Only four out of 26 (15%) of senior nurses (grade F to I) and no senior doctors (registrars and consultants) were able to offer their junior colleagues the correct advice.

2.2.6 Should the Source Patients Have Blood Taken for Testing?

Staff were asked whether blood should be taken from the source patient following an inoculation injury. The Infection Control Policy and Procedure Manual (UHB NHS Trust, 1997) states that where the inoculation injury has involved blood and body fluids the source patients blood should be taken for testing as advised in, following consent from the patient.

- 186 out of 200 (93%) of staff agreed that the source patient should be tested.

2.2.7 Who Should Request and Take the Source Patients Blood?

Staff were asked to identify from a pre-determined list who should take the source patients blood following an inoculation injury. The options included: themselves, medical team, OHD, ward manger, other. The results are shown in table 2.4.

Table 2.4: Personnel Identified by Healthcare Workers at the UHB NHS Trust as Having the Responsibility for Taking Source Patient Blood Following an Inoculation Injury (n=200).

OHD	Medical Team	Medical Team and Ward Manager	Medical Team and OHD	Medical Team and the individual	The Individual	Other	Blank
52 (26%)	80 (40%)	22 (11%)	12 (6%)	3 (1.5%)	11 (5.5%)	4 (2%)	15 (7.5%)

The correct response is that the medical team responsible for the source patient has the responsibility to counsel and consent patient before taking bloods for testing following an inoculation incident (UHB NHS Trust, 1997). Only 117 out of 200 (59%) of staff were aware of who held this responsibility.

2.2.8 Is it Routine Practice to Wear Gloves Whilst Carrying out Percutaneous Procedures?

It is recommended that protective clothing is worn each time there is a likelihood of coming into contact with blood (UK Health Departments, 1998) and body fluids and when handling sharp or contaminated instruments (EPIC, 2001). Therefore it is advisable that gloves are worn whenever a percutaneous procedure is instigated.

Staff were asked to state whether they would wear gloves when carrying out ten standard procedures: giving a SC or an IM (intramuscular) injection, inserting a PVC, a SC butterfly, an intravenous butterfly or a central venous catheter (CVC), obtaining a blood glucose or an arterial blood gas or taking blood and finally when doing acupuncture.

This question had been misunderstood by the respondents. Some staff clearly thought that they were answering whether gloves should be worn by healthcare workers when undertaking these procedures. However, the question was asking whether it was their

routine practice to wear gloves whilst carrying out the procedure; the responses requested in the questionnaire were yes, no and not applicable.

This misunderstanding is demonstrated in the responses to whether it is routine practice to wear gloves whilst inserting a CVC; 100 out of 200 (50%) of the respondents replied that they would wear gloves as their routine practice. However, two out of 200 (1%) were phlebotomists and 59 out of 200 (29%) were nurses. Within the UHB NHS Trust it is currently only doctors who insert CVC. Therefore, the results for this question are unreliable. Nevertheless, if the data for those who stated that gloves do not need to be worn when undertaking these procedures is viewed (Figure 2.5), it demonstrates that gloves are not regarding as necessary protective equipment for some procedures where staff are at risk from inoculation injury.

Figure 2.5: Percentage of Healthcare Workers at the UHB NHS Trust Who Do Not Wear Gloves Whilst Carrying Out Identified Percutaneous Procedures (n=200).

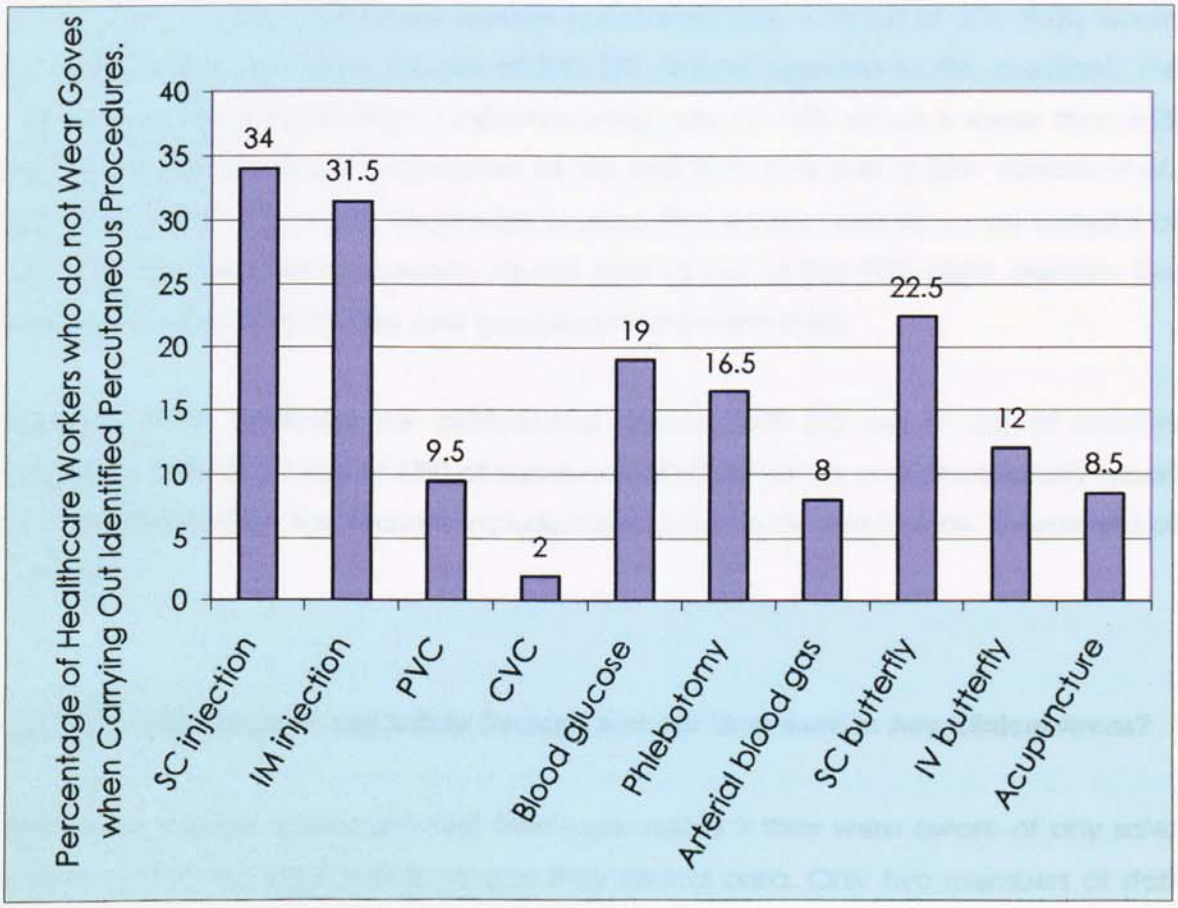


Table 2.5: Healthcare Workers at the UHB NHS Trust Who Do Not Wear Gloves When Performing Percutaneous Procedures (n=200).

	Doctors	Nurses	Phlebotomists	Theatre staff
SC injection	16 (8%)	49 (24.5%)	2 (1%)	1 (0.5%)
IM injection	15 (7.5%)	45 (22.5%)	2 (1%)	1 (0.5%)
PVC insertion	14 (7%)	4 (2%)	1 (0.5%)	-
CVC insertion	2 (1%)	1 (0.5%)	1 (0.5%)	-
Blood glucose	17 (8.5%)	20 (10%)	1 (0.5%)	-
Phlebotomy	15 (7.5%)	10 (5%)	8 (4%)	-
Arterial blood gas	13 (6.5%)	1 (0.5%)	2 (1%)	-
SC butterfly	16 (8%)	22 (11%)	6 (3%)	1 (0.5%)
IV butterfly	14 (7%)	9 (4.5%)	1 (0.5%)	-
Acupuncture	5 (2.5%)	10 (5%)	1 (0.5%)	1 (0.5%)

2.2.9 Is it Routine Practice to Report Percutaneous Inoculation Injuries?

All inoculation injuries should be reported as per UHB NHS Trust guidelines (UHB, 1997). However, of the 200 healthcare workers questioned only 170 out of 200 (85%) would report an inoculation injury (16 out of 200; 8%, did not respond to the question). This represents an inoculation injury under-reporting rate of 14%, which is lower than 65% reported in a similar study undertaken at the UHB NHS Trust during 2001 (Dobie *et al.*, 2002). Eleven out of 200 (6%) healthcare workers (five doctors and six nurses) stated that they had not reported inoculation injuries and 15 out of 200 (8%: eight doctors, five nurses and two phlebotomists) only occasionally reported them.

Therefore when analysed per professional groups; 37% (13 out of 35) of doctors compared with 8% (11 out of 139) of nurses would either not, or only occasionally report an inoculation injury. The reasons included being too busy and low risk assessment of the patient.

2.2.10 Are Staff Aware of any Safety Devices and Are They Used In Any Clinical Areas?

Healthcare workers at the UHB NHS Trust were asked if they were aware of any safer devices and if any were being using in their clinical area. Only two members of staff reported using safer devices; a safety PVC and blunt suture needles in theatre.

2.3 Discussion.

Correct risk assessment and knowledge of policies and procedures are essential, both in the undertaking of percutaneous procedures and the actions required should an inoculation injury occur. Without this knowledge it has been clearly identified in several studies that compliance with UP and therefore inoculation injury awareness is poor (Wong *et al.*, 1991; Stotka *et al.*, 1991; Gershon *et al.*, 1995; Godin *et al.*, 2000).

Gershon *et al.* (1995) and Bermingham and Kippax (1998) noted that compliance with UP was statistically associated with a fear of occupational transmission of HIV. When 200 healthcare workers at the UHB NHS Trust were questioned about the risks of transmission of blood borne viruses following a percutaneous inoculation injury, their awareness was poor. Only 42 out of 200 (21%) knew the actual risks from HBV, 49 out of 200 (30%) from HCV and 54 out of 200 (27%) from HIV. Viewing the data overall only nine out of 200 (4.5%) of staff were able to correctly evaluate the risks of all three viruses. This inadequate perception of risk may be responsible for the high number of staff who reported that they do not wear gloves whilst undertaking percutaneous procedures. Sullivan *et al.* (2000) noted that only 21% of medical students in Birmingham, England wore gloves during venepuncture. In comparison, 57% of doctors in this study did state that they wore gloves. However, this still leaves 43% who do not acknowledge the protection that gloves can offer from the acquisition of blood borne viruses.

Another key factor in the risk assessment process is the actual device associated with the injury. Hollow bore needles which may be filled with blood including PVC are allied to the greatest risk of blood borne virus transmission (Collins and Kennedy, 1987). Only 104 out of 200 (57%) of staff identified these devices.

Healthcare staff in this study considered an inoculation injury was primarily from injuries associated with a used needle. Inoculation injury reporting is low (McCormick and Maki, 1981; OSHA, 1997; CDC, 1997; Burke and Madan, 1997; Dobie *et al.*, 2002). However, what has not been previously determined is whether staff appreciate which injuries should be reported; if staff are unable to define what an inoculation injury is, this may explain under reporting.

To minimise the risks associated with an inoculation injury prompt treatment is essential. Staff were asked to identify what first aid treatment should be given and what secondary actions they should take in order to correctly report inoculation incidents. Guidelines are available in all clinical areas both in the Infection Control Policy and

Procedure Manual (UHB, 1997), the UHB NHS Trust intranet site and advice can be sought from the Occupational Health Department. Only 108 out of 200 (54%) of staff were able to correctly identify the first aid treatment required following a percutaneous inoculation injury. When knowledge of the secondary care a recipient of an inoculation injury required was analysed 180 out of 200 (90%) of the healthcare workers were unable to correctly identify what follow-up actions were required. Junior staff ask for advice from senior colleagues; when senior nurses (grade F to I) and senior doctors (registrars and consultants) responses were evaluated, only four out of 26 (15%) nurses and no doctors were able to offer their junior colleagues the correct advice.

It has been frequently stated that inoculation injuries are under-reported (McCormick and Maki, 1981; OSHA, 1997., Burke and Madan, 1997; Dobie *et al.*, 2002). This was confirmed in this study where an overall under-reporting rate of 14% was noted, 37% (13 out of 35) of doctors questioned would either not, or only sometimes report an injury compared with 8% (11 out of 139) of nurses. However disappointing this data appears it is lower than some reported studies (OSHA, 1997; CDC, 1997; Burke and Madan, 1997).

The reasons cited for occasional/non reporting of inoculation injuries in this study included being too busy and carrying out a risk assessment of the patient. When the data for non reporting was compared with knowledge of the risk of transmission of infection, none of the respondents were able to correctly identify the risk of transmission of blood borne viruses supporting the findings of Burke and Madan (1997) and Haiduven *et al.* (1999).

Finally, when staff were questioned about safer devices, their awareness that such devices existed was limited; despite a Trust "open day" where over 140 clinical staff attended. It is clear that the UK has a long way to go before it catches up with USA where such devices are now mandatory.

This survey demonstrates a continued lack of knowledge relating to the risks associated with inoculation injuries by healthcare staff within the UHB NHS Trust; despite a robust educational strategy being implemented by Infection Control and Occupational Health.

Future Recommendations.

The results have demonstrated that many healthcare workers are unaware of the key fundamentals relating to percutaneous inoculation injuries. Therefore, Infection Control and Occupational Health educational strategies should be reviewed, in order to improve healthcare workers knowledge of; what constitutes an inoculation injury; risk of blood borne virus transmission from percutaneous injury; the importance of protective clothing when undertaking a percutaneous procedure and the correct primary and secondary treatments required following an inoculation injury.

To maximise the effectiveness of the above strategy, intervention programmes' such as mandatory Inoculation Injury awareness sessions should be developed for all staff within the UHB NHS Trust. In addition, given the potential seriousness of this lack of awareness, an annual audit of staff knowledge should be undertaken by the UHB NHS Trust in order to evaluate the effectiveness of educational interventions. Recently safer needle devices have been introduced into the UK. The effect of these new devices needs to be evaluated to assess their effectiveness in reducing NSI (discussed in future chapters).

In conclusion, these results support earlier findings regarding compliance with inoculation policies/procedures (reporting, protective clothing, risk awareness) but it has also identified an important new variable; that of staff being unaware of what an inoculation injury is and therefore unaware that they require follow up treatment. It is clearly not reliable to assume that just because staff are being educated about inoculation injuries they retain the knowledge and that it affects their practice. Therefore, specific educational strategies are required and evaluations of the new safer needle devices need to be undertaken to evaluate the most effective approach to protect healthcare workers from NSI.

2.4 Study Limitations.

Although these results provide a focus for developing new educational interventions within the UHB NHS Trust, it is not possible to generalise them to other healthcare facilities in the UK. Each hospital will have its own baseline level of risk; the UHB NHS Trust specialises in renal, liver and cardiac medicine/surgery. Therefore, staff have a greater awareness (if a limited knowledge of risks) of blood borne viruses. In addition many different approaches may be required to minimise the risks associated with percutaneous inoculation injuries; education may only be one aspect. Both safer devices and an organisation which places emphasis up on a safety climate is also required (Gershon *et al.*, 2000a).

This work was undertaken as a shared project with Mrs Joanna Trim who submitted her MPhil "Occupational Exposure to Blood Borne Pathogens among Healthcare Workers and Preventative Strategies" at Aston University 2004. The data was re-evaluated for this thesis.

Chapter Three:

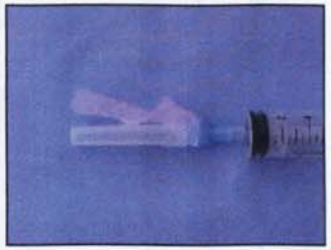
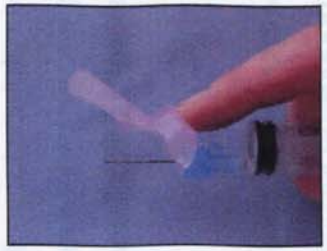
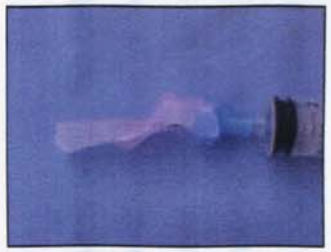
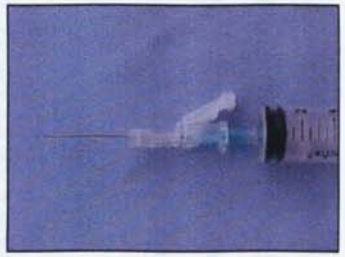
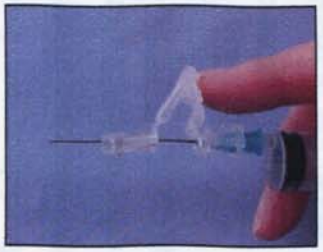
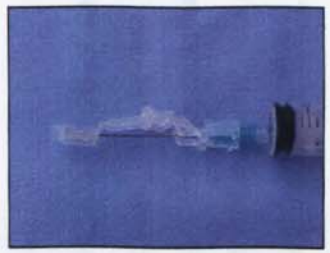
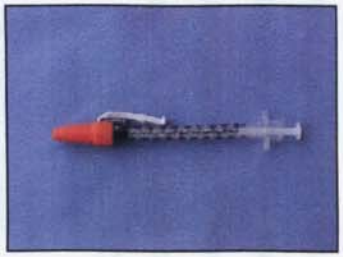
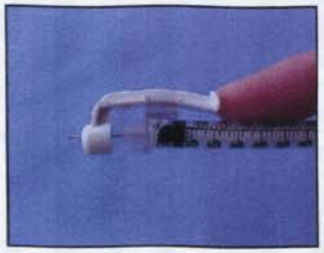
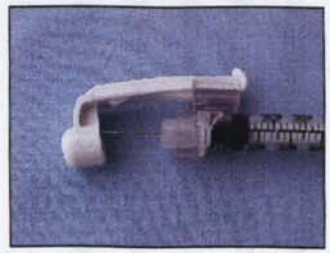
User Acceptability Study of Needle Protective Devices; Eclipse™, SafetyGlide™ and SafetyGlide™ insulin (BD).

3 Introduction.

An informal product trial of three needle protective devices from Becton Dickinson (BD); Eclipse™, SafetyGlide™ and SafetyGlide™ insulin (Figure 3.1) was carried out.

The aims of the study were:
To obtain product evaluations from frontline healthcare workers of key features and preferences of the three needle protective devices. In addition, to evaluate how the devices were manipulated, utilizing an observational study.

Figure 3.1: Three Needle Safety Devices from BD; (Eclipse™, SafetyGlide™ and SafetyGlide™ insulin unit) Before, During and After Activation of the Safety Feature.

	Before Activation.	During Activation.	Safety Feature Activated.
Eclipse™.			
SafetyGlide™.			
SafetyGlide™ insulin unit.			

3.1 Methodology.

a). Syringes, Needles and Saline Flush.

- Standard needle (Terumo; Leuven, Belgium); 21g
- SafetyGlide™ needles (BD; New Jersey, USA); 21g and 25g.
- SafetyGlide™ Insulin syringe (BD; New Jersey, USA); 28g.
- Eclipse™ needles (BD; New Jersey, USA); 21g and 25g.
- Luer-lok™ syringes (BD; New Jersey, USA); 5ml.
- Luer slip syringes (BD; New Jersey, USA); 5ml.
- Sodium Chloride 5ml flush; Mini-Plasco® (BBraun; Melsungen, Germany).

b). Product Evaluation.

It is essential that frontline workers are involved in all aspects of product appraisal. Neglecting this important feature of the change process has demonstrated that the devices were not accepted by staff and therefore needlestick injuries (NSI) were not reduced (OSHA, 1997; Fahey and Henderson 1999; Perry 1999).

The most common way to assess a new product is by informal evaluation. The advantages of using this methodology are: Evaluations take relatively short periods of time to complete; they provide valuable information regarding user preferences and product characteristics and offer an initial step in evaluating a product prior to final selection (Pugliese *et al.*, 2001).

The healthcare workers most commonly associated with giving intramuscular (IM) and subcutaneous (SC) injections within the University Hospital Birmingham (UHB) NHS Trust are nurses. Therefore they were chosen to evaluate the needle protective devices in this study.

A total of 50 clinical nurses from a range of specialties within the UHB NHS Trust were randomly recruited to complete the device evaluations over a two week period during 2002. A standardized "User Evaluation Data Sheet" tool (Table 3.1) was developed to collect the data from the nurses evaluating the product (adapted from Emergency Care Research Institute; ECRI, 2002). The tool was divided into two sections; in the first section the nurse was asked to score each device against ten standard statements. The statements evaluated three fundamentals for any safety device:

- Safety; Questions: three, five, seven, nine and 10.
- Human factors; Questions: one, two, four, six and eight.

- Compatibility; Questions: four and six.

A Likert scale was chosen as it enables attitudes to be measured. Five categories were chosen; strongly agree, agree, ambivalent, disagree and strongly disagree. A positive attitude towards the statement was awarded a score of one compared with five given to a negative attitude. This enabled the statements to be nominally scored. The summation feature of the Likert scale allows for a fine discrimination between the needles being studied (Polit and Hungler, 1991).

In the second section the nurse was questioned about the usability of the devices:

- Whether the device "popped off" during activation of the device.
- Whether splashing occurred on activation of the device.
- Needle and syringe device preference.
- If they could foresee any situations where the device would not be suitable.

Responses in this section were limited to dichotomous items; yes/no, SafetyGlide™/Eclipse™. If the respondent answered yes to any of the questions a comments option was available.

Each nurse was required to demonstrate the use of each needle protective device using a simulated dummy model (Adam Rouilly, Kent). In order to evaluate the devices effectively, no education or training on how the devices worked was provided by the researcher. This matched the usual clinical situation where no training is associated with the use of these type of devices.

Initially a control scenario with a standard green needle and slip lock syringe was used to evaluate "routine" practice within the UHB NHS Trust. Following this, five different combinations of the three needle protective devices with two types of syringe using both SC and IM injection routes were devised;

1. SafetyGlide™ insulin.
2. SafetyGlide™ with slip lock syringe.
3. SafetyGlide™ with Luer-lok™ syringe.
4. Eclipse™ with slip lock syringe.
5. Eclipse™ with Luer-lok™ syringe.

Table 3.1: User Evaluation Data Collection Tool.

Name: _____ Grade: ____ Ward: _____ Right/Left Handed? Number: ____ (to be filled out by researcher)
Please grade the statements below: **1= STRONGLY AGREE, 2 = Agree, 3 = Ambivalent, 4 = Disagree, 5 = STRONGLY DISAGREE**

Product Statements	Insulin (mark 1-5)	SafetyGlide™ (mark 1-5)	Eclipse™ (mark 1-5)
1. The safety feature: - is easily activated.			
2. - is intuitive to use.			
3. - can be activated using one hand.			
4. - does not hinder routine use.			
5. - does not hinder visualisation of the tip of the needle.			
6. - does not require more time to use than conventional products.			
7. There is a clear unmistakeable awareness of when the safety feature has been activated.			
8. The product does not require detailed training to use.			
9. The device would be effective in reducing needle stick injuries.			
10. The device is not easily de-activated.			

1. Did the safety device become detached from the syringe at any time during its use? Yes/No. (please circle)
2. If yes; Please state which device and describe when it detached _____.
3. When activating the safety feature did splashing occur? Yes/No. (please circle)
4. If yes: which device _____.
5. Which of the two products did you PREFER? Safety Glide/Eclipse (please circle)
6. Do you foresee any situations when the use of these products would not be suitable? Yes/No.
7. If so please discuss.

   _____.
8. Did you feel that there was any difference regarding SAFETY if a Luer Lock syringe was used compared to a Slip Lock syringe? Yes/No (please circle). If yes; why? _____.
9. Comments? _____.

Table 3.2: Observational Data Collection Tool.

Number: _____
Date: _____ Unit: _____ Grade: _____ Name: _____

	Control	1st	2nd	3rd	4th	5th
Scenario	X					
Needle: Insulin Eclipse; colour SG; colour	standard/green					
Attachment	push/twist	push/twist	push/twist	push/twist	push/twist	push/twist
Eclipse fully retracted		y/n	y/n	y/n	y/n	y/n
Device lined up with barrel		y/n	y/n	y/n	y/n	y/n
Did device obstruct procedure		y/n	y/n	y/n	y/n	y/n
Splash?		y/n	y/n	y/n	y/n	y/n
If yes; when/where (zone/distance: e.g. N1)						
How was safety feature activated?		forefinger thumb two handed surface other	forefinger thumb two handed surface other	forefinger thumb two handed surface Other	forefinger thumb two handed surface other	forefinger thumb two handed surface other
Did device need to be reattached?	y/n	y/n	y/n	y/n	y/n	y/n
If yes; when?						
Force needed to remove device from syringe?						
Comments						

These needle combination scenarios were computer randomized in order to ensure no bias was given to the final device being evaluated. On completion of the scenarios the nurse completed the evaluation form.

In addition to the user evaluation, the research observer also evaluated the devices as the scenarios were being undertaken. The "Observational Data Collection Sheet" tool (Table 3.2) was developed in order that the research observer could monitor:

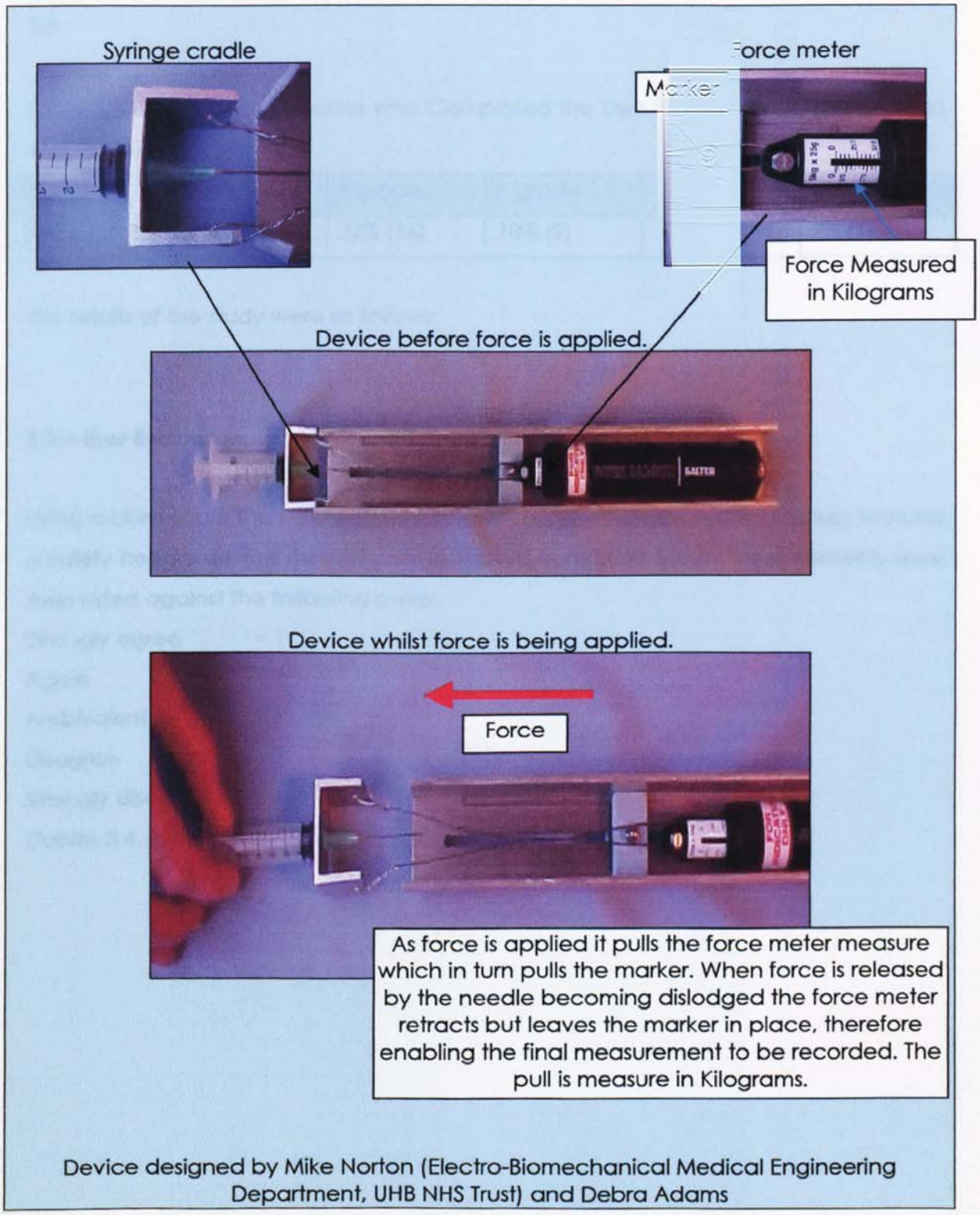
- How the devices were attached to the slip lock syringes; push on or push and twist method.
- How the devices were activated.
- Whether the devices splashed on activation.
- Whether the devices "popped off" on activation.
- The force required to remove the needle from the slip lock syringe. This was measured by attaching a force meter (Figure 3.2) to the needle in order to record the force required to detach the needle from the slip lock syringe.

The tool was completed at the end of each scenario.

c). Ethics Committee Approval.

Permission to undertaken this study was obtained from the UHB NHS Trust Research and Development Department and the Local Research Ethics Committee prior to its commencement (Appendix 1).

Figure 3.2: The Device Used to Measure the Force Required to Remove the Needles (Conventional, SafetyGlide™ and Eclipse™) from Slip Lock Syringes Which Had Been Attached by Fifty Randomly Selected Nurses at the UHB NHS Trust.



3.2 Results.

A series of 18 questions (Table 3.1) were completed by 50 clinical nurses working at the UHB NHS Trust. The grades of nurses who completed the study are shown in table 3.3.

Table 3.3: The Grades of Nurses who Completed the User Evaluation Data Collection Tool (n=50).

Students	D grade	E grade	F grade	G grade	H grade
14% (7)	22% (11)	32% (16)	18% (9)	12% (6)	2% (1)

The results of the study were as follows:

3.2.1 User Evaluation.

Using a Likert scale the nurses scored 10 statements which evaluated the key features a safety needle device should have (adapted from ECRI, 2002). The statements were then rated against the following scale:

Strongly agree = 1
Agree = 2
Ambivalent = 3
Disagree = 4
Strongly disagree = 5

(Tables 3.4, 3.5 and 3.6).

Table 3.4: Evaluation of the SafetyGlide™ Insulin Needle and Syringe Unit by 50 Nurses at the UHB NHS Trust during 2002.

Statement: The **SafetyGlide™ insulin** syringe and needle safety feature....	Total score from 50 respondents whose evaluations could range between1to 5. (Optimum score = 50).	Mean score and 95% CI_ from 50 respondents whose evaluations could range between 1 to 5 (Optimum score = 1).	Range of scores provided by 50 respondents whose evaluations could range between 1 to 5. (Optimum score = 1).
- is easy to activate?	82	1.64; CI=1.44-1.85	1 to 4
- is intuitive to use?	89	1.78; CI=1.57-1.99	1 to 4
- could be activated using one hand?	89	1.80; CI=1.51-2.90	1 to 4
- did not hinder routine use?	85	1.82; CI=1.53-2.11	1 to 5
- does not hinder visualisation of the tip of the needle?	83	1.64; CI=1.41-1.87	1 to 4
- does not require more time to use than conventional products?	87	1.74; CI-=1.48-1.97	1 to 5
- had a clear unmistakable awareness of when the safety feature had been activated?	79	1.58; CI=1.34-1.82	1 to 5
- does not require detailed training to use?	87	1.66; CI=1.46-1.86	1 to 4
- would be effective in reducing NSI?	68	1.36; CI=1.20-1.52	1 to 3
- could not be easily deactivated?	74	1.48; CI=1.55-1.76	1 to 4

Table 3.5: Evaluation of the SafetyGlide™ Needle by 50 Nurses at the UHB NHS Trust during 2002.

Statement: The **SafetyGlide™** needle safety feature.....	Total score from 50 respondents whose evaluations could range between 1 to 5. (Optimum score = 50).	Mean score and 95% CI from 50 respondents whose evaluations could range between 1 to 5. (Optimum score = 1).	Range of scores provided by 50 respondents whose evaluations could range between 1 to 5. (Optimum score = 1).
- is easy to activate?	79	1.60 CI=1.45-1.91	1 to 4
- is intuitive to use?	89	1.78; CI=1.53-2.03	1 to 5
- could be activated using one hand?	90	1.80 CI=1.49-2.11	1 to 5
- did not hinder routine use?	87	1.74 CI=1.49-1.99	1 to 5
- does not hinder visualisation of the tip of the needle?	78	1.56; CI=1.37-1.75	1 to 4
- does not require more time to use than conventional products?	85	1.70; CI=1.42-1.98	1 to 5
- had a clear unmistakable awareness of when the safety feature has been activated?	67	1.34; CI=1.18-1.50	1 to 3
- does not require detailed training to use?	80	1.60; CI=1.36-1.84	1 to 5
- would be effective in reducing NSI?	74	1.34; CI=1.19-1.49	1 to 4
- could not be easily deactivated?	75	1.50; CI=1.27-1.73	1 to 5

Table 3.6: Evaluation of the Eclipse™ Needle by 50 Nurses at the UHB NHS Trust during 2002.

Statement: The **Eclipse™** needle safety feature.....	Total score from 50 respondents whose evaluations could range between 1 to 5. (Optimum score = 50).	Mean score and 95% CI from 50 respondents whose evaluations could range between 1to 5. (Optimum score = 1).	Range of scores provided by 50 respondents whose evaluations could range between 1-5. (Optimum score = 1).
- is easy to activate?	85	1.70; CI=1.42-1.98	1 to 4
- is intuitive to use?	87	1.74; CI=1.51-1.97	1 to 4
- could be activated using one hand?	94	1.64; CI=1.44-1.85	1 to 4
- did not hinder routine use?	105	2.10; CI=1.76-2.44	1 to 5
- does not hinder visualisation of the tip of the needle?	91	1.82; CI=1.55-2.09	1 to 4
- does not require more time to use than conventional products?	93	1.86; CI=1.59-2.13	1 to 5
- had a clear unmistakable awareness of when the safety feature had been activated?	72	1.44; CI=1.27-1.61	1 to 3
- does not require detailed training to use?	84	1.68; CI=1.45-1.91	1 to 4
- would be effective in reducing NSI?	74	1.48; CI=1.26-1.70	1 to 4
- could not be easily deactivated?	78	1.56; CI=1.34-1.78	1 to 4

3.2.2 Pop Off

The needle safety devices SafetyGlide™ and Eclipse™ were evaluated to assess whether "pop off" occurred when the safety device was attached to a slip lock syringe (standard syringe design used with UHB NHS Trust).

"Pop off" was defined as detachment of the needle from the slip lock syringe on activation of the safety feature. This has a significant risk attached to it as the needle will have been used and "pop off" could lead to an inoculation injury caused directly by activation of the safety feature.

A total of 50 SafetyGlide™ and 50 Eclipse™ needles were evaluated using slip lock syringes. Three devices "popped off":

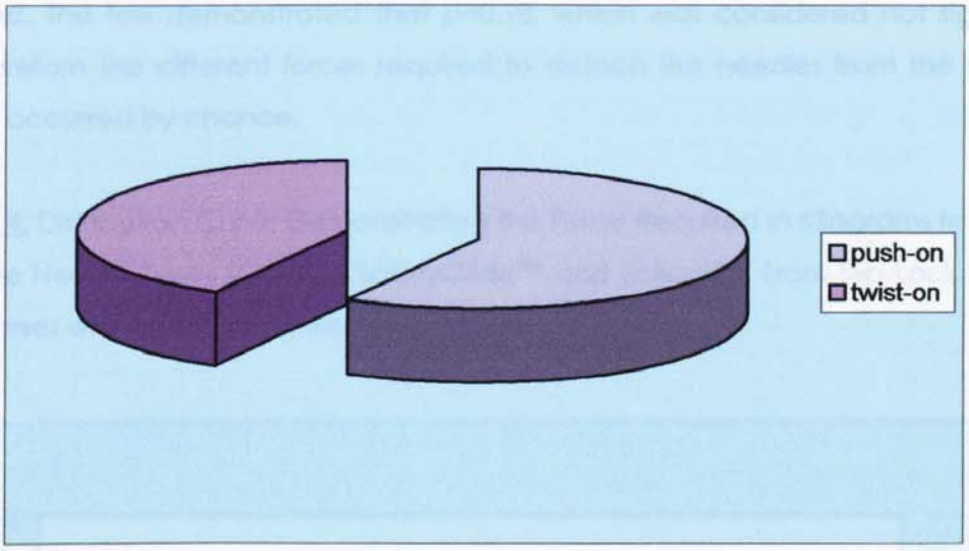
SafetyGlide: Two out of 50 needles "popped off" when the safety feature was activated.
This resulted in a failure rate of 4%.

Eclipse: One out of 50 needles "popped off" when the safety feature was activated.
This results in a failure rate of 2%.

Comment.

On the three occasions where "pop off" occurred, the device had been attached by right handed nurses, using the "push on" method, rather than the "push and twist" method and in each case the device was the last one to be evaluated in the scenarios. When standard practice for attaching slip-lock syringe and conventional needle was analyzed, it was noted that 26 out of 50 (58%) of nurses at the UHB NHS Trust attach needles to the syringe using the "push on" method (Figure 3.3).

Figure 3.3: A Review of Methods Used by Nurses at the UHB NHS Trust to Attach Conventional Needles to Slip-Lock Syringes (n=50).



In addition to observing whether "pop off" occurred, the needles (conventional, SafetyGlide™ and Eclipse™) which had been attached to slip lock syringes were also examined to analyze how much force was required to detach them from the syringes.

On average, more force was required to detach the new safer designed needles than the conventional needles (Table 3.7 and Figure 3.3), indicating that they had been attached more securely than conventional needles. However, comparing the forces per individual user rather than product, this was not the case (Table 3.8).

Table 3.7: The Force in Kgs' Required Detaching Conventional, SafetyGlide™ and Eclipse™ Needles From Their Slip Lock Syringes, After Use, Using a Force Meter.

	Mean force (Kg)	Range (Kg)	Standard Deviation
Control needle (n=37)	0.7 95% CI = 0.56 to 1.6	0.1 to 1.6	0.43
SafetyGlide™ needle (n=40)	0.78 95% CI = 0.62 to 0.94	0.12 to 1.75	0.48
Eclipse™ needle (n=42)	0.89 95% CI = 0.76 to 1.02	0.25 to 2.25	0.42

Statistical Analysis:

As three groups were compared in this study, a one-way analysis of variance (ANOVA) was used. The test demonstrated that p=0.18; which was considered not significant and therefore the different forces required to detach the needles from the slip lock syringes occurred by chance.

Figure 3.4: Distribution Curve Demonstrating the Force Required in Kilograms to detach the Three Needle Types (Control, SafetyGlide™ and Eclipse™) From Slip Lock Syringes by 50 Nurses at the UHB NHS Trust.

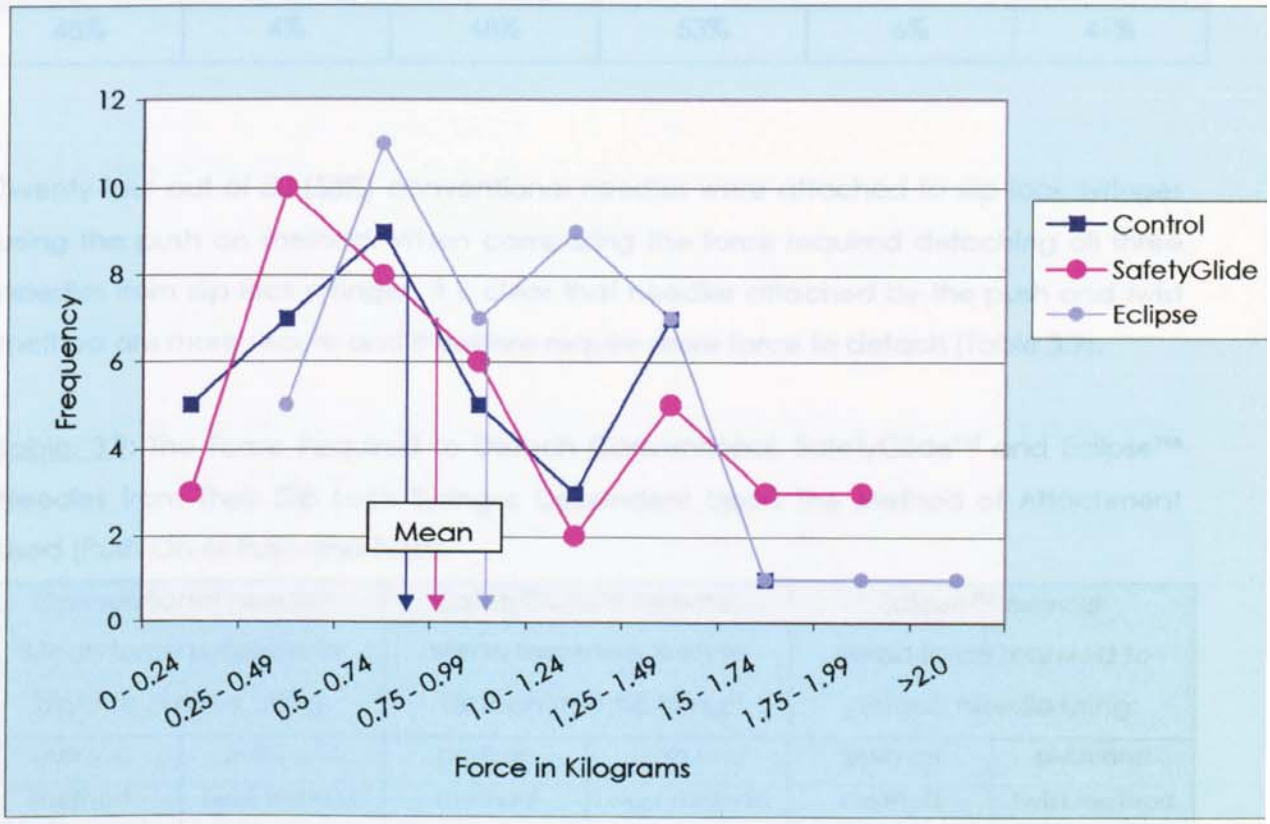


Table 3.8: A Comparison of Whether More/Less/Equivalent Force Was Required to Detach the Needle Protective Devices (SafetyGlide™ and Eclipse™) From the Slip Lock Syringes, Compared with the Conventional Needles, for Each Individual User.

SafetyGlide™ needle			Eclipse™ needle		
Increased force required compared to conventional needle.	Equivalent force required compared to conventional needle.	Decreased force required compared to conventional needle.	Increased force required compared to conventional needle.	Equivalent force required compared to conventional needle.	Decreased force required compared to conventional needle.
48%	4%	48%	53%	6%	41%

Twenty-four out of 50 (58%) conventional needles were attached to slip lock syringes using the push on method. When comparing the force required detaching all three needles from slip lock syringes, it is clear that needles attached by the push and twist method are more secure and therefore require more force to detach (Table 3.9).

Table: 3.9: The Force Required to Detach Conventional, SafetyGlide™ and Eclipse™ Needles from Their Slip Lock Syringes Dependent Upon The Method of Attachment Used (Push On or Push and Twist).

Conventional needle: Mean force required to detach needle using;		SafetyGlide™ needle: Mean force required to detach needle using;		Eclipse™ needle: Mean force required to detach needle using;	
push on method (n=29)	push and twist method (n=21)	push on method (n=25)	push and twist method (n=25)	push on method (n=26)	push and twist method (n=24)
0.59Kg	0.82Kg	0.74Kg	0.81Kg	0.73Kg	1.05Kg

When the nurses were asked whether they felt a Luer-lok™ syringe would be safer than a slip lock syringe 20 out of 50 (40%) stated that it would. Their comments included:

- Felt safer/more secure.
- Less likely to disconnect.

3.2.3 Splashing.

The three safety devices were evaluated to assess whether splashing occurred when the safety feature was activated.

Splashing was defined as the production of a spray of liquid from the needle when the safety feature was activated.

Splashing on activation of the safety feature was noted in three out of 100 (3%) SafetyGlide™ needles evaluated. The splash occurred directly in front of the needle. No splashing was noted with either SafetyGlide™ insulin or Eclipse™ devices.

3.2.4 Preferred Device.

The nurses were asked to decide which device from either SafetyGlide™ or Eclipse™ they would prefer to use (Table 3.10).

Table 3.10: A Comparison of the Nurses Stated Preferred Device With the Overall Score Rating Obtained in Tables 3.4 to 3.6 (n=50).

	SafetyGlide™	Eclipse™	Blank
Preferred device	66% (33)	32% (16)	2% (1)
Overall device rating (mean score out of 250, optimum score = 10)	79.8 95% CI = 73.97 to 85.63	86.3 95% CI = 79.12 to 93.49	

The findings demonstrated that nurses preferred the SafetyGlide™ needle compared to the Eclipse™ Needle (p=0.0011. Fishers Exact test; nominal, independent, non parametric data).

3.2.5 Device Activation.

As each scenario was carried out, the researcher observed several aspects of how the devices were being used. These included:

- When using the Eclipse™ needle was the operator fully retracting the device prior to use (Table 3.11).

Table 3.11: How Frequently the Eclipse™ Safety Feature was Fully Retracted Prior to Use (n=50).

1st use	2nd use
78% (39)	84% (42)

- How the safety feature was being activated e.g. two handed, forefinger, thumb, surface or other method. The initial method of activation of each device was then compared with the method of activation when the device was used the second time (this did not apply to SafetyGlide™ insulin as the device was only used once. See table 3.12).

Table 3.12: How the Safety Feature Was Activated; Two Handed, Forefinger or Thumb.

	SafetyGlide™ insulin	SafetyGlide™ needle		Eclipse™ needle	
	1st time	1st time	2nd time	1st time	2nd time
2 handed activation	10% (5)	14% (7)	8% (4)	28% (14)	14% (7)
forefinger activation	14% (7)	16% (8)	6% (3)	24% (12)	32% (16)
thumb activation	76% (38)	70% (35)	86% (43)	48% (24)	54% (27)

3.2.6 Unsuitable Situations.

Nurses were questioned as to whether they could foresee any situations where the safety devices would not be suitable.

Comments include:

- Phlebotomy; where a needle had to be bent in order to access a difficult vein.
- Eclipse needle was bulky and "therefore might get in the way".
- Patient self administration.

3.2.7 General Comments.

The final section was left for general comments on the devices. These included the following:

- "Staff safety should be given priority."
- "They are all as easy to use as what is used in current practice."
- "Difficult to use with one hand."
- "Very good idea to help improve safety."
- "I think these products would be useful and effective to reducing needlestick injuries."
- "With training I believe safety devices would be the preferred system to use."
- "Like the new syringes."
- "Difficult to remove the protective sheaths."
- "SafetyGlide™ was the preferred product; however the potential for splashing was worrying."
- "SafetyGlide™ more obvious to use; appeared safer and less bulky."

3.3 Conclusion.

The three evaluation criteria; Safety, Human Factors and Compatibility were used to analyse both the User and the Observational data.

3.3.1 Safety.

3.3.1.1 The Design of Safety Devices Should enable them to be Operated Using a One Handed Technique.

One of the important factors of a needle safety device is that it can be activated using only one hand. Single handed activation reduces the risk of injury to the other hand and minimises the chances that the device will not be activated (ECRI, 2001). The mean results for all three safety needles ranged from 1.64 to 1.80 (optimum score = one out of five). Therefore, all of the devices met the agreed safety standard for this criterion.

Although the nurses agreed with the statement, the observational data was studied to assess whether the nurses actually operated the device single handed. It was evident even without any training that after only two uses of the devices nurses were becoming familiar with the techniques required to activate them. When activation of the safety feature was analysed; 28 put of 50 (14%) activated SafetyGlide™ using a two handed technique the first time this reduced to 16 out of 50 (8%) on the second use. The activation of Eclipse™ demonstrated similar results; 12 out of 50 (24%) on first activation, down to seven out of 50 (14%) on second use. Although this is statistically not significant it does demonstrate a trend towards single handed activation as the user familiarises themselves with the product.

3.3.1.2: The User Should have a Clear and Unmistakable Awareness that the Device has been Activated and when Using Reasonable Force the Device Should not be Easily Deactivated.

When evaluating the products in relation to whether it was clear the device had been activated the nurses agreed that that all three devices showed a clear unmistakeable awareness of activation (mean score = 1.34 to 1.58, optimum score one out of five).

In addition they were asked to evaluate if the safety feature could not be easily deactivated. The scores demonstrated when reasonable force was applied the safety feature could not be deactivated (mean scores for the three products = 1.48 to 1.56).

3.3.1.3: *Safety Devices Should Not Create Additional Infection Control Issues.*

Two further safety aspects of SafetyGlide™ and Eclipse™ were evaluated in this study; pop off and splashing on activation. Slip lock syringes are the standard syringe used within UHB NHS Trust, therefore it was important to evaluate whether these safety devices popped off when the safety feature was activated.

A failure rate of two out of 50 (4%) was associated with SafetyGlide™ and one out of 50 (2%) with Eclipse™. All three needles had been attached using "push on" rather than a "push and twist" method.

When the devices were activated, splashing was observed with only the SafetyGlide™ needle (three out of 100; 3%). This may have been associated with a lack of familiarity with the product, as no education or training had been given prior to its use.

3.3.2 *Human Factors: The design of protective devices should enable them to be easily assembled, easily used and the technique for using the device should be similar to that of standard products.*

Evaluation of these criteria showed that the nurses found the three devices were: Easy to activate, intuitive to use, did not hinder routine use, did not require more time to use than conventional products and did not require detailed training to (Section 3.2.1).

3.3.3 Compatibility: A safety design product should be able to be used wherever a standard product is used and should be compatible with devices from other suppliers.

The nurses in this study agreed that neither SafetyGlide™ nor Eclipse™ would hinder routine use (Section 3.2.1). When nurses were asked whether they could envisage any situations where the devices would not be suitable the majority answered no. However three out of 50 (6%) were concerned whether the devices could be used for phlebotomy. In response to these concerns the Eclipse™ needle range includes a vacutainer blood collection system; therefore, phlebotomy using this device would not be a concern. However, a simulated evaluation of SafetyGlide™ needles would need to be undertaken to assess whether the device can be used in this situation.

When asked which of the safety needles each nurse would choose, the SafetyGlide™ needle was the preferred device by a significantly greater number of nurses than the Eclipse™ needle (p=0.0011) (Section 3.2.5). In addition, this was confirmed in the numerical evaluation of the individual statements of the products. SafetyGlide™ scored 79.8 in contrast with Eclipse™ which scored 86.3 (optimum score = 50 out of 250) (Section 3.2.1).

It is evident from the analysed results that nurses who trialled the devices agreed with the 10 set statements made regarding the evaluation criteria of the products. The three safety needles mean score for all 10 statements ranged between 1.34 and 2.10 = strongly agree-agree (Tables 3.4, 3.5 and 3.6).

3.4 Recommendations.

When the safety needles were attached to a slip lock syringe by the push on method "pop off" was seen in two out of 50 (4%) of the cases when SafetyGlide™ needles were used and one out of 50 (2%) when Eclipse™ needles were used. In order to overcome this potentially dangerous occurrence two options are available: Training of all staff, specifying that needles must be attached using the push and twist method, which was proven to increase the force the needle had been attached to the syringe with or the introduction of Luer-lok™ syringes.

As it would not be possible to guarantee that all staff would receive training in attaching the needles by the push and twist method, it is essential that Luer-lok™ syringes are recommended for use with these safety needles.

Splashing was noted with the SafetyGlide™ needle in three out of 100 (3%) of the devices being activated. This may be due to unfamiliarity with the product. However, mucutaneous splashing is not acceptable and education in how to use the device and correct activation of the safety feature is essential. In order that the training of staff meets the criteria advised by BD it is advisable that an experienced trainer is part of the educational team when the study commences within UHB NHS Trust.

Chapter Four:

Determining the Usability, Acceptability and Effect on Needlestick Injuries of the SafetyGlide™ Needle Protective Devices in the Clinical Setting.

4 Introduction.

Hypodermic needles are essential in the provision of healthcare. Nonetheless, needles can pose a significant risk for healthcare workers. The risk of acquiring a blood borne virus from an infected patient via an inoculation injury may be as high as one in three for hepatitis B virus (HBV), one in 30 for hepatitis C virus (HCV) and one in 300 for human immunodeficiency virus (HIV) (UK Health Departments, 1998). However, the number of newly identified cases reported to the Health Protection Agency (HPA) of HCV and HIV are increasing each year (Figure 4.1). Therefore the potential risk of transmission of HBV, HCV and HIV is also increasing.

Figure 4.1: The Number of New Cases of HBV, HCV and HIV Reported to the HPA from 1995 to 2003 (HBV and HCV; England and Wales. HIV; United Kingdom). Data obtained from www.hpa.org.uk/infections/topics-az.htm Accessed on 17th June 2005.

Those who are most at risk of acquiring a needlestick injury (NSI) are frontline workers, indeed, nurses account for between 50 to 63% of reported NSI and medical staff 13 to 17%. (Tan *et al.*, 2001; NHS Scotland, 2001). May and Churchill (2001) identified that almost 40% of NSI occurred downstream, to workers such as hotel services staff, commonly due to inappropriate disposal.

Studies have shown that the device commonly identified with NSI is the hollow bore needle which has been responsible for up to 68% of all injuries associated with reported NSI. (May and Churchill, 2001; Tan *et al.*, 2001). It is unfortunate; therefore, that the hollow bore needle has the greatest capacity for inoculating blood (Jeans, 1999) and is also associated with the transmission of blood borne pathogens (International Healthcare Worker Safety Centre, IHCWSC, 1999; Cardo *et al.*, 1997). Hollow bore needles are primarily used in association with syringe and needle, butterfly cannula and peripheral vascular access catheters.

Recently in the UK, engineered safety needle protective devices have been introduced. In the USA, the issue of occupationally acquired NSI has already been addressed. On November 6th 2000, the "Needle Stick Safety and Prevention Act" was introduced into the United States of America (USA). This act requires that all health care facilities in the USA purchase and provide needle protective devices in order to reduce the risk of staff acquiring a blood borne virus (HBV, HCV and HIV).

Several studies have attributed a reduction in NSI to safety needle devices (Younger *et al.*, 1992; Siddharta, 2001). However, the studies did not evaluate other factors which may have affected the results including, staffing levels and standard devices still being available for use. For example, Mulherin *et al.* (1996) reported that staff considered the safety needles unsatisfactory and that over 40% of the devices had not had their safety feature activated on disposal. Occupational Safety and Health Administration (OSHA, 1997) reported that safety devices were not accepted by healthcare staff because a comprehensive training programme was not offered and the change process had been poorly implemented.

The costs associated with the implementation of engineered safety devices are not inexpensive. Mulherin *et al.* (1998) reported an additional cost of $230 per 1000 bed days when an intravenous (IV) access device was introduced in the USA. These costs however, have to be weighed against the costs associated with NSI, which include; psychological trauma; treatment following the incident and potential litigation.

No one, single, strategy will reduce the number of NSI. Alzahrani *et al.* (2000) suggested that Occupational Health Department's need to continually reinforce vaccination policies. Staff also require regular educational updates on universal precautions, handling and disposal of sharps and inoculation injury and reporting policies. However, experiences in both the USA and the UK indicate that even by adopting these robust procedures to reduce NSI, they may not be sufficient to significantly reduce the incidence. Engineered needle protective devices may be the only available strategy left to explore. It is difficult to perceive a healthcare environment without hollow bore needles. Therefore, strategies need to be employed to reduce the risk of healthcare workers acquiring a blood borne virus from an occupational NSI.

The aims of the current study presented in this Chapter are outlined below:

- Chapter 4.1: Describes a user evaluation study by healthcare workers in four clinical areas at the University Hospital Birmingham (UHB) NHS Foundation Trust of three needle protective devices developed by Becton Dickinson (BD); SafetyGlide™ needle (Figure 4.2), SafetyGlide™ insulin unit (Figure 4.3) and Blunt fill needle (Figure 4.4).
- Chapter 4.2: Presents an audit of sharps containers to assess whether the needle protective devices have been activated by healthcare workers prior to disposal.
- Chapter 4.3: Reviews reported serious adverse incidents associated with the SafetyGlide™ needle device trial.
- Chapter 4.4: Determination of the numbers of reported NSI within the clinical trial and control areas; prior to any intervention to reduce NSI, after educational strategies focussing on improving healthcare workers knowledge of the risks associated with NSI were implemented and on completion of a 12 month study using the SafetyGlide™ needle protective device range.
- Chapter 4.5: Cost analysis comparing needle protective devices, with standard needles in the four clinical trial areas.
- Chapter 4.6: Recommendations and implications for future practice.

Figure 4.2: showing SafetyGlide™ needle (scale in cm).

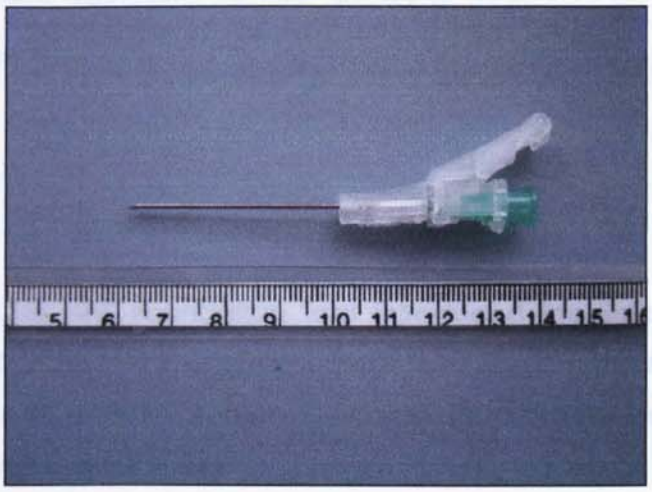


Figure 4.3: showing the SafetyGlide™ insulin unit (scale in cm).

Figure 4.4: showing the Blunt fill needle (scale in cm).

4.1 User Evaluation Study of SafetyGlide™ Needle Protective Devices by Clinical Healthcare Workers in the Clinical Trial Areas at the UHB NHS Foundation Trust.

4.1.1 Introduction.

During April 2003, UHB NHS Foundation Trust introduced the SafetyGlide™ range of needle protective devices into four clinical areas following a product evaluation of two needle protective ranges from Becton Dickinson (BD); SafetyGlide™ and Eclipse™ (Chapter 3). The clinical areas were:
East 3 Liver Unit (E3LU); a mixed sex, 21 bedded, liver medical ward.
West 3 Liver Unit (W3LU); a mixed sex, 20 bedded, liver surgical ward.
West 2 (W2); a mixed sex, 32 bedded, general surgical ward.
Liver Outpatient Department (LOPD); five clinic rooms.

Occupational Health and Safety Administration (OSHA. 1997) reported that studies evaluating the effectiveness of needle protective devices have failed due to; poor training and implementation of the change process. Therefore, prior to the introduction of the SafetyGlide™ needles and Luer-lok™ syringes (SafetyGlide™ needles are currently only recommended for use with Luer-lok™ syringes; Chapter 3) into the four clinical trial areas, a planned process of change was developed.

Change Process.
Action Research was developed by the social psychologist Kurt Lewin in 1958 and embodies the "learning by doing" approach (Revans, 1982). The focus of Action Research is on specific issues, identified in local situations (Clifford and Gough, 1990). Two characteristics of this approach differentiate it from other research styles. Firstly this application has a "bottom up" approach rather than "top down" and aims to collaborate with everyone who will be affected by the change. Secondly, the approach is participatory. The people involved i.e. the ward staff, participate in the research. This process was utilized in several phases of the present study, the user acceptability study which adopted both observational studies and participant evaluations of the products under review. The method was chosen as it is a normative/re-educative method which builds upon the assumption that actions and practices are supported by socio-cultural norms and by the commitment on the part of the individuals to these norms (Bennis *et al.*, 1985). Lewin's change strategy theorises

that man must participate in his own re-education; thus action research as a strategy for change and participation in groups acts as a medium for self re-education.

Lewin identified three phases in any change programme;

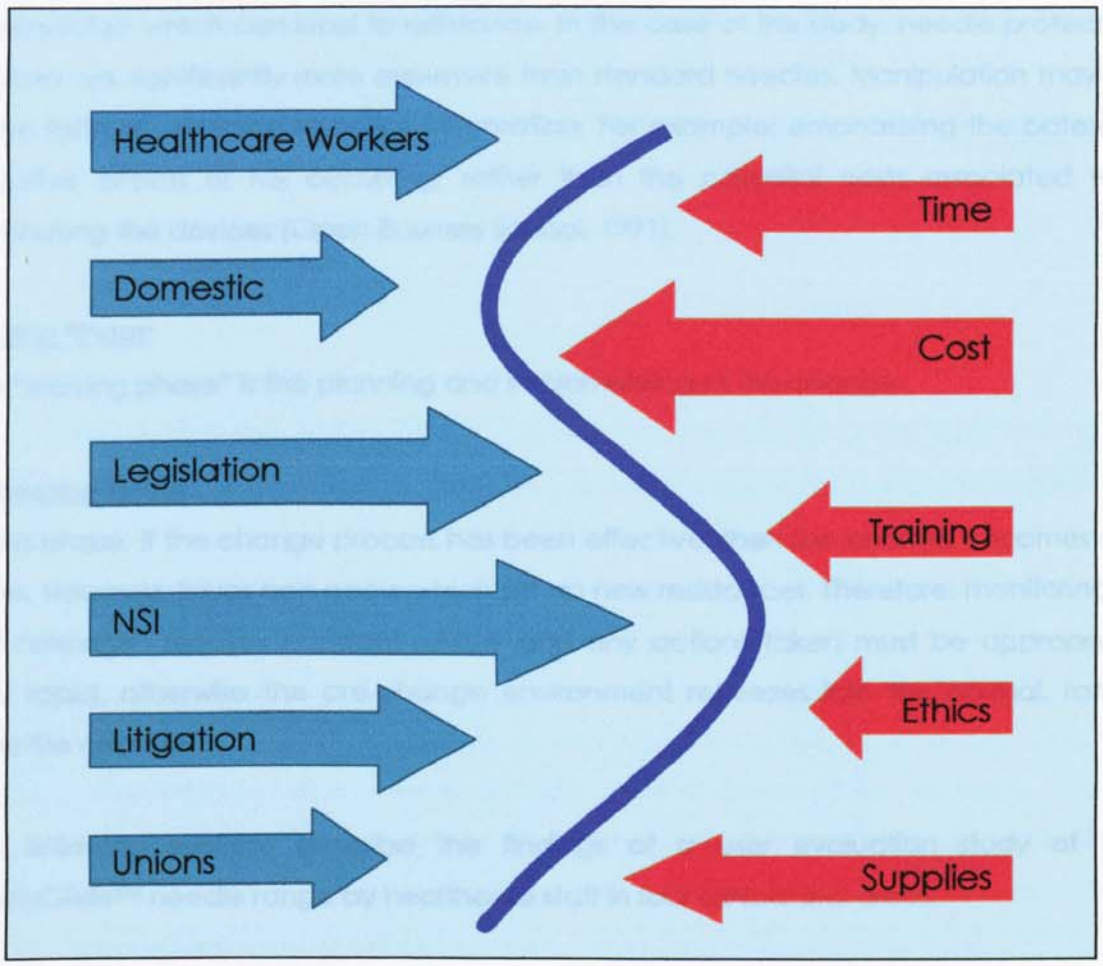
- Unfreezing; the phase when people accept that there is a need for change.
- Moving; putting the change into effect.
- Refreezing; the phase when the "new" behaviours become the norm.

Unfreezing:

The Force Field Analysis was devised by Lewin; it assumes that in any change process there are two sets of forces, those which will help to drive the change process and those which will oppose it.

Figure 4.5 demonstrates some of the driving and opposing forces in a force field analysis associated with the introduction of safety devices within the clinical trial areas.

Figure 4.5: Force Field Analysis Demonstrating the Driving and Opposing Forces for Implementing Safer Needle Devices within Clinical Areas at the UHB NHS Foundation Trust.



Overcoming resistance to any change is paramount to its success and must not be underestimated. Several of methods were utilized by the author to ensure the potential resistance highlighted above was minimised. These included;

Education and communication; in situations where previous knowledge is limited it has been noted that this will often assist with the implementation of change. However, this strategy requires time and effort. Therefore, persuading healthcare workers using accurate information on the number of, and the causes associated with reported NSI in their clinical areas may assist in decreasing resistance (Open Business School, 1991).

Participation and involvement; it has been reported that healthcare workers who participate in and who are involved with the change will be committed to the implementation change. In addition their knowledge and experiences can be incorporated into the change plan (Open Business School, 1991).

Manipulation and co-option; this method has benefits if the change is seen as too expensive. However, individuals involved within the change process may feel manipulated which can lead to resistance. In the case of this study, needle protective devices are significantly more expensive than standard needles. Manipulation may be in the form of providing selective information. For example; emphasising the potential negative effects of NSI occurring, rather than the potential costs associated with purchasing the devices (Open Business School, 1991).

Moving Phase:
The "moving phase" is the planning and implementing of the change.

Refreezing Phase:
In this phase, if the change process has been effective, then the change becomes the norm. However, issues can occur which set up new resistances. Therefore, monitoring of the "change" requires constant review and any actions taken must be appropriate and rapid, otherwise the pre-change environment refreezes into the normal, rather than the change.

The following sections describe the findings of a user evaluation study of the SafetyGlide™ needle range by healthcare staff in four clinical trial areas.

4.1.2 Materials and Methods.

a). Syringe and Needles Used in the Trial.

- SafetyGlide™ needles (BD; Franklin Lakes, New Jersey, USA). Sizes; 21g, 23g and 25g.
- SafetyGlide™ Insulin syringe (BD; Franklin Lakes, New Jersey, USA). Size; 28g.
- Blunt Fill cannula (BD; Franklin Lakes, New Jersey, USA). Size; 18g.
- Luer-lok™ syringes (BD; Franklin Lakes, New Jersey, USA). Sizes; 3ml, 5ml, 10ml, 20ml and 50ml.

b). Educational Programme.

Prior to introducing the SafetyGlide™ devices into the clinical areas staff education programmes were undertaken. Training of the healthcare workers was undertaken by the author and took place in the four trial areas. To ensure that identical instruction was given a "Points to Practice" sheet, was utilized (Appendix 2). Training consisted of both practical demonstrations on how the devices should be used and activated (Figures 4.6 and 4.7), mock use of the devices and in addition, information regarding; product packaging, device selection, aseptic technique, safe disposal and handling. To reinforce the information provided product leaflets were given to each trainee (Appendix 3) and large A3 size posters demonstrating device activation were placed in several areas of each ward and department to facilitate product awareness and to continue reinforcement of good practice.

Figure 4.6: Demonstration of SafetyGlide™ Needle Activation Sequence.

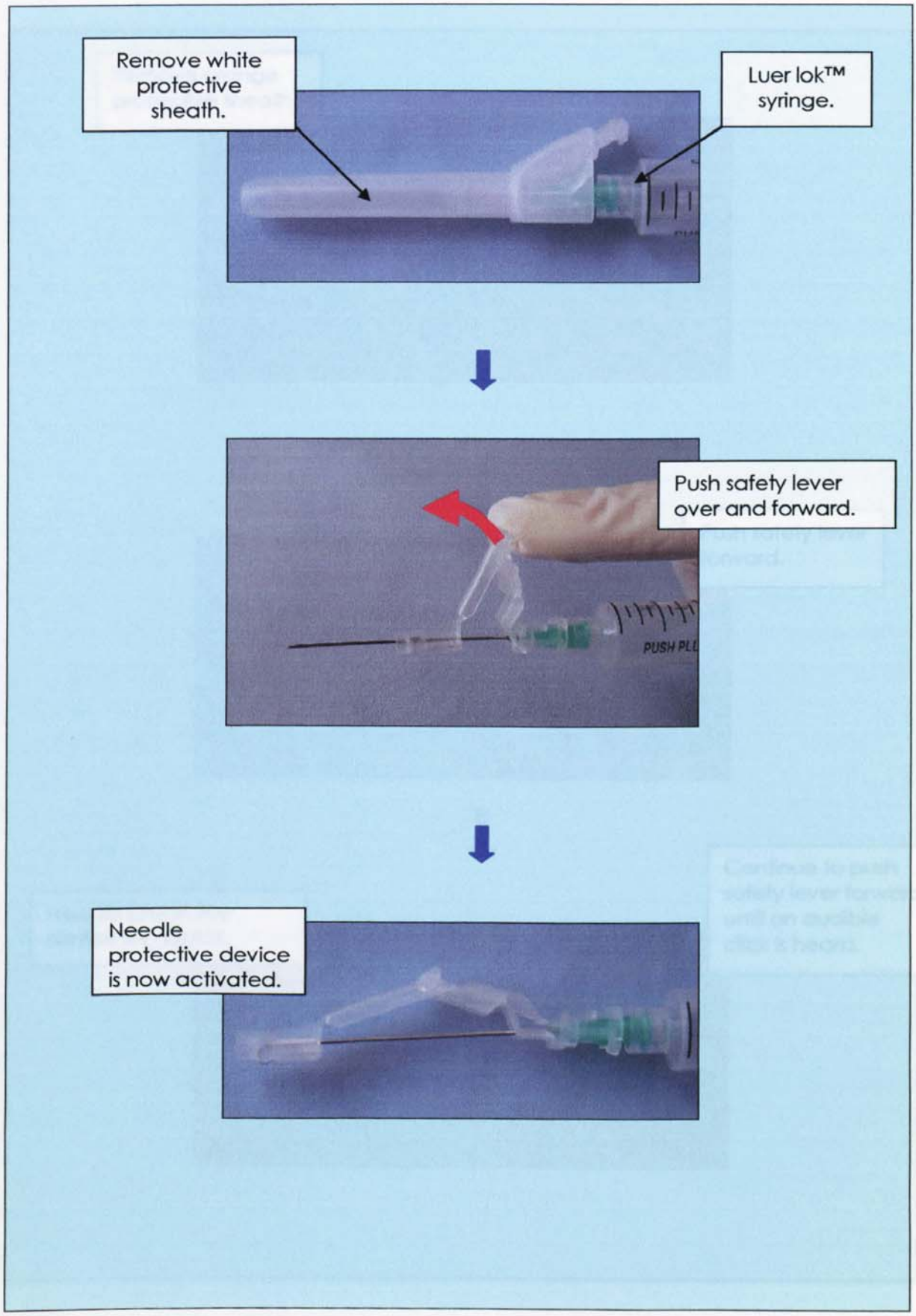
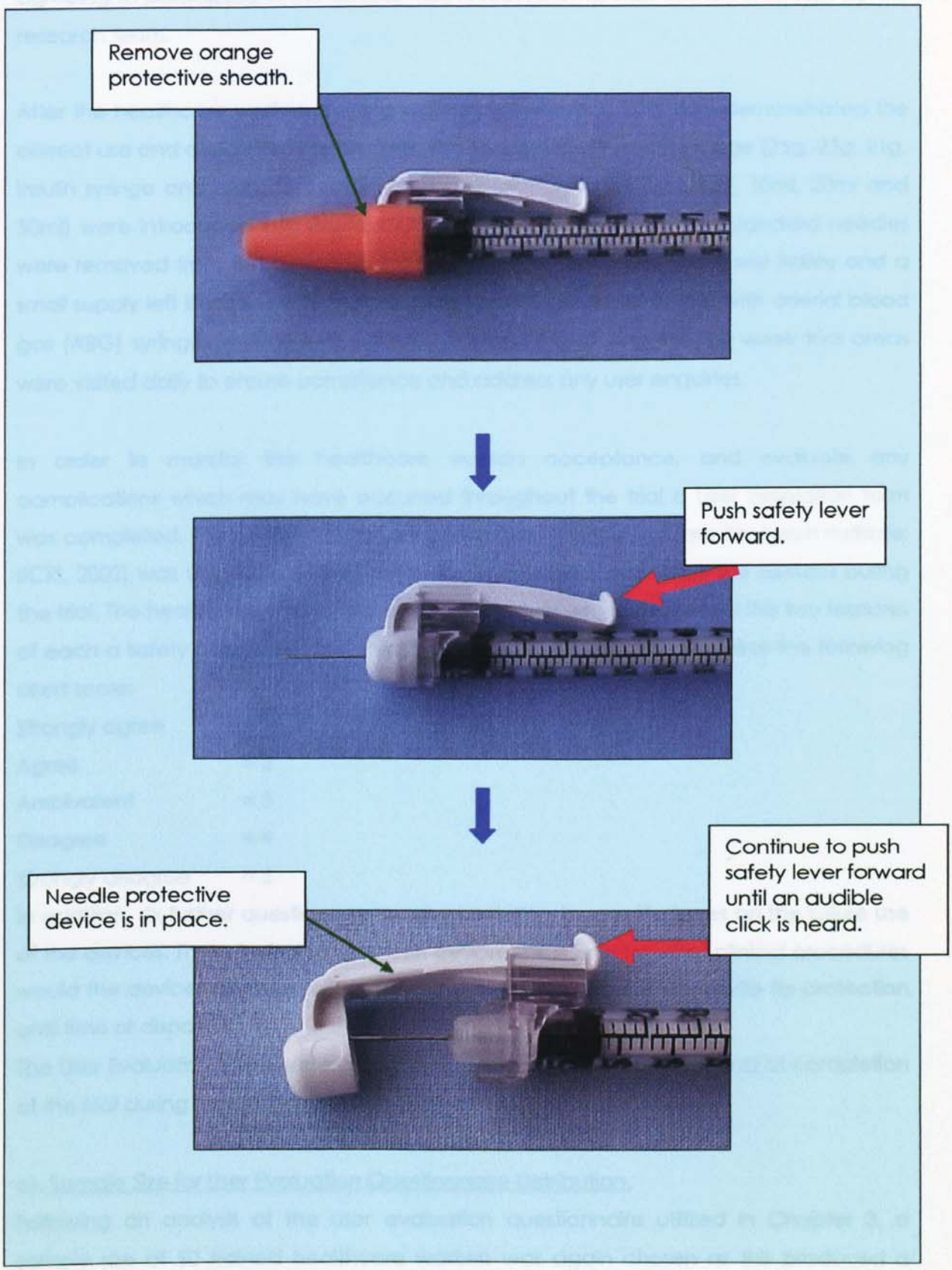


Figure 4.7: Demonstration of SafetyGlide™ Insulin Activation Sequence.



Following training, each healthcare worker completed a consent form (Appendix 4) agreeing to participate in the clinical trial. A record of all staff trained was kept by the research team.

After the healthcare workers training was completed and they had demonstrated the correct use and disposal of the devices, the SafetyGlide™ needle range (25g, 23g, 21g, insulin syringe and blunt fill needle) and Luer-lok™ syringes (2ml, 5ml, 10ml, 20ml and 50ml) were introduced into the four clinical trial areas in April 2003. Standard needles were removed from the clinical trial areas (except for the cardiac arrest trolley and a small supply left in each of the charge nurses offices in order for use with arterial blood gas (ABG) syringes which have slip lock connectors). During the first week trial areas were visited daily to ensure compliance and address any user enquiries.

In order to monitor the healthcare workers acceptance, and evaluate any complications which may have occurred throughout the trial a User Evaluation form was completed. The questionnaire (adapted from Emergency Care Research Institute; ECRI, 2002) was utilized to collect the data from clinical staff using the devices during the trial. The healthcare worker scored 10 statements which evaluated the key features of each a safety needle device. The statements were then rated against the following Likert scale:

Strongly agree	= 1
Agree	= 2
Ambivalent	= 3
Disagree	= 4
Strongly disagree	= 5

In addition, six further questions were asked, relating to specific issues on the future use of the devices. These included; in which clinical areas and for what clinical procedures would the devices be most suitable for and did the devices give needle tip protection until time of disposal?

The User Evaluation forms were distributed at one month, six months and at completion of the trial during month 11 to randomly selected healthcare workers.

c). Sample Size for User Evaluation Questionnaire Distribution.

Following an analysis of the user evaluation questionnaire utilized in Chapter 3, a sample size of 50 trained healthcare workers was again chosen as this produced a mean 95% CI width of <0.5. Assuming a similar variability in responses as in the previous study (i.e. a standard deviation of 1), this sample size was considered sufficient to

detect a difference of 0.6 in the means of the two samples with 80% power at the 5% significance level.

d). Ethics Committee Approval.

Permission to undertake this study was obtained from the UHB NHS Foundation Trust Research and Development Department and the Local Research Ethics Committee prior to its commencement (Appendix 5).

4.1.3 Results of the Healthcare Worker User Evaluation Questionnaire at Week Four and Week Eighteen Following the Introduction of the SafetyGlide™ Needle Protective Devices in the Four Clinical Trial Areas for Eighteen Weeks in 2003.

A total of 54 trained healthcare workers completed the user evaluation questionnaire at week four and 49 trained healthcare workers at week 18. Table 4.1 shows the range of staff grade at each sample point was similar.

Table 4.1: The Grades of Healthcare Workers who Completed the User Evaluation Questionnaires at Week Four and Week Eighteen, Following the Introduction of the SafetyGlide™ Needle Range into the Clinical Trial Areas.

Grades	Number at Week Four	Number at Week Eighteen
Nurse Grade: D	16	12
Nurse Grade: E	16	16
Nurse Grade: F	10	9
Nurse Grade: G	3	3
Nurse Grade: H	0	1
Nurse Grade: student	5	0
Medical grade: Registrar	0	2
Medical grade: Pre-Registration House Officer (PRHO).	3	6
Medical grade: student	1	0
Total	54	49

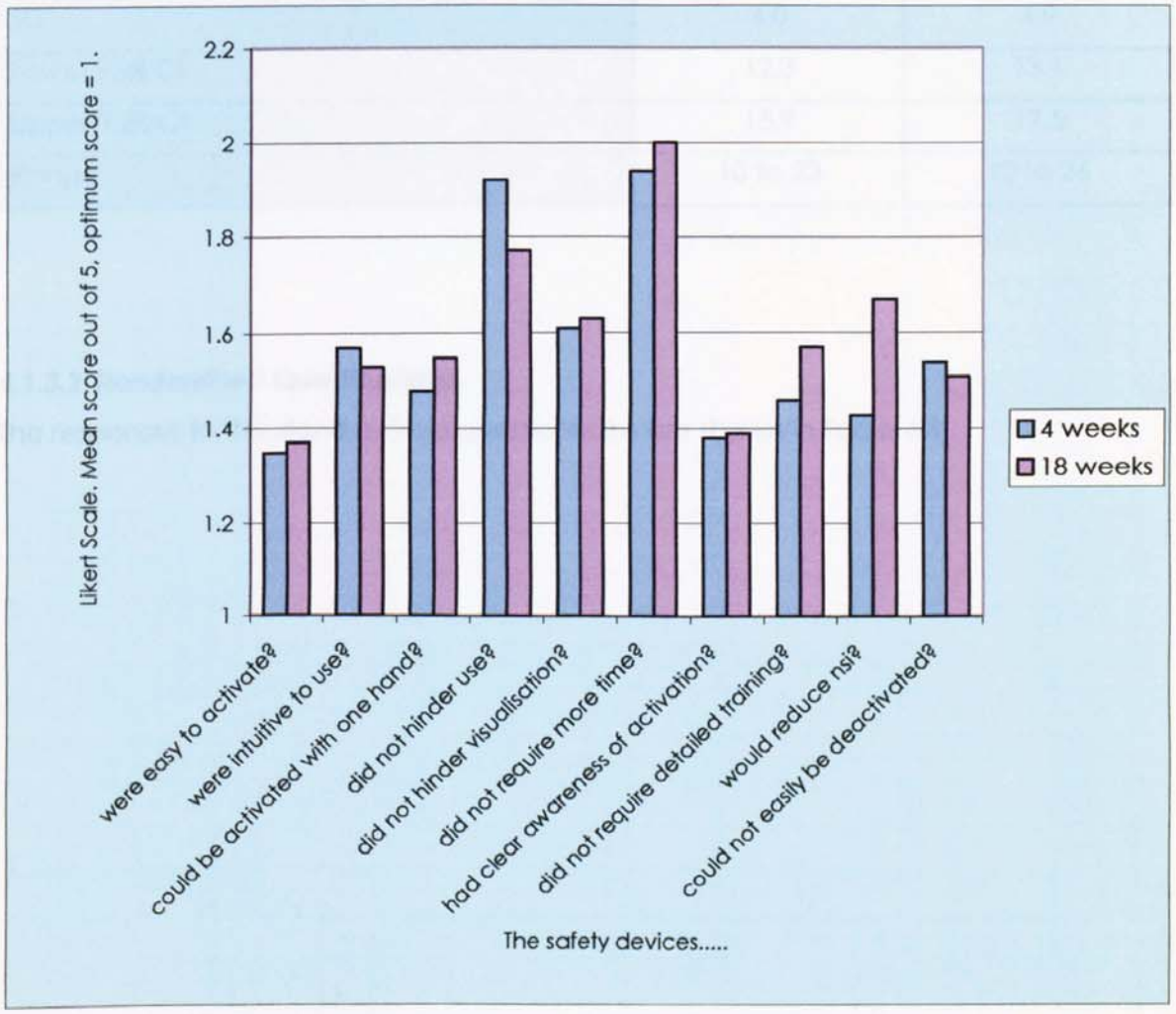
4.1.3.1 Standardised Likert Evaluation.

The first 10 questions of the User Evaluation requested that staff evaluate the products against a standard statement using the Likert scale ; strongly agree = 1, agree= 2, ambivalent= 3, disagree = 4 and strongly disagree= 5 (Table 4.2 and Figure 4.8).

Table 4.2: Evaluation of the SafetyGlide™ Needle Protective Devices (insulin unit and needle) at Week Four Post Introduction (n=54) and Week 18 (n=49) Post Introduction, by Trained Healthcare Staff Working in the Four Clinical Trial Areas at UHB NHS Foundation Trust, 2003.

Statement: The safety devices....	Evaluation (weeks)	Mean score out of 5 (optimum score =1)	SD	95% CI	Range (1 to 5)
- were easy to activate?	4	1.35	0.48	1.22 to 1.48	1 to 2
	18	1.37	0.49	1.23 to1.51	1 to 3
- were intuitive to use?	4	1.57	0.53	1.42 to 1.72	1 to 3
	18	1.53	0.58	1.36 to 1.70	1 to 5
- could be activated using one hand?	4	1.48	0.54	1.35 to 1.63	1 to 3
	18	1.55	0.87	1.30 to 1.80	1 to 3
- did not hinder routine use?	4	1.92	0.96	1.66 to2.19	1 to 5
	18	1.77	0.94	1.50 to 2.0	1 to 4
- did not hinder visualisation of the tip of the needle?	4	1.61	0.74	1.41 to 1.81	1 to 5
	18	1.63	0.83	1.39 to 1.87	1 to 4
- did not require more time to use than conventional products?	4	1.94	1.04	1.66 to 2.23	1 to 4
	18	2.0	1.14	1.67 to 2.33	1 to 5
- had a clear unmistakable awareness of when the safety feature had been activated?	4	1.38	0.52	1.24 to 1.53	1 to 3
	18	1.39	0.61	1.21 to 1.56	1 to 3
- did not require detailed training to use?	4	1.46	0.60	1.30 to 1.63	1 to 3
	18	1.57	0.84	1.33 to 1.81	1 to 4
- would be effective in reducing NSI?	4	1.43	0.60	1.26 to 1.59	1 to 3
	18	1.67	1.03	1.38 to 1.97	1 to 5
- could not be easily deactivated?	4	1.54	0.54	1.40 to 1.68	1 to 3
	18	1.51	0.62	1.33 to 1.69	1 to 4

Figure 4.8: A Comparison of the Mean Scores Awarded by Trained Healthcare Staff, When Evaluating Ten Statements Against a Likert Scale for SafetyGlide Needle Devices at Four Weeks and Eighteen Weeks Post Introduction of the SafetyGlide™ Needle Protective Device range into the Clinical Trial Areas (mean score out of 5, optimum score = 1).



When the total scores awarded by the 25 trained healthcare workers who completed both User Evaluation questionnaires (Table 4.3), are compared there was no significant difference between the scores obtained in weeks four and 18 ($p = 0.64$. Wilcoxin Test; paired, ordinal, non-parametric).

Table 4.3: A Comparison of the Total Scores Awarded by Healthcare Workers Who Completed the Evaluation in Both Week Four and Week Eighteen Post Introduction of the SafetyGlide™ Needle Protective Device range into the Clinical Trial Areas.

	Week Four	Week Eighteen
Mean Score	14.1 (range 10-50)	15.3 (range 10-50)
SD	4.0	4.9
Lower 95% CI	12.3	13.1
Upper 95% CI	15.9	17.5
Range	10 to 23	10 to 26

4.1.3.2 Standardised Questionnaire.

The responses to the standardised questionnaire are shown in Table 4.4.

Table 4.4: A Comparison of the Comments Made by the Healthcare Workers when Evaluating Five Standardised Questions at Week Four and Week Eighteen, Post Introduction of the SafetyGlide™ Needle Devices into the Clinical Areas, During 2003.

Standardised Questions.	Week Four (n=54)	Week Eighteen (n=49)
Did the SafetyGlide™ needle devices give needle tip protection from the time of use through to time of disposal?	100% (n= 54) agreed with the statement.	96% (47 out of 49) of the staff in week 18 agreed that the devices offered them needle protection until disposal. 4% (two out of 49) who did not agree felt the devices were "too cumbersome".
Did the SafetyGlide™ devices become detached from the Luer-lok™ syringe at anytime during their use? "Detachment" was defined as disconnection of the needle from the Luer-lok™ syringe.	100% (n=54) of healthcare workers did not identify any disconnection of the SafetyGlide™ needle from the Luer-lok™ syringe.	2% (one out of 49) reported a disconnection between Luer-lok™ syringe and needle. However, it was noted that it had not been attached correctly. Therefore, this was not a failure of the device.
Was there any perceived difference regarding safety, if a Luer-lok™ syringe was used compared to a slip lock syringe?	59% (32 out of 54) stated that the Luer-lok™ syringe would be safer with a non response rate of 7% (four out of 54).	33% (16 out of 49) stated that the Luer-lok™ syringe would be safer, with a non response rate of 18% (nine out of 49).
In which clinical settings would the devices be of most benefit?	94% (51 out of 54) of the staff who completed the questionnaire responded to this question. The following areas were highlighted; ▪ All areas: 35% (18 out of 51) ▪ Intramuscular/ intravenous/subcutaneous (IM/IV/SC) and phlebotomy: 29% (15 out of 51) ▪ High risk areas: 25% (13 out of 51) ▪ Their current clinical area: 5% (three out of 51) ▪ Community: 5% (two out of 51)	n/a
In which clinical procedures would the devices be of most benefit?	n/a	Ninety-two percent (45 out of 49) of the staff who completed the questionnaire responded to this question. The two following areas were highlighted; ▪ All procedures: 20% (nine out of 45) ▪ IM/IV/SC/phlebotomy: 78% (35 out of 45)
Further comments made.	▪ Needles are a bit longer than normal and hence a bit clumsier, but safety device good. ▪ Like everything new, takes a bit of time. As it will obviously reduce risk of injury then let's keep it up. ▪ Not needed when drawing up drugs. ▪ Lids are very tight, much pressure needed to remove cover. ▪ I like this product. In my view it would help to reduce NSI. ▪ Difficult to see any flashback when taking blood. ▪ Excellent; safe to use. ▪ Needles bend/flimsy/ bendy/flexible. ▪ Good device easy to use. ▪ User friendly and should decrease NSI. ▪ Cumbersome to use. ▪ Did not feel so confident with the safety device. ▪ Popular with staff.	

4.1.4 Results of the Healthcare Worker User Evaluation Questionnaire at Month One, Month Six and Month Eleven Following the Introduction of the SafetyGlide™ Needle Protective Devices in the Four Clinical Trial Areas in 2004.

A total of 51 trained healthcare workers from the four trial areas completed the evaluation forms at one, six and 11 months. Table 4.5 shows the range of staff grades at each sample point was similar. Ten healthcare workers completed all three evaluations.

Table 4.5: Grades of Staff who Completed the Questionnaires at Month One, Month Six and Month Eleven, Post Introduction of the SafetyGlide™ Needle Protective Device range into the Clinical Trial Areas.

	Month One	Month Six	Month Eleven
Nurse Grade: D	17	18	12
Nurse Grade: E	18	17	15
Nurse Grade: F	6	5	12
Nurse Grade: G	2	4	4
Nurse Grade: H	0	1	2
Nurse Grade: student	1	1	2
Medical grade: PRHO	3	4	3
Medical grade: SHO	1	1	1
Medical grade: Registrar	3	0	0
Total	51	51	51

4.1.4.1 Standardised Likert Evaluation.

The first 10 questions requested that staff evaluate the products against a standard statement using the Likert scale provided (Table 4.6 and Figure 4.9).

Table 4.6: Evaluation of the SafetyGlide™ Needle Protective Devices (insulin unit and needle): month one, six and eleven, by Qualified Healthcare Staff working in the Four Clinical Trial Areas at UHB NHS Foundation Trust.

Statement: The safety devices	Evaluation month	Mean score out of 5 (optimum score=1)	SD	95% CI	Range (1-5)
- were easy to activate?	1	1.27	0.45	1.15-1.40	1-2
	6	1.25	0.44	1.13-1.40	1-2
	11	1.56	0.37	1.05-1.26	1-2
- were intuitive to use?	1	1.75	0.84	1.51-1.98	1-5
	6	1.35	0.65	1.17-1.54	1-4
	11	1.45	0.73	1.25-1.65	1-4
- could be activated using one hand?	1	1.65	0.91	1.39-1.90	1-5
	6	1.35	0.52	1.21-1.50	1-3
	11	1.29	0.50	1.15-1.44	1-3
- did not hinder routine use?	1	1.86	0.72	1.66-2.07	1-4
	6	1.57	0.83	1.34-1.80	1-4
	11	1.65	0.91	1.39-1.90	1-4
- did not hinder visualisation of the tip of the needle?	1	1.51	0.58	1.35-1.67	1-3
	6	1.35	0.56	1.20-1.51	1-3
	11	1.45	0.81	1.22-1.68	1-4
- did not require more time to use than conventional products?	1	1.78	0.88	1.54-2.03	1-4
	6	1.55	0.95	1.28-1.82	1-5
	11	1.63	0.92	1.37-1.89	1-4
- had a clear unmistakable awareness of when the safety feature had been activated?	1	1.37	0.53	1.22-1.52	1-3
	6	1.24	0.43	1.12-1.36	1-2
	11	1.22	0.46	1.09-1.35	1-3
- did not require detailed training to use?	1	1.61	0.78	1.39-1.83	1-4
	6	1.51	0.70	1.31-1.71	1-4
	11	1.45	0.67	1.26-1.64	1-3
- would be effective in reducing NSI?	1	1.35	0.52	1.21-1.50	1-3
	6	1.43	0.73	1.23-1.64	1-5
	11	1.24	0.55	1.08-1.39	1-4
- could not be easily deactivated?	1	1.61	0.78	1.39-1.83	1-4
	6	1.47	0.76	1.23-1.64	1-5
	11	1.29	0.73	1.09-1.50	1-5
Overall total (score out of 50, optimum = 10)	1	15.8	4.44	14.48-16.98	10-26
	6	14.2	4.92	12.83-15.60	10-24
	11	13.5	4.12	12.35-14.67	1-5

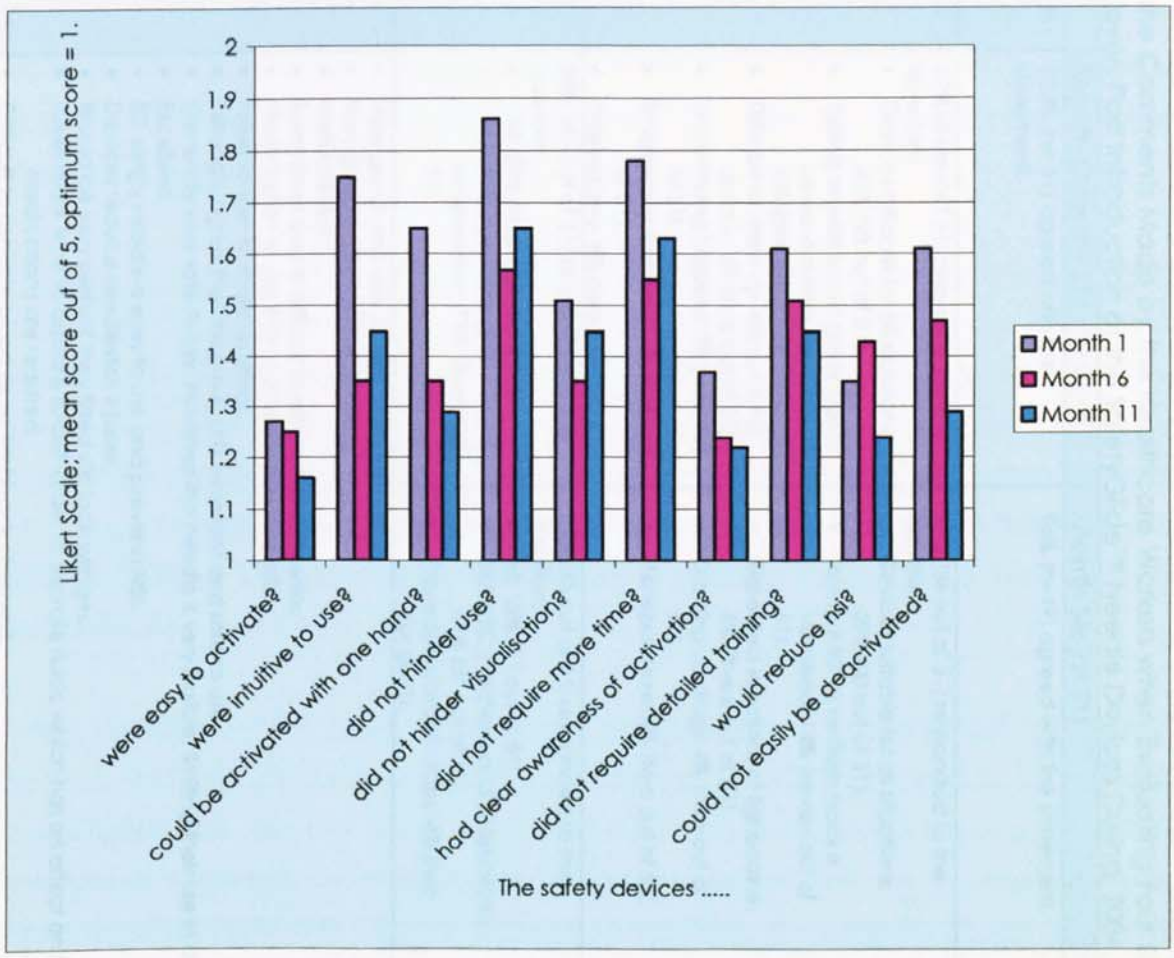
A comparison of the total scores obtained during month one, six and 11 has shown that there was a significant improvement (see below) in healthcare workers perceptions of the SafetyGlide™ needle devices after the first months use and this continued up to month 11.

Statistical analysis: Mann-Whitney Test (ordinal data, non parametric, independent).

- Comparing the results obtained in month one with month six showed a statistically significant improvement (two tailed p value = 0.0355).

- Comparing the results obtained in month one with month 11 showed also demonstrated a significant improvement in healthcare workers appreciation of the devices (two tailed p value = 0.0044).

Figure 4.9: A Comparison of the Mean Scores Awarded by Healthcare Staff, When Evaluating Ten Statements Relating to SafetyGlide Needle Devices at Month One, Month Six and Month Eleven Post Introduction into the Clinical Area (mean score out of 5, optimum =1).



When the total scores awarded by the 10 healthcare workers who completed all three questionnaires in months one, six and 11 (Table 4.6) were compared, there was no significant difference between the scores obtained (p value = 0.22, Friedman Test; related, non parametric, ordinal data).

4.1.4.2 Standardised Questionnaire.

The responses to the standardised questionnaire are shown in Table 4.7.

Table 4.7: A Comparison of the Comments Made by the Healthcare Workers when Evaluating Four Standardised Questions at Month One; Month Six and Month Eleven Post Introduction of the SafetyGlide™ Needle Devices During, 2004.

Standardised Questions.	Month One (n=51)	Month Six (n=51)	Month Eleven (n=51)
Did the SafetyGlide™ needle devices give needle tip protection from the time of use through to time of disposal?	100% (n= 51) agreed with the statement.	96% (n=49) agreed with the statement.	98% (n=50) agreed with the statement.
Are there any procedures the device would not be suitable for?	67% (34 out of 51) responded to the question. • Devices suitable for all situations: 45% (23 out of 51). • Taking arterial blood gases (ABG) as we currently use slip lock syringes: 6% (three out of 51). • Difficult to draw up viscous fluids quickly: 4% (two out of 51) • Undertaking biopsies: 2% (one out of 51). • Emergency situations: 2% (one out of 51). • Phlebotomy: 4% (two out of 51)	67% (34 out of 51) responded to the question. • Devices suitable for all situations: 39% (20 out of 51). • Taking ABG as no flash back is visualised: 14% (seven out of 51). • Repeated injections of lignocaine: 6% (three out of 51). • Drawing up drugs: 4% (two out of 51). • Venepuncture: 4% (two out of 51).	70% (36 out of 51) responded to the question. • Devices suitable for all situations: 41% (21 out of 51). • Taking ABG as no flash back is visualised: 18% (nine out of 51). • Emergency situations: 2% (one out of 51). • Ascitic taps: 2% (one out of 51). • Miscellaneous: 8% (four out of 51).
In which clinical procedures would the devices be of most benefit?	88% (45 out of 51) responded to the question. • All: 20% (nine out of 51). • IM/IV/SC injections and phlebotomy: 71% (36 out of 51).	89% (45 out of 51) responded to the question. • All: 22% (11 out of 51). • IM/IV/SC injections and phlebotomy: 61% (31 out of 51). • Procedures/ascetic taps: 4% (two out of 51).	Month Eleven: 67% (34 out of 51) responded to the question. • All: 8% (four out of 51). • IM/IV/SC injections and phlebotomy: 55% (28 out of 51). • Infectious diseases: 4% (two out of 51).
Further comments made.	• Very good and safe to use. • Very good and practical product. • Useful device. • Sometimes cap is difficult to remove from needle. • Much better to use than conventional products. • Takes longer to draw up drugs. • I strongly agree that this product is excellent and safe to use. • Generally very safe to use. However the needle is very flexible, limiting their use in difficult procedures. • Excellent! • BD safety needle is easy to use and prevents NSI. • Devices reduce needlestick injuries. • Would be very useful if they fitted slip lock syringes. • Takes more time to aspirate fluids/harder to aspirate fluids, which has an affect on repetitive strain when several medications are required. • Difficult to aspirate blood as no flashback observed. • Outer casing is difficult to remove.		

4.1.5 Conclusion.

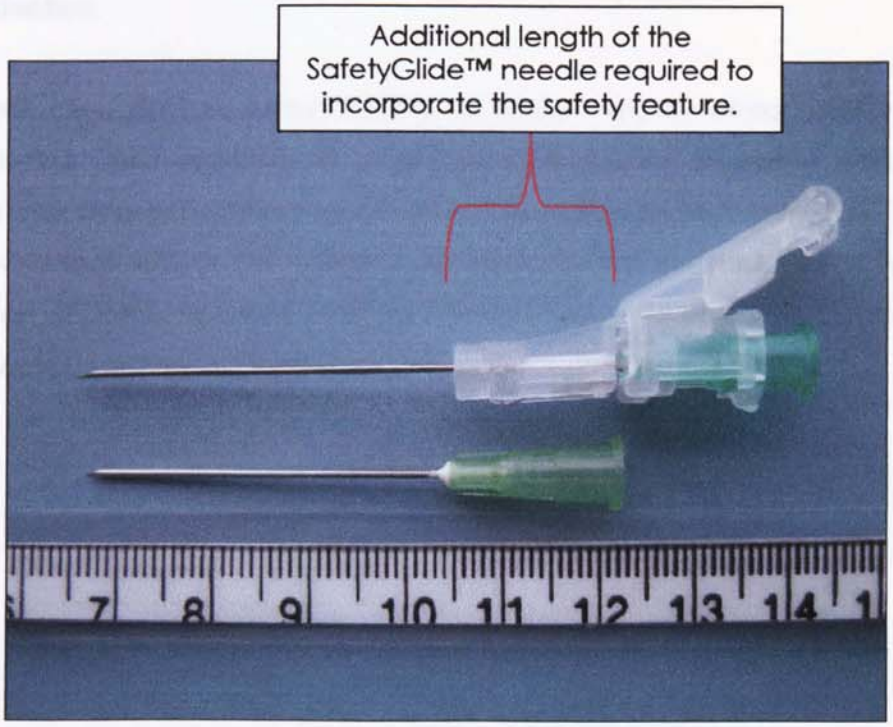
Several authors have highlighted the importance of ensuring a comprehensive training programme for healthcare workers is provided prior to the implementation of safety devices, as this improves compliance and acceptance (OSHA, 1997; Fahey and Henderson, 1999; Alvarado-Ramy *et al.*, 2003; Marini *et al.*, 2004). It is evident from the results of the one year study that the healthcare workers considered that the devices offered them needle protection until disposal and agreed with all 10 statements regarding; safety, compatibility and usability. Statistical analysis of the product evaluation demonstrated that there was a continuous improvement in opinion of the product when comparing the results with the first month. Therefore, when evaluating safety devices for future studies prolonged use and increasing familiarity may result in more reliable findings.

The two statements which continuously received the poorest scores were; "hinders use" and "requires more time" (Table 4.2 and 4.5). When linked to the comments section it is evident that when the SafetyGlide™ needle devices is used, it requires more time to aspirate fluids and therefore may hinder routine practice. This is probably due to the increased length of needle required to facilitate the safety feature, compared to the standard needle length (Figure 4.10). However, when this issue was discussed further, staff reported that the safety features of the devices outweighed the inconvenience that this caused.

When deciding which areas and clinical activities would benefit most from these devices, staff indicated that all areas should be using them. When specific factors had been stated, the two key areas were; high risk areas and situations e.g. phlebotomy and giving injections. In comparison, healthcare workers felt the procedure which these devices would not suitable for were taking ABG; the operator could not easily visualise flash back and secondly the ABG syringes in the UHB NHS Foundation Trust are slip lock and are therefore not compatible with the SafetyGlide™ needles.

To conclude; following training the SafetyGlide™ devices evaluated positively in the three areas of assessment. The study confirms the findings of ECRI (2003) that the devices are suitable for most syringe-needle applications.

Figure 4.10: Length of SafetyGlide™ Needle Compared to a Standard Needle, Measured in cm.



4.2 An Audit of Sharps Box Contents to Assess Whether the SafetyGlide™ Devices Had Been Activated After Use.

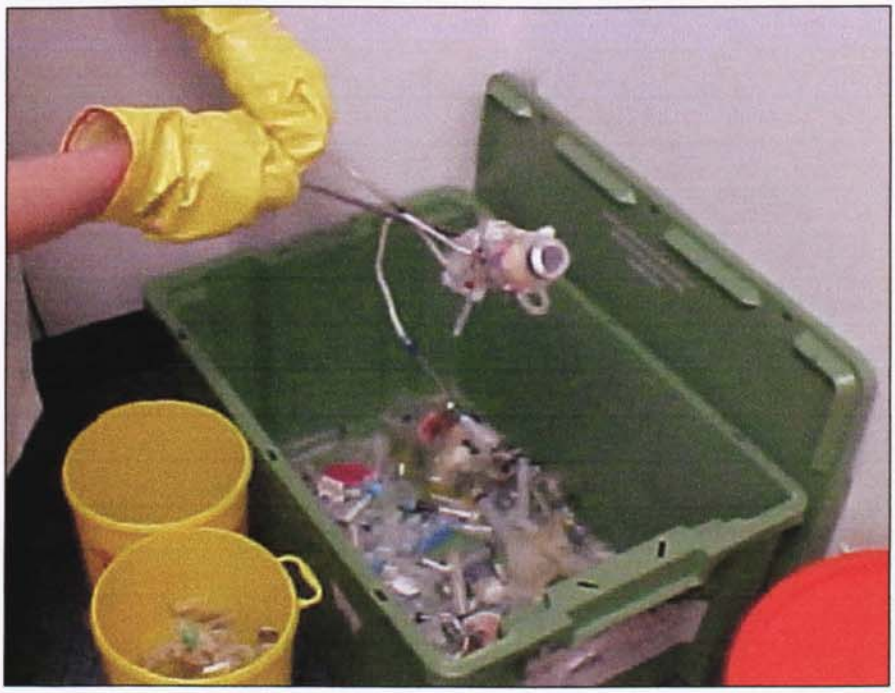
4.2.1 Introduction.

Needle protective devices which require activation are by design, only effective if they are being used correctly. A prospective evaluation of safety syringes which required a one step activation process was undertaken by Mulherin *et al.,* (1996). This study showed that 40% of the needle safe devices had not had their safety feature activated on disposal. To assess whether this would be a factor in the current study an audit of sharps container contents was devised.

4.2.2 Material and Methods.

A total of 200 used SafetyGlide™ needles were evaluated by auditing the contents of sharps containers at one, six and 12 months. In order to reduce the risk of blood borne virus transmission from accidental NSI to the researcher, prior to viewing the contents the sharps containers were autoclaved at 121°C for 15 minutes and the contents discharged into a large box to aid visualisation (Figure 4.11). In addition, further protection was obtained from the use of specialist safety gloves KCL-Stitchstop 180® (KCL, Germany) and forceps.

Figure 4.11: Audit of Sharps Box Contents after Autoclaving.



Permission to undertake this study was obtained from the UHB NHS Foundation Trust Research and Development Department and the Local Research Ethics Committee prior to its commencement (Appendix 5).

4.2.3 Results.

Eight sharps containers which were 2/3rds full were randomly selected from the clinical trial areas after one month's implementation of the SafetyGlide™ needles. Autoclaving the sharps containers at 121°C for 15 minutes resulted in the plastic components being distorted and bound together. This made an accurate quantitative evaluation of the actual number of the SafetyGlide™ needles which had been activated prior to disposal difficult to achieve and offered an unacceptable risk. However as far as could be ascertained the majority of the SafetyGlide™ needles observed had been activated.

4.3 Evaluation of the Impact which Different Interventions had on the Number of Reported Needlestick Injuries within the Eight Clinical Areas at the UHB NHS Foundation Trust between 2001 and 2005.

4.3.1 Introduction.

In order to evaluate the size of the problem associated with NSI within UHB NHS Foundation Trust, a continuous review of all reported injuries commenced in 2001. Four hundred and thirty NSI were reported in this year. To address this situation a robust educational strategy was developed by the Infection Control and Occupational Health Teams which began in 2001.

Following this enhanced educational input, the number of reported NSI fell in 2002 by 29% to 303. However, when healthcare workers knowledge was assessed (Chapter 2) it was evident that retained knowledge was poor and that further direct action was required to address the issues of NSI. Following the safety device open day and a user evaluation study (Chapter 3) it was decided to develop a clinical trial of a needle protective device in four clinical areas and four control areas, to assess the effect on the number of reported NSI over a twelve month period.

This study aimed to quantitatively evaluate the impact of the interventions designed to reduce the number of reported NSI within eight clinical areas at the UHB NHS Foundation Trust; between 2001 and 2005.

4.3.2 Materials and Methods.

a). Data Collection.

Anonamised data of reported contaminated NSI information were obtained from Occupational Health and Risk Management databases.

b). Interventions.

Determination of the effectiveness of the strategies introduced to reduce NSI in four trial and four control areas commenced in 2001.

- During the first year (2001) base line data was gathered and no additional interventions were evaluated.
- During the second year (2002) a robust educational strategy was implemented across the Trust. This incorporated; road-shows, inoculation injury information for Trust employees with all payslips (Appendix 6), a safety device open day, the introduction of sharps trays with integral containers to the clinical areas, inclusion of sharps awareness education in the mandatory healthcare worker updates, a review of inoculation injury and sharps awareness posters in ward areas (Appendix 7) and the determination of reported contaminated NSI rates to the Senior Nurses for dissemination to healthcare workers in their clinical areas.
- During the third year (2003) SafetyGlide™ needle protective devices were introduced into the four trial areas. Standard needles were removed from the clinical areas except for supplies on the cardiac arrest trolleys and for procedures where SafetyGlide™ was deemed not to be suitable by the users. Healthcare workers in the trial areas were trained on how to activate and dispose of the devices safely. A consent form was then completed by the healthcare worker and filed in the study files.

c). Determination of Number of Devices Used.

Information on the number of hypodermic needle devices used in the trial and control areas was obtained from the procurement department at the UHB NHS Foundation Trust.

d). Determination of NSI Rate per 100,000 Devices used.

The NSI rate per 100,000 devices was calculated as follows:

$$\frac{100{,}000}{\text{Number of Devices Used}} \times \text{Number of Reported NSI}$$

e). Determination of Bed Occupancy.

There were a total of 26,282 available bed days per year in the trial wards and 35,770 in the control wards. Determination of the percentage bed occupancy for these wards was undertaken annually; 2001, 2002, 2003 and 2004. Data was obtained from the informatics department at the UHB NHS Foundation Trust. Bed occupancy was calculated as follows;

$$\frac{\text{Total Bed Days Occupied}}{\text{Total Bed Days Available}} \times 100 = \% \text{ Bed Occupancy}$$

f). Determination of Nurse Staffing Levels.

The percentage of nurse staffing on the trial areas was determined as follows:

$$\frac{\text{Actual Nursing Establishment in WTE}}{\text{Funded Nursing Establishment in WTE}} \times 100 = \% \text{ Nurse Staffing Levels.}$$

(WTE = whole time equivalent)

Determination of the nurse staffing levels in the trial areas was undertaken for one month (June) in each year; 2001, 2002, 2003 and 2004. This data was obtained from human resource department at the UHB NHS Foundation Trust.

g). Funding.

Funding for the study was obtained from BD to supply SafetyGlide™ needle devices, blunt needles and Luer-lok™ syringes to the trial areas for a 12 month period at zero cost to the Trust.

h). Ethical Permission.

Permission to undertaken this study was obtained from the UHB NHS Foundation Trust Research and Development Department and the Local Research Ethics Committee prior to commencement (Appendix 4).

4.3.3 Results.

Unfortunately, during 2003 the control wards underwent considerable changes in the ward dynamics caused by having several beds closed for prolonged periods which progressed to the ward eventually being closed and moved to another clinical facility within the hospital. This had a major impact on the study, which culminated in the comparator study being discontinued and a prospective evaluation of the effect of the interventions in the trial wards commencing.

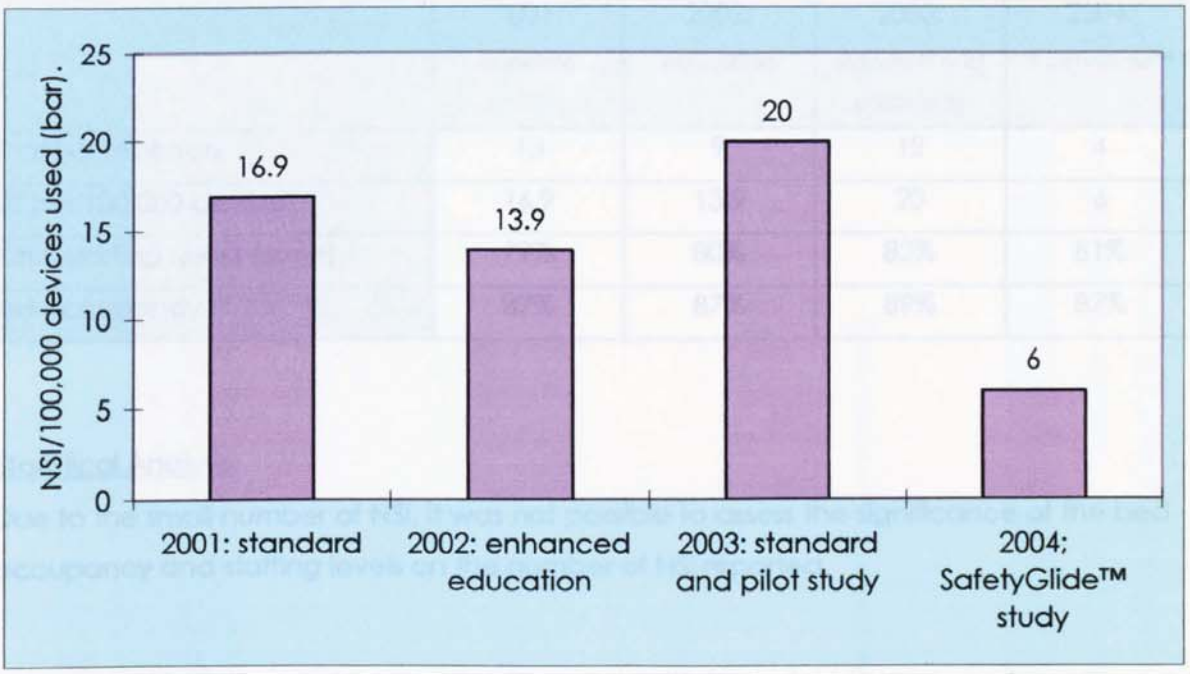
In addition, after 18 weeks the SafetyGlide™ needle trial was suspended in 2003 following the reporting of a serious adverse incident (Chapter 4.4). Therefore, standard needles were re-introduced into the trial wards. The SafetyGlide™ needle protective study recommenced in March 2004 to March 2005.

The impact of the different strategies introduced over the four year period (2001 to 2005) to reduce NSI in the four trial areas was evaluated in relation to 100,000 devices used (Table 4.8, Figure 4.12).

Table 4.8: The Number of Reported Contaminated NSI and the Associated Procedures. The Number of Needles Used and Types per Year; 2001, 2002, 2003 and 2004 in the Clinical Trial Areas is Also Presented.

	2001 standard intervention (52/52)	2002 education (52/52)	2003 standard intervention and 18/52 pilot study	2004 SafetyGlide™ trial (52/52)
Number of:				
• Standard needles used	77,000	64,800	48,350	3,300
• SafetyGlide™ used	0	0	10,750	63,650
TOTAL	77,000	64800	59,100	66,950
Number of NSI reported and associated procedures:				
• Standard needles				
o administration	5	3	4	2
o phlebotomy	3	1	1	1
o disposal	4	5	5	0
o unknown	1	0	1	0
• SafetyGlide™				
o administration	0	0	1	0
o phlebotomy	0	0	0	1
o disposal	0	0	0	0
o unknown	0	0	0	0
TOTAL	13	9	12	4

Figure 4.12: A Comparison of Rates of Reported Contaminated NSI 100,000 Devices within the Trial Area during 2001, 2002, 2003 and 2004.



It is evident from the data comparing NSI per 100,000 devices in 2001 to 2002 that there was a reduction in reported NSI following the implementation of the education programme; 16.9/100,000 devices to 13.9/100,000 devices (18%). This however did not reach statistical significance (Chi-square with Yates correction = 0.056 with 1 degree of freedom. Two tailed $p = 0.827$).

Comparing the data from 2003 to 2004 where SafetyGlide™ devices were implemented for the 12 month study demonstrated a reduction in reported NSI; 20/100,000 devices to 6/100,000 devices (70%). Indeed, there was a significant reduction in reported contaminated NSI following the implementation of the SafetyGlide™ needle protective devices in 2004 (Chi-square with Yates correction = 4.011 with 1 degree of freedom. Two tailed $p = 0.045$).

In order to assess whether the reduction in reported NSI occurred from the introduction of the needle protective devices in to the trial areas and not due to a possible reduction in needle usage, as reported by the NHS Purchasing and Supply Agency (http://www.pasa.doh.gov.uk/medsurg/intravenous/needlestick/prod-needles.stm, accessed 26th September 2003), or a decrease in bed occupancy and staffing levels, the rate of NSI per 100,000 devices used was analysed against the bed occupancy for 2001, 2002, 2003 and 2004 (Table 4.9 and Figure 4.13).

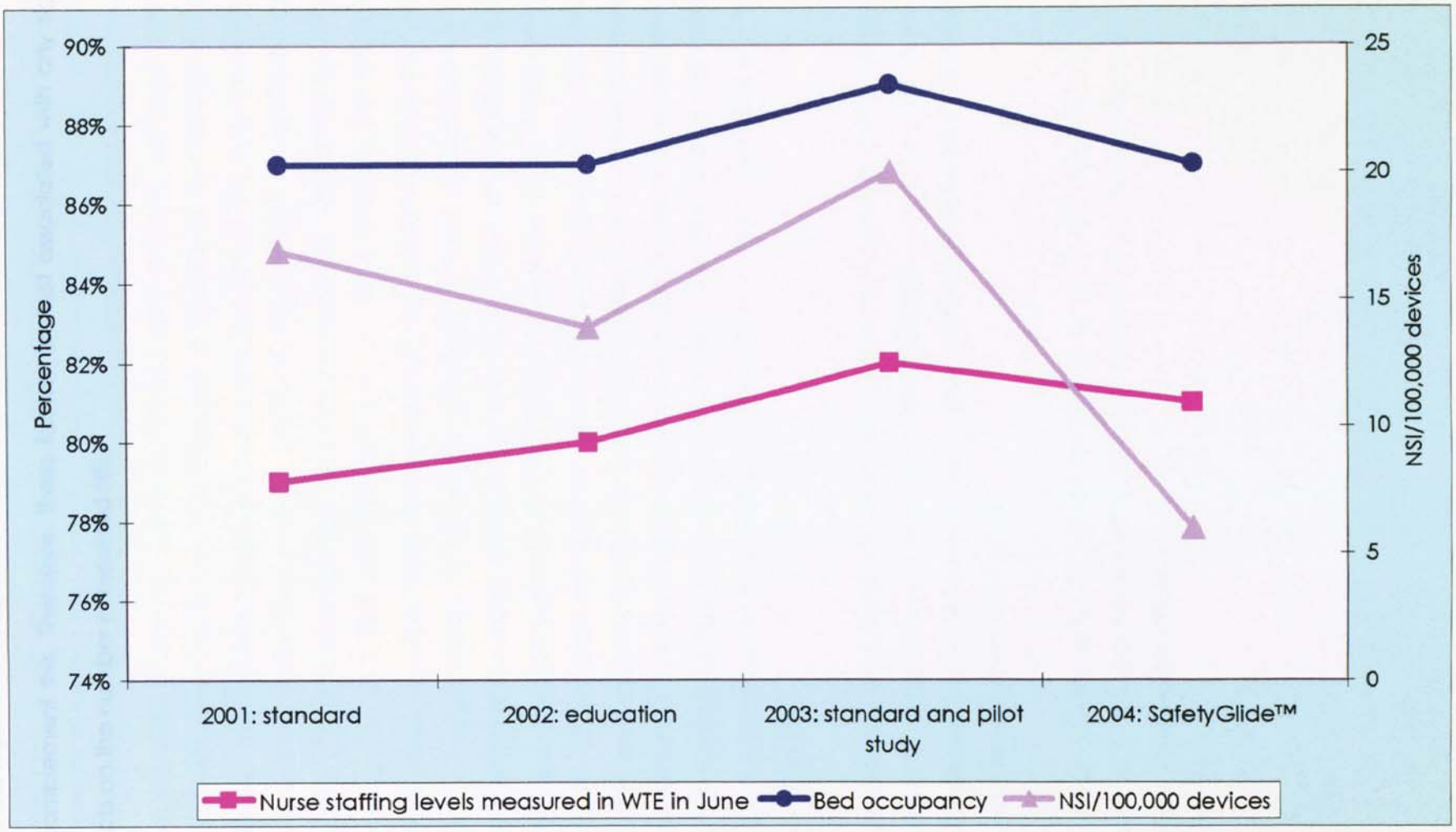
Table 4.9: A Comparison of: Reported NSI, NSI per 100,000 Devices Used, Nurse Staffing Levels and Bed Occupancy in the Clinical Trial Areas; 2001 to 2004.

	2001: standard	2002: education	2003: standard and pilot study	2004: SafetyGlide™
N° of NSI reported	13	9	12	4
NSI per 100,000 devices	16.9	13.9	20	6
Nurse staffing levels (June)	79%	80%	82%	81%
Bed occupancy	87%	87%	89%	87%

Statistical Analysis.

Due to the small number of NSI, it was not possible to assess the significance of the bed occupancy and staffing levels on the number of NSI reported.

Figure 4.13: A Comparison of the Rates of Reported NSI per 100,000 Devices Used with; the Bed Occupancy and the Nurse Staffing Levels Occurring Within the Trial Area during 2001, 2002, 2003 and 2004.



As demonstrated, although the bed occupancy rate increased during 2003 and fell in 2004, this was mirrored by the rise and fall in the number of nursing staff in the trial areas to complement this. Therefore, these factors are not associated with any significant effects on the number of reported NSI.

4.3.4 Conclusion.

The objective of this study was an assessment of the effectiveness of interventions on the number of reported NSI. The results demonstrated an 18% reduction in reported NSI from 16.9/100,000 devices used to 13.9/100,000 devices, following the implementation of the educational strategy; however, this was not statistically significant (p=0.823). In the following year there was an increased in reports of contaminated NSI up to 20/100,000 devices when there was not a continuation of the educational program. Following the introduction of safety needle devices in 2004, a statistically significant reduction of 70% in reported NSI was observed (p=0.045). Similar findings were noted by Younger *et al.* (1992) and Siddhartha *et al.* (2001) following the introduction of safety devices. However, both these studies still had standard devices available in the clinical trial areas. Initially, in this current trial standard devices were removed from all areas except the cardiac arrest trolley and for use with arterial blood gases. ECRI (2003) had assessed SafetyGlide™ as being suitable for most, if not all situations, however, clinical staff felt that for some procedures they were "too bulky", for example, multi-injecting lignocaine and aspirating breast fluid. Standard needles were available for use in these situations. Comparing the numbers of standard devices used with the number of SafetyGlide™ devices during the 2004 clinical trial (3,300 versus 63,650) demonstrates that the reduction in reported NSI was associated with the use of safety devices.

In comparison, previous studies had not reported the possible confounding variables provided by fluctuations in staffing levels and bed occupancy. This current study demonstrated that over the four year period both variables remained constant and did not therefore affect the results.

This study would support the development of a multi-focussed and continuous approach to maintaining healthcare worker awareness and providing an environment in which safety is paramount.

4.4 Serious Adverse Incidents.

The UHB NHS Foundation Trust Research and Development Office (2001) have defined a Serious Adverse Event as

> *"an untoward medical occurrence in a patient during clinical research involving a pharmaceutical product, medical device or clinical intervention that: is fatal, is life threatening, results in persistent or significant disability/incapacity; requires inpatient hospitalisation or prolongs hospitalisation; results in a congenital anomaly in offspring, or an event that may jeopardise the patient or may require intervention to prevent one of the outcomes listed above"* (UHB NHS Trust, 2001).

Number 1.

On the 13th August 2003 a NSI occurred whilst a junior doctor was using a SafetyGlide™ needle to repeatedly re-inject lignocaine into a patient prior to performing a liver biopsy. The patient was known to have HIV and HCV. The incident was reported to the research team on the 14th August 2003. Following an initial investigation and completion of the Healthcare Worker Consent to Interview Following a Needlestick Injury Form (Appendix 8) by the registrar, it was decided to suspend the trial of SafetyGlide™ needles pending further investigation by the lead clinician for that area.

The underlying reason for suspending the clinical trial after this NSI was:

- The doctor stated the NSI occurred because the needle protective device obstructed their view and was "too bulky", causing the device to knock their finger and then penetrate the left middle finger.
- The injury was high risk, which required reporting as a serious adverse event.

The following bodies at UHB NHS Foundation Trust and other interested parties were immediately informed of the incident by the clinical trial team:

- Risk Management Team and Clinical Governance Director.
- Local Research Ethics Committee and Research and Development Office.
- Occupational Health Team, who reported the incident to the Health and Safety Executive (HSE) and RIDDOR (The Reporting of Incidents, Diseases and Dangerous Occurrences Regulations, 1985).
- The HSE is a statutory body whose aim is to protect workers and those who may be affected by work related activities. It is the enforcement agency for the Health and Safety at Work Act 1974, COSHH 1994, Management of Health and Safety at Work Regulations 1994 and RIDDOR 1995. Under RIDDOR it is a legal

requirement that employers report any "Dangerous Occurrences". A dangerous occurrence is a specified event which may not result in a reportable injury, but may have the potential to do significant harm e.g. a NSI from a syringe known to contain hepatitis B positive blood.

- Becton Dickinson: Medical Research Director.
- On investigation by the Occupational Health and Safety team it was decided that the incident did not require reporting to the Medical Devices Agency (MDA) as the device had not failed.

On completion of the investigation by the lead clinician, it was noted that practices related to the procedure of injecting lignocaine prior to a biopsy required review; this was subsequently undertaken and procedures amended accordingly. The NSI which instigated this investigation was not found to be directly associated with the safety device, therefore the investigator recommended that the devices should be reinstated on the unit and the trial recommenced.

Number 2.

On the 15th June 2004 a fifth year medical student who was visiting the ward obtained blood from a patient using a syringe and SafetyGlide™ needle. Whilst filling the blood collection tube the syringe slipped, causing a NSI from a patient who was assessed as being a low risk for a blood borne virus. The medical student reported the NSI to Occupational Health and completed a UHB NHS Foundation Trust incident report. The research team reported the incident to the Medical Research Director at Becton Dickinson and the South Birmingham Research Ethics Committee. The SafetyGlide™ needle was found not to be a direct cause of the injury and no further action was taken.

4.5 Cost Benefit Analysis.

4.5.1 Introduction.

The introduction of needle protective devices into the clinical arena is an expensive investment in protecting healthcare workers from the potential risk of an occupationally acquired blood borne virus. Therefore, it is essential that any devices chosen are fully evaluated by the healthcare workers who will use them and have been found to be suitable for their intended purpose.

Following a systematic evaluation of the intended device, a cost benefit analysis should be undertaken to determine the predicted annual change in expenditure. This is a measure of the expected cost increases associated with device implementation compared with the standard devices currently used. However, a court in Scotland has deemed that any decision by an employer not to provide safer equipment could not be justified on the grounds of cost alone (Skinner versus the Scottish Ambulance Service, 2004).

The aims of this study were to determine the costs associated with the implementation of SafetyGlide™ needle protective devices into the four trial areas.

4.5.2 Materials and Methods.

4.5.2.1 Determination of the Initial Financial Costs Associated with a Needlestick Injury at the UHB NHS Foundation Trust.

- Costs associated with pharmacology treatments were obtained from the British National Formulary 49 (BNF, 2005).
- Nurses pay scales were obtained from the Royal College of Nursing (RCN, 2005).
- Costs of serological tests for hepatitis B, C and HIV were obtained from the clinical microbiology department at the UHB NHS Foundation Trust.
- Costs associated with legal claims were obtained from the legal services department at the UHB NHS Foundation Trust.

4.5.2.2 Determination of the Financial Costs Associated the Initial Six Months Treatment of a Healthcare Worker who has Seroconverted to Hepatitis B, Hepatitis C or HIV.

- Costs associated with pharmacology treatments were obtained from the BNF 49, (2005).
- Consultant pay scales (mid grade, basic salary) were obtained from the National Health Service (NHS) Career (2005a).
- Senior Pharmacist pay scales were obtained from the NHS Careers (2005b).
- Dietician pay scales were obtained from NHS Careers (2005b)
- Costs of serological tests were obtained from the clinical microbiology department at the UHB NHS Foundation Trust and Heartlands Hospital NHS Foundation Trust.

4.5.2.3 Determination of the Financial Costs Associated with the Introduction of Safety Needles within the Four Trial Areas.

- Information on the cost and number of hypodermic needle devices used in the trial and control areas were obtained from UHB NHS Foundation Trust; Procurement Department.
- Costs of SafetyGlide™ needle protective devices (personal correspondence).

4.5.2.4 Determination of the Cost Benefit Analysis for the Introduction of the SafetyGlide™ Needle Protective Device Range.

The cost per 1000 beds associated with NSI and devices was calculated as follows:

$$\frac{1{,}000}{\text{Number of Bed Days Available/Year (26,300 approx on 3 clinical wards)}} \times \text{Cost/Year}$$

4.5.2.5 Determination of the Legal Costs Associated with Needlestick Injuries within the Four Clinical Trial Areas at the UHB NHS Foundation Trust during the Four Year Period; 2001 to 2005.

- Data was obtained from UHB NHS Foundation Trust; Legal Department.

4.5.3 Results.

4.5.3.1 Determination of the Initial Financial Costs Associated with a Needlestick Injury at the UHB NHS Foundation Trust.

The financial burden of the initial costs sustained by the UHB NHS Foundation Trust for a mid range, E grade staff nurse who receives a contaminated NSI are:

- Low risk NSI: £118.30
- Hepatitis B NSI (non immune member of staff): £1539.53
- Hepatitis C NSI: £235.23
- HIV NSI: £938.23

These costs include; occupational health assessment, administration, laboratory investigation and drug prophylaxis. A breakdown of the expenditure is detailed in Table 4.10. However, these cost are only the financial ones, and do not reflect the personal costs experienced by the healthcare worker, nor the additional costs born by the National Health Service, should the healthcare worker seroconvert.

Table 4.10: Evaluation of Initial Costs Associated with NSI; 2005 (part 1 of 2).

Low Risk NSI Assessment	
Initial Assessment	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment (Occupational Health Advisor; OHA, mid G grade nurse): 30 minutes,	£7.07
Counselling (OHA, mid G grade nurse): 30 minutes	£7.07
Staff/Patient Screening	
Staff member: Anti hepatitis B serum and blood storage	£12.72
Patient blood testing: Hepatitis B virus antigen test	£9.88
Patient blood testing: Hepatitis C virus antibody test	£14.14
Patient blood testing: HIV antibody test	£22.61
Post Inoculation Prophylaxis	
Hepatitis B booster	£8.70
Administration	
Management (mid I grade nurse): 30 minutes	£8.32
Follow up Assessment	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment (OHA, mid G grade nurse): 30 minutes	£7.07
TOTAL ESTIMATED COST	**£118.30**

High Risk NSI Assessment: Confirmed Hepatitis B Source Patient.	
Initial Assessment	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment (OHA, ,mid G grade nurse): 30 minutes	£7.07
Counselling (OHA, mid H grade nurse): 1 hour	£15.13
Staff/Patient Screening	
Staff member: Anti hepatitis B serum and blood storage	£12.72
Patient blood testing: Hepatitis B virus antigen test	£9.88
Patient blood testing: Hepatitis C virus antibody test	£14.14
Patient blood testing: HIV antibody test	£22.61
Post Inoculation Prophylaxis	
Hepatitis B booster	£8.70
Hepatitis B virus immunoglobulin	£1,250.00
Hepatitis B virus vaccination; accelerated course (x3)	£26.10
Administration	
Management (mid I grade nurse): 30 minutes	£8.32
Follow up Assessment at; 6/52; 12/52; 24/52	
1 hour nursing time away from ward (mid E grade nurse) (x3)	£31.08
Assessment (OHA, mid H grade nurse): 30 minutes (x3)	£22.80
Staff member: Hepatitis B virus antigen test (x3)	£29.64
Administration costs (x3)	£30.00
Follow up Assessment at 60/52	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment (OHA, mid H grade nurse): 30 minutes	£7.60
Staff member: Hepatitis B virus antibody test	£12.72
Administration costs	£10.00
TOTAL ESTIMATED COST	**£1,539.13**

Table 4.10 Continued: Evaluation of Initial Costs Associated with NSI; 2005 (part 2 of 2).

High Risk NSI Assessment: Confirmed Hepatitis C Source Patient.	
Initial Assessment	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment:(OHA , mid G grade nurse): 30 minutes	£7.07
Counselling (OHA, mid H grade nurse): 1 hour	£15.13
Staff/Patient Screening	
Staff member: Anti hepatitis B serum and blood storage	£12.72
Patient blood testing: Hepatitis B virus antigen test	£9.88
Patient blood testing: Hepatitis C virus antibody test	£14.14
Patient blood testing: HIV antibody test	£22.61
Post Inoculation Prophylaxis	
Hepatitis B booster	£8.70
Administration	
Management: 30 minutes (mid I grade nurse)	£8.32
Follow up Assessment at: 6/52; 12/52; 24/52	
1 hour nursing time away from ward (mid E grade nurse) (x3)	£31.08
Assessment (OHA ,mid H grade nurse): 30 minutes (x3)	£22.80
Staff member: Hepatitis C antibody test (x3)	£42.42
Administration costs (x3)	£30.00
TOTAL ESTIMATED COST	**£235.23**

High Risk NSI Assessment: Confirmed HIV Source Patient.	
Initial Assessment	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Assessment (OHA ,mid G grade nurse): 30 minutes	£7.07
Counselling (OHA ,mid H grade nurse): 1 hour	£15.13
Consultant genito-urinary medicine physician (mid grade): 30 minutes	£20.25
Initial Staff/Patient Screening	
Patient blood testing: Hepatitis B virus antigen test	£9.88
Patient blood testing: Hepatitis C virus antibody test	£14.14
Patient blood testing: HIV antibody test	£22.61
Staff member: Full Blood Count (FBC), Urea and Electrolytes (U and E) and Liver Function Tests (LFT)	£8.82
Staff member: Anti hepatitis B serum and blood storage	£12.72
Post Inoculation Prophylaxis: 4 weeks treatment	
Hepatitis B booster x1	£8.70
Combivir: Zidovudine 600mg/day and Lamivudine 300mg/day	£319.67
Nelfinavir; 2,500mg/day	£300.00
Metaclopramide; 3 tablets/day	£2.80
Loperamide as required	£18.48
Follow up Assessment at: 2/52; 6/52	
Consultant virologist (mid grade): 1 hour (x2)	£40.50
FBC, U and E and LFT (x2)	£17.64
Administration	
Management (mid I grade nurse): 30 minutes	£8.32
Follow up Assessment at: 12/52; 26/52	
1 hour nursing time away from ward (mid E grade nurse) (x2)	£20.72
Assessment (OHA, mid H grade nurse): 30 minutes (x2)	£15.20
Staff member: HIV test (x2)	£45.22
Administration costs (x2)	£20.00
TOTAL ESTIMATED COST	**£938.23**

4.5.3.2 Determination of the Financial Costs Associated with the Initial Treatment of a Healthcare Worker who has Seroconverted to Hepatitis B, Hepatitis C or HIV.

The approximate costs associated with the initial six to 12 months therapy of an E grade staff nurse who has seroconverted to hepatitis B, C or HIV are:

- Hepatitis B; £607.24
- Hepatitis C; £7298.25
- HIV; £937.85

Breakdowns of the costs are detailed in Table 4.11. These costs are approximated as each infected patient will have their treatment tailored to their individual needs. The costs include; assessment, drug therapies and serological tests. The costing does not take into account the personal and psychological costs experienced by the healthcare worker and their families nor the potential effects on future career options should the treatments be unsuccessful.

Table 4.11: Evaluation of the Initial Costs Associated with an E grade Nurse Who Has Seroconverted to a Blood Borne Virus; HBV, HCV or HIV (part 1 of 3).

Acute Hepatitis B Viral Infection Confirmed Seroconversion	
Initial Assessment: time zero	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Consultant hepatologist (mid grade): 30 minutes	£20.25
Screening: time zero	
Hepatitis B virus antigen test	£9.88
Hepatitis B IgM	£16.45
HBV DNA	£53.85
LFT and ALT	£4.24
U and E	£2.43
FBC	£2.15
Liver microsomal antibodies	£2.23
Liver antibodies blot	£21.45
Assessments: Month One, Two, Three, Four and Five.	
Consultant hepatologist (mid grade): 10 minutes (x5)	£33.75
1 hour nursing time away from ward (mid E grade nurse, x5)	£51.80
Screening: Month One, Two, Three, Four and Five.	
Hepatitis B virus antigen test (x5)	£49.40
Hepatitis B IgM (x5)	£82.25
Hepatitis eAg status (x5)	£59.85
LFT an ALT (x5)	£21.20
U and E (x5)	£12.15
FBC (x5)	£10.75
Liver microsomal antibodies (x5)	£11.15
Liver antibodies blot (x5)	£107.25
Six Monthly Review	
Consultant hepatologist (mid grade): 15 minutes	£10.13
Clinical Nurse Specialist (CNS; mid H grade nurse): 15 minutes	£3.91
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Total Cost	£607.24
90% to 95% of patients with acute HBV infection lose detectable levels of HBsAg by six months (Moonka and O'Brien, 1999).	

Table 4.11: Evaluation of the Initial Costs Associated with an E grade Nurse Who Has Seroconverted to a Blood Borne Virus; HBV, HCV or HIV (part 2 of 3).

Acute Hepatitis C Viral Infection Confirmed Seroconversion.	
Initial Assessment: time zero	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Consultant hepatologist (mid grade): 30 minutes	£20.25
CNS (mid H grade nurse): 30 minutes	£7.81
Screening: time zero	
Hepatitis C RNA	£56.83
LFT and ALT	£4.24
U and E	£2.43
FBC	£2.15
Liver microsomal antibodies	£2.23
Liver antibodies blot	£21.45
Thyroid Function Tests (TFT)	£9.20
Drug Therapy	
Pegylated Interferon (Pegasys®; Roche. 180µg SC weekly injection=£142). Therefore, 26 injections for 6 months	£3,692
Ribavirin (1g/day, based upon weight. Roche. 168x200mg tablets = £497.28. Therefore 930 tablets for 6 months	£2,983
Month One: x4 Weekly Injection Training	
CNS (mid H grade nurse): 15 minutes (x4)	£15.62
1 hour nursing time away from ward (mid E grade nurse, x4)	£41.44
Assessments: Month One, Two, Three, Four, Five and Six	
Consultant hepatologist (mid grade): 15 minutes (x6)	£60.75
Senior Pharmacist (mid F grade): 10 minutes (x6)	£21.82
1 hour nursing time away from ward (mid E grade nurse, x6)	£62.16
Screening: Month One, Two, Three, Four, Five and Six	
LFT and ALT (x6)	£25.44
U and E (x6)	£14.58
FBC (x6)	£12.19
TFT (x6)	£9.20
Early Virological Response Test (EVR) at Month 3: hepatitis C polymerase chain reaction (PCR) quantitative essays (x2) at Month 3	£186.00
Hepatitis C Antibody test (x1) at end of treatment	£14.14
Assessment: Month Twelve	
Consultant hepatologist (mid grade): 15 minutes	£12.13
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Screening: Month Twelve	
Hepatitis C Antibody test (x1) 6/12 post treatment	£14.14
LFT and ALT	£4.24
U and E	£2.43
FBC	£2.15
TOTAL COST	£7,298.25
If Hepatitis C antibody test = negative then treatment was successful (80% to 90% success rate reported Gow and Mutimer, 2001). A positive result indicates treatment has failed and currently no further treatment is available.	

Table 4.11: Evaluation of the Initial Costs Associated with an E grade Nurse Who Has Seroconverted to a Blood Borne Virus; HBV, HCV or HIV (part 3 of 3).

HIV Infection; confirmed seroconversion.	
Initial Assessment: time zero	
1 hour nursing time away from ward (mid E grade nurse)	£10.36
Consultant virologist (mid grade): 30 minutes	£20.25
CNS (mid H grade nurse): 30 minutes	£7.81
Dietician (mid grade senior 1): 30 minutes	£6.70
Pharmacist (mid Grade F): 30 minutes	£10.91
Screening: time zero	
HIV Antibodies	£23.93
LFT and ALT	£4.24
U and E	£2.43
Creatine Phosphokinase	£1.03
Gamma Glutamyltranspeptidase	£1.03
Amylase	£3.73
Total and High Density Lipoprotein Cholesterol	£3.60
Triglycerides	£1.03
Phosphate	£0.89
Viral load	£58.49
Resistance test	£209.56
CD4	£23.90
FBC	£2.15
Glucose 6 Phosphate Dehydrogenase	£3.75
Haemoglobin Electrophoresis	£5.62
Sickle cell	£8.31
Toxoplasma IgG	£10.46
Cytomegalovirus IgG	£10.46
Hepatitis A virus antigen test	£16.45
Hepatitis B virus antigen test	£9.88
Hepatitis C RNA	£56.83
Syphilis serology	£11.97
Chest X-ray	£30.00
Follow up assessments at Week 2, Month 3 and Month 6 (3 monthly there after)	
1 hour nursing time away from ward (mid E grade) (x3)	£31.08
Consultant virologist (mid grade): 30 minutes (x3)	£60.75
CNS (mid H grade nurse): 30 minutes (x3)	£23.43
Viral load (x3)	£175.20
CD4 (x3)	£71.70
U and E (x3)	£7.29
LFT and ALT (x3)	£12.72
TOTAL COST	£937.85
Patients are monitored three monthly; CD4 and Viral load levels are indicative of when antiviral therapy should be considered.	

4.5.3.3 Determination of the Financial Costs Associated with the Introduction of Safety Needles within the Four Trial Areas.

In 2004, a total of 63,650 SafetyGlide™ devices were used in the clinical trial areas. The purchase costs associated with these prototype devices would have been £16,679.85. The same size, gauge and number of standard devices would have cost the trial areas £1,138.82. The introduction of the SafetyGlide™ needle device range would have incurred a 15 fold increase in costs had the clinical areas purchased the devices rather than participated in the trial. However, the cost of an alternative safety device such as Eclipse™ would have been £7,147 (Table 4.12).

Table 4.12: Total Number of Needle Protective Devices Used in 2004 and the Financial Costs Attributed to their Purchase and a Comparison with the Costs of Similar Standard Devices.

Month: 2004-2005	Number of Boxes					Total Cost
	Blunt Needle (BD) 100/box	SafetyGlide™ Prototype Needles (BD) 50/box			SafetyGlide™ Insulin (BD) 100/box	
		21g	23g	25g		
Mar	12	45	53	6	8	
Apr	2	17	40	2	0	
May	2	26	52	4	0	
Jun	4	25	54	9	1	
Jul	5	44	75	3	1	
Aug	5	28	49	4	0	
Sep	4	34	52	3	2	
Oct	8	26	36	7	5	
Nov	4	44	61	3	0	
Dec	4	39	63	0	2	
Jan	4	28	60	15	4	
Feb	5	38	60	0	2	
TOTAL	59x100	394x50	655x50	56x50	25x100	
Cost; SafetyGlide™ Prototype Devices (BD)						
Cost/box	£6.40/100	£14.20/50	£14.20/50	£14.20/50	£24.45/100	
Cost/year	£377.60	£5,594.80	£9,301.00	£795.20	£611.25	£16,679.85
Cost; Eclipse™ Safety Devices (BD)						
	Blunt Needle (BD)	Eclipse™ Safety Devices (BD)			SafetyGlide™ Insulin (BD)	
Cost/box	£6.40/100	£11.13/100	£11.13/100	£11.13/100	£24.45/100	
Cost/year	£377.60	£2,193.00	£3651.30	£311.70	£611.25	£7,146.75
Cost; Standard Devices						
Manufacturer	Terumo	Terumo	Terumo	BD	Terumo	
Cost/box	£1.98/100	£1.53/100	£1.53/100	£1.64/100	£6.96/100	
Cost/year	£116.82	£301	£501.08	£45.92	£174.00	£1,138.82

4.5.3.4 Determination of the Cost Benefit Analysis for the Introduction of the SafetyGlide™ Needle Protective Device Range.

The total costs associated with NSI for 2001 to 2004 in the trial areas was determined using a costs benefit analysis worksheet (Table 4.13). In order to compare the results obtained in this study with other published data, a comparison of the total costs (devices, costs associated with initial treatment of NSI and compensation and legal claims) per 1,000 bed days (Section 4.5.2d) was evaluated.

- In 2001 the cost per 1,000 bed days (N.B. one litigation claim is currently being processed):

  $\frac{1,000}{26,300}$ x £6,801 = £259

- In 2002 the cost per 1,000 bed days:

  $\frac{1,000}{26,300}$ x £2,310 = £88

- In 2003 the cost per 1,000 bed days:

  $\frac{1,000}{26,300}$ x £3,539 = £135

- In 2004 the cost per 1,000 bed days:

  $\frac{1,000}{26300}$ x £17,270 = £657

Therefore, to replace standard needles with safety needles additional costs of £398 (2001) to £569 (2002) per 1,000 bed days would be incurred by the UHB NHS Foundation Trust.

Table 4.13: Cost Benefit Analysis for the Implementation of SafetyGlide™ Needle Protective Devices within Four Clinical Areas at the UHB NHS Foundation Trust.

Cost Benefit Analysis Worksheet: Complete Replacement.					
Standard needles					
		2001	2002	2003	2004
A	Quantity/Year	77,000	68,000	59,100	63,650
B	Standard Device Cost/Year (based on 2004 costs)	£1,350	£1,245	£855	£1,139
Protective Devices: SafetyGlide™ (prototype), SafetyGlide™ Insulin and Blunt Fill					
A	Quantity/Year 2004	63,650			
C	Protective Device Cost/Year (based up 2004 costs)	£16,679.85			
Protective Devices: Eclipse™ , SafetyGlide™ Insulin and Blunt Fill					
A	Quantity/Year 2004	63,650			
D	Protective Device Cost/Year (based up 2004 costs)	£7,146.75			
NSI Costs: 2001					
E	No of NSI with Standard Devices/Year 2001	13			
F	Low Risk Injuries: No X Cost	X12= £1,419.60			
G	High Risk: No X Cost	X1 HIV/Hep C= £1,031.22			
F+G	Total Cost	£2,450.92			
NSI Costs: 2002					
H	No of NSI with Standard Devices/Year 2002	9			
I	Low Risk Injuries: No X Cost	X9= £861.21			
J	High Risk Injuries: No X Cost	none			
I+J	Total Cost	£1,064.70			
NSI Costs: 2003					
K	No of NSI with Standard Devices/Year 2003	12			
L	Low Risk Injuries: No X Cost	X8 = £946.40			
M	High Risk Injuries: No X Cost	X3 Hep C = £705.69 X1 HIV/Hep C= £1032.22			
L+M	Total Cost	£2,684.31			
NSI Costs: 2004					
N	No of NSI During SafetyGlide™ Trial/Year 2004	4			
O	Low Risk Injuries: No X Cost	X3 = £354.90 (x2 with standard needle, x1 with SafetyGlide™)			
P	High Risk Injuries: No X Cost	x1 Hep C = £235.23 with standard needle)			
O+P	Total Cost	£590.13			
Compensation and Litigation Costs					
	X1 compensation payment in 2001 on W3	£3,000			
Total Expenditure.					
2001	Standard Devices + NSI Costs + Compensation (x1 litigation claim currently with legal team)	£6,800.92 (+ claim outstanding)			
2002	Standard Devices + NSI Costs	£2,309.70			
2003	Standard Devices + NSI Costs	£3,539.31			
2004	SafetyGlide™ Device Range + NSI Costs	£17,269.98			
2004	Eclipse Device Range + NSI Costs	£7736.88			

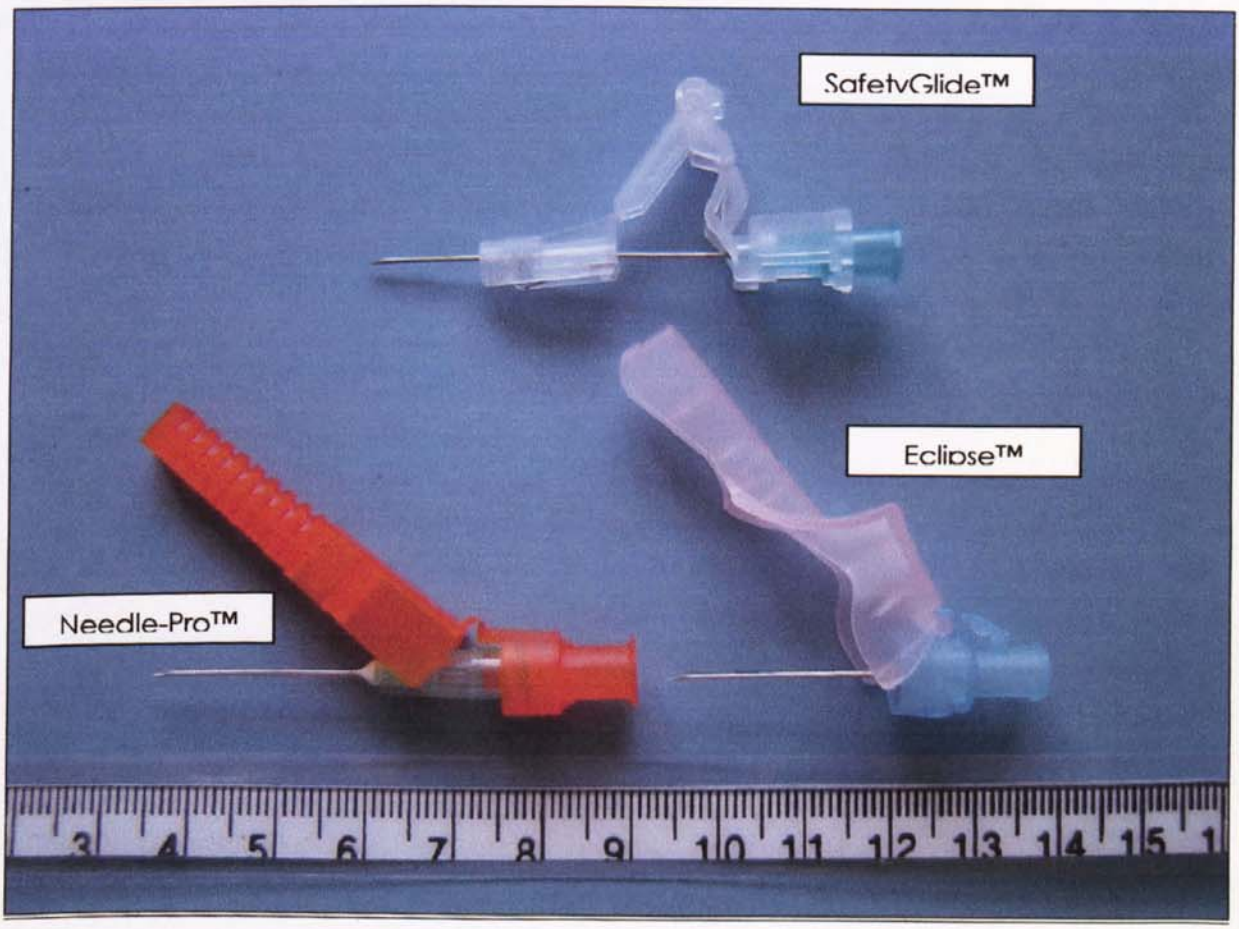
4.5.3.5 Determination of the Legal Costs Associated with Needlestick Injuries within the four Clinical Trial Areas at the UHB NHS Foundation Trust during the Four Year Period; 2001 to 2005.

Between the period of 2001 and 2004 one compensation payment of £3,000 was made to a healthcare worker related to incorrect disposal of a needle, causing a NSI. In addition, one further litigation case from 2001 remains outstanding.

4.5.4 Conclusion.

At present (2005) the SafetyGlide™ needle (£0.28) is not commercially available in Europe (SafetyGlide™ insulin and Blunt Fill needles are available). Nevertheless, the introduction of the SafetyGlide™ needle protective device range would have incurred an additional expenditure of £398 to £569/1,000 bed days. However, there are other similar devices, currently available, such as Eclipse™ (£0.11: BD; New Jersey, USA) and Needle-Pro™ (£0.14: Smiths Industries; New Hampshire, USA) (Figure 4.13). In addition, these alternative safety needle devices would not require conversion to Luer-lok™ syringes, so would therefore be more compatible with other currently used products such as the ABG syringes. The introduction of Eclipse™ needles with the SafetyGlide™ insulin needles would result in an increase of £35/1000 bed days (2001) to £206/1,000 (2002) bed days which compares with data published by Mulherin *et al.* (1996) who reported an increase of $230/1,000 bed days.

Figure 4.14: SafetyGlide™ Needle (BD), Eclipse™ Needle (BD) and Needle-Pro™ Needle (Smiths Industries); scale in cm.



It is difficult to quantify the costs attributable to the NHS from a member of staff, should they seroconvert to a blood borne virus, as so many factors apply; such as response to treatment, tolerance of treatment and drug resistance. However, the associated costs for six months initial treatment and investigations determined in this study demonstrated a potentially large financial burden.

4.6 Recommendations and Implications for Practice.

Inclusion of Healthcare Workers in the Utilization of Safety Devices in the Clinical Area.

One of the first steps in initialising research is acknowledging that a problem exists. To correct the problem often involves a change of practice or theory. Wright (1989) stated that "change begins with existing structures and processes a plan for revising them, proceeds to the actions to achieve the desired outcomes and the evaluation of the success in creating something new or different".

The inclusion of healthcare staff in deciding which needle protective devices should be utilised in their clinical areas, is essential in implementing any change in practice. It has been demonstrated in several studies (OSHA, 1997; Ihrig, 1997; Fahey and Henderson, 1999) that, if healthcare workers are not part of the decision making process then acceptability of the devices may not be achieved and this may compromise safety. This study demonstrated that by incorporating staff in all levels of the evaluation study that the devices were accepted and evaluated positively. In addition, the change policy chosen was suitable for the study and worked effectively from the unfreezing stage, through to the moving stage. The study has now concluded and a decision from the Trust on whether to implement safety devices is awaited; therefore proceeding into the re-freezing stage is currently on hold.

The study also suggests that any decisions on the introduction of safety devices into the UHB NHS Foundation Trust should incorporate a healthcare worker user evaluation study and a clinical trial period of at least four weeks, prior to a decision being made regarding their implementation.

Are Safety Devices Suitable for All Situations Where Standard Needles are Currently Used?

Following the user evaluation of the SafetyGlide™ needles at one, six and 11 months, it was evident that the devices were a success in all aspects evaluated, including; safety, usability and compatibility. One proviso which should be incorporated into the training and evaluation of needle protective devices, of any kind, is that of risk assessment for their use. In the ECRI report (2003) evaluation of the SafetyGlide™ needle, it states, "the products can be used for most (if not all) syringe application." The results of this study would conclude that the SafetyGlide™ needle protective device range is suitable for most situations. However, each clinician must evaluate the procedure being undertaken and assess the suitability and appropriateness of any

device being used. Limitations of this study included the use of ABG syringes which had slip lock attachments and therefore were not compatible with SafetyGlide™.

Reduction of Occupationally Acquired Needlestick Injuries?

The current study demonstrated that the introduction of SafetyGlide™ needle protective devices can significantly reduce healthcare workers exposure to percutaneous injury. Nevertheless, when introducing safety devices they may be examined for potential user associated problems more closely than their standard counterparts (Jagger, 1996). Consequently, any concerns highlighted, must be accompanied by a comparison of the qualities of the standard device, in order to achieve a balanced review of the options. This was demonstrated following the serious adverse event in August 2003.

Subsequently, the recommendations following this study are that multivariate approaches are introduced to sustain the reduction in NSI. Therefore, robust mandatory educational strategies should be implemented alongside the introduction of needle protective devices for procedures where there is a risk from a contaminated NSI e.g. injections via IM, IV and SC routes.

Cost Implications of Introducing Needle Protective Devices.

This study has demonstrated that safety devices can significantly reduce healthcare workers percutaneous exposure to potential blood borne viruses. Therefore, as with universal precautions, safety devices should be utilized whenever a risk of exposure exists and the provision of safety needles alongside standard devices should be made a priority for future healthcare funding.

4.7 Study Limitations.

The final study protocol had three key limitations which should be recognised; prospective clinical trial rather than a prospective comparative study, standard needles had to remain on the trial areas and all healthcare workers required training prior to utilizing the devices.

Initially the study was to have been a comparative study, to ensure that any reduction in NSI was due to the device and not a reduction which was observed in the control wards as well. Due to factors outside the control of the study it was not possible to continue with this aspect and therefore the study continued as a prospective study only.

In addition, as with other studies (Younger *et al.*, 1992; Siddharta *et al.*, 2001) some standard needles had to remain in the clinical areas to facilitate procedures which the healthcare workers did not feel the safety devices were appropriate for.

All healthcare workers required training on the safe use and disposal of the safety needle devices. This may have had an effect on the numbers of NSI reported and heightened healthcare workers awareness of the risks associated with NSI. This can be summarised as potentially having a Hawthorne effect, in as much as the knowledge of being included in a trial can be sufficient to change people's behaviour (Polit and Hungler, 1991). However, it was not possible to conduct the study as a double blind trial and therefore this limitation has to be accepted.

Chapter Five:

Evaluation of the Efficacy of a New Disinfectant, ChloraPrep®, with a Range of Standard Antimicrobial Agents against *Staphylococcus epidermidis* RP62A using *In Vitro* Time Kill Studies.

5 Introduction.

Coagulase negative staphylococci are frequently associated with catheter related bloodstream infections (CRBSI) (Elliott *et al.*, 1994; Mermel *et al.*, 2001; Graninger *et al.*, 2002). A characteristic feature of these microorganisms is their ability to adhere and form biofilms around prosthetic devices which makes the organism more resistant to antimicrobial agents. In order to reduce the risk of microbial colonisation of the peripheral vascular catheter (PVC) tip on insertion through the skin, the entry site should be disinfected for 30 seconds with an antimicrobial solution (Infection Control Nurses Association; ICNA 2001). A chlorhexidine gluconate (CHG) preparation is preferred, however, povidone iodine (PI) or 70% isopropyl alcohol (IPA) may be used (Pratt *et al.*, 2001; CDC, 2002). These agents use different modes of action to achieve antisepsis, which may be reduced in the presence of organic matter (Ayliffe *et al.*, 1993. Hugo and Russell, 1999).

Medi-Flex Incorporated (Kansas, USA) has recently developed ChloraPrep®; a 2% (w/v) alcoholic CHG solution for skin decontamination prior to insertion of intravenous (IV) catheters. Clinical studies in the USA have demonstrated that ChloraPrep® provided a significant and more persistent antimicrobial activity than 70% (v/v) IPA, 10% (w/v) PI or 2% (w/v) aqueous CHG at 24hours in the clinical area (Hibbard *et al.*, 2002). This was supported by Garcia (2002) who also concluded that 2% (w/v) alcoholic CHG had a significant immediate and prolonged effect than 10% (w/v) PI. This residual antimicrobial activity may potentially reduce the risk of phlebitis for patients requiring PVC.

In order to assess the efficacy of an antimicrobial agent, it is essential to determine the activity against microorganisms *in vitro*. This also includes evaluating the effectiveness of the disinfectant in the presence of protein. Presence of protein and other organic matter may result in neutralisation of biocides by surface adsorption leading to reduced availability of the disinfectant for the microorganism (Best *et al.*, 1990). Iodine can be

particularly inhibited in the presence of proteins (Cremieux *et al.*, 2000). The criterion for activity of a disinfectant is measured by the rate of kill of the exposed microorganisms. The most widely recognised definition with regards to bactericidal activity is a five Log_{10} reduction (Cremieux *et al.*, 2000). Assessing the efficacy of a disinfectant may be undertaken by various quantitative *in vitro* methods including suspension tests, capacity tests or carrier tests (Reybrouck, 1999).

Quantitative tests allow for surviving microorganisms to be enumerated following a given exposure to a disinfectant. To enumerate viable microorganisms accurately following a given exposure it is essential the residual antimicrobial activity of the biocide has to be nullified with a neutralising agent.

Aims of the Study.

To compare the antimicrobial efficacy of an innovative disinfectant, 2% (w/v) CHG in 70% (v/v) IPA (ChloraPrep®) with that of traditional skin disinfectants; 70% (v/v) IPA; 0.5% (w/v) aqueous CHG; 2%% (w/v) aqueous CHG; 0.5% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, utilizing quantitative time kill suspension and carrier tests against *Staphylococcus epidermidis* RP62A both in the presence and absence of protein.

5.1 Materials and Methods.

a). Standardised solutions.

- Neutralising Agent: Neutralising agents must completely inactivate all of the bacteriostatic activity of the antimicrobial agent and in addition be non-bactericidal to the challenge organism (Sheikh, 1981).

  One hundred ml of neutralising agent was prepared containing:

  - 2% (v/v) Tween 80 (BDH; Poole, UK)
  - 1.17% (w/v) Lecithin (Fisher Scientific; Loughborough, UK)
  - 0.1% (v/v) Triton X-100 (Sigma; St Louis, USA)
  - 0.5% (w/v) Sodium Thiosulphate (BDH; Poole, UK)
  - 100ml sterile distilled water (adapted from Sheikh 1981).

The neutralising agent was dispensed into bijoux bottles in 900µl aliquots, autoclaved at 121°C for 15minutes and then stored at 4°C until required.

b). Antimicrobial Agents:

- 30% (v/v), 40% (v/v), 50% (v/v), 60% (v/v) and 70% (v/v) IPA. Test dilutions of IPA were prepared by diluting 100% (v/v) IPA (BDH; Poole, UK) with sterile distilled water.
- 0.5% (w/v) and 2%, (w/v) aqueous CHG (Sigma; St Louis, USA). Test dilutions of CHG were prepared by diluting 20% (w/v) CHG in sterile distilled water.
- 0.5% (w/v) CHG in 70% (v/v) IPA (Adams Healthcare; Leeds, UK).
- 2% (w/v) CHG in 70% (v/v) IPA (Medi-Flex; Kansas, USA).
- 10% (w/v) PI (Seton Healthcare; Oldham, UK)

c). Challenge Microorganism:

- *S. epidermidis* RP62A (ATCC; American Type Culture Collection 35984); a reference biofilm-positive strain (Sadovaskaya *et al.*, 2004).

Microorganisms stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) were revived by placing one bead in 3ml of brain heart infusion (BHI) broth (Oxoid; Basingstoke, UK) and incubating at 37°C in air for 24 hours. The suspension was adjusted to the required concentration by dilution in 0.9% (w/v) sterile phosphate buffered saline (PBS) and confirmed using the Miles and Misra technique (1938).

d). Human Serum; from clotted human male whole blood (Sigma; St Louis, USA. Catalogue number H1388).

e). Alcian Blue Stain.

One hundred millilitres of Alcian blue solution was prepared containing

- 100ml distilled water
- 3ml Acetic acid (Fisher Scientific International. Loughborough, UK)
- 1g Alcian blue 8GX (Sigma; St Louis, USA).

f). Preparation of a Carrier System Containing Bacterial Biofilm:

An overnight suspension of the challenge microorganism was diluted in BHI to approximately $1x10^4$. Two hundred µl aliquots of the suspension were inoculated into the wells of a sterile microtitre tray (Immulon® 2HB Thermo Labsystems, Franklyn M.A). This was then covered with a microplate sealer (Greiner-Bio-One. Gloucester, UK) and incubated at 37°C in air for 24 hours.

g). Preparation of a Carrier System Containing Bacterial Biofilm Enriched with 10% (v/v) Human Serum:

An overnight suspension of the challenge microorganism was diluted in BHI to approximately $1x10^4$ cfu/ml and enriched with 10% (v/v) human serum. Two hundred microlitre aliquots of the suspension were inoculated into the wells of a sterile microtitre tray (Immulon® 2HB Thermo Labsystems; Franklyn, M.A). This was then covered with a microplate sealer (Greiner-Bio-One. Gloucester, UK) and incubated at 37°C in air for 24 hours.

h). Removing a Biofilm from the Microtitre Well Using the "Scrape and Wash" Method.

The microbial culture containing loose bacteria was removed from each microtitre well by gentle inversion of the plate and then careful washing with 250µl of PBS. Two hundred µl aliquots of BHI were added to each inoculated well. Using a sterile pipette tip, the side wall of each well was scraped around 10 times, the bottom was scraped; horizontally 10 times, vertically 10 times and cross wise in each direction 10 times. The inoculum was removed by pipette and collected in separate sterile bijoux for each well. This procedure was repeated a further three times until each bijoux contained 800µl (4x200µl) from each well. This was then mixed thoroughly.

i). Estimation of the Number of *S. epidermidis* RP62A in the Biofilm:

The number of viable *S. epidermidis* RP62A recovered from the biofilm by the scrape and wash method were enumerated by serial dilutions on BHI agar plates, using the

Miles and Misra technique (1938). The plates were then incubated at 37°C in air for 24 hours

j). Time Kill Studies.

Evaluation of the efficacy of each antimicrobial agent was undertaken at 30 seconds as this is the recommended time for disinfecting the intended site of a PVC prior to insertion (ICNA, 2001).

k). Risk Assessment: Low Risk.

Laboratory risk assessment was undertaken utilizing risk UHB NHS Foundation Trust and Aston University assessment forms.

5.1.1 Determination of the Efficacy of the Neutralising Agent and the Antimicrobial Agents.

An overnight suspension of *S. epidermidis* RP62A was adjusted to $1x10^6$ cfu/ml and 100µl inoculated over the surface of a BHI agar plate which was allowed to dry at room temperature for 30 minutes. To demonstrate antimicrobial activity, 10µl of each antimicrobial agent was placed onto the centre of an inoculated agar plate and allowed to dry at room temperature. Each test was performed in triplicate. All plates were incubated at 37°C in air for 24 hours and were then inspected for zones of bacterial inhibition.

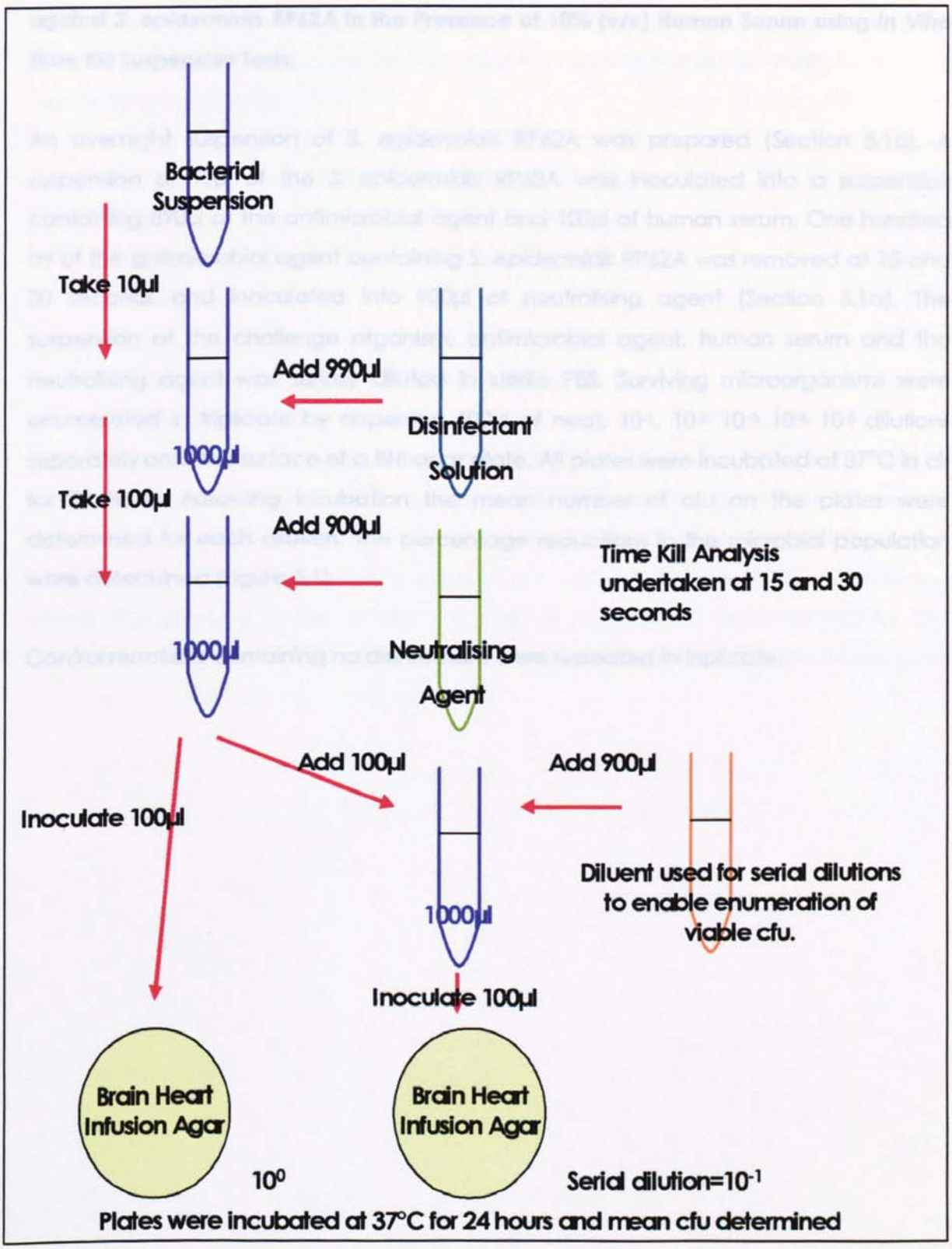
To determine the effectiveness of the neutralising agent (Section 5.1.1.a) 100µl of the antimicrobial agent was dispensed into 900µl of neutralising solution. Ten microlitres of *S. epidermidis* RP62A at a concentration of $1x10^6$ cfu/ml was then added and mixed thoroughly for 60 seconds and 100µl spread over the surface of a letheen agar plate. Each test was performed in triplicate. All plates were incubated at 37°C in air for 24 hours and were then inspected for bacterial growth.

5.1.2 Determination of the Efficacy of; 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A using *In Vitro* Time Kill Suspension Tests.

An overnight suspension of *S. epidermidis* RP62A was prepared (Section 5.1c). Ten microlitres of the suspension was transferred to 990µl of the antimicrobial agent. One hundred microlitres of the antimicrobial agent containing *S. epidermidis* RP62A was removed at 15 and 30 seconds and inoculated into 900µl of neutralising agent (Section 5.1a). The suspension of the challenge organism, antimicrobial agent and the neutralising agent was serially diluted in sterile PBS. Surviving microorganisms were enumerated in triplicate by spreading 100µl of neat, 10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5} dilutions separately onto the surface of a BHI agar. All plates were incubated at 37°C in air for 24 hours. Following incubation the mean number of cfu on the plates were determined for each dilution. The percentage reductions in the microbial population were determined (Figure 5.1).

Control reactions containing no disinfectant were repeated in triplicate.

Figure 5.1: Diagrammatic Representation of the *In vitro* Quantitative Suspension Test Utilized for the Disinfection Time Kill Studies.



5.1.3 Determination of the Efficacy of; 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A in the Presence of 10% (v/v) Human Serum using *In Vitro* Time Kill Suspension Tests.

An overnight suspension of *S. epidermidis* RP62A was prepared (Section 5.1c). A suspension of 10µl of the *S. epidermidis* RP62A was inoculated into a suspension containing 890µl of the antimicrobial agent and 100µl of human serum. One hundred ml of the antimicrobial agent containing *S. epidermidis* RP62A was removed at 15 and 30 seconds and inoculated into 900µl of neutralising agent (Section 5.1a). The suspension of the challenge organism, antimicrobial agent, human serum and the neutralising agent was serially diluted in sterile PBS. Surviving microorganisms were enumerated in triplicate by dispersing 100µl of neat, 10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5} dilutions separately onto the surface of a BHI agar plate. All plates were incubated at 37°C in air for 24 hours. Following incubation the mean number of cfu on the plates were determined for each dilution. The percentage reductions in the microbial population were determined (Figure 5.1).

Control reactions containing no disinfectant were repeated in triplicate.

5.1.4 Determination of the Ability of *S. epidermidis* RP62A to Produce Slime.

Confirmation of the challenge microorganisms' ability to produce slime was undertaken using the Congo red agar plate method described by Freeman *et al.* (1989).

Congo Red Agar Plates:

Solution 1:

- 15g Tryptone Soya broth (Oxoid; Basingstoke, UK),
- 5g glucose (Sigma; St Louis, USA),
- 7.5g Agar No1 (Oxoid; Basingstoke, UK)
- 400ml distilled water.

Solution 2:

- 0.4g Congo red (Hopkin and Williams Ltd: Essex, UK)
- 100ml distilled water.

The solutions were autoclaved separately at 121°C for 15 minutes, allowed to cool to 55°C and then mixed together. The Congo red solution was then poured into sterile Petri dishes and allowed to set. The challenge microorganisms; *S. epidermidis* RP62A and *S. hominis*, were inoculated and incubated at 37°C in air for 24 hours. Slime producing strains of staphylococci spp produce a positive result; this is demonstrated by the development of dry, crystalline, black colonies. Non slime producing strains remain pink.

5.1.5a Assessment of Biofilm Production by *S. epidermidis* RP62A (Christenson *et al.*, 1982; O'Toole *et al.*, 1999).

An overnight suspension of the *S. epidermidis* RP62A was prepared (Section 5.1c) and then the suspension inoculated into the wells of a sterile microtitre tray (Section 5.1f). A further microtitre tray was also inoculated with 200µl aliquots of BHI, as a control; this was then covered with a microplate sealer. The trays were then incubated at 37°C in air for 24 hours.

The fluid was removed from each well and the plates were gently washed with 250 µl PBS, 200µl aliquots of Alcian blue stain (Section 5.1e) was then added to each well for five minutes. The fluid was removed and the wells gently washed with PBS. The stain was released from the wall adherent biofilm with ethanol. The Alcian blue stain intensity was determined (optical density at 570nm), this correlates with the quantity of biofilm present (McLean *et al.*, 2004). This was repeated in eight wells for each suspension.

5.1.5b Assessment of Biofilm Production by *S. epidermidis* RP62A in the Presence of 10% (v/v) Human Serum (O'Toole and Kolter, 1998).

This was carried out as for section 5.1.5a, however, the microtitre tray was inoculated with an overnight suspension enriched with 10% (v/v) human serum (Section 5.1g).

5.1.6 Development of an Effective Method of Biofilm Removal Prior to Determining the Efficacy of the Antimicrobial Agents Using an *In Vitro* Carrier Test.

An overnight suspension of *S. epidermidis* RP62A was prepared (Section 5.1c). The suspension was inoculated into eight wells of the microtitre tray (Section 5.1f) and incubated at 37°C in air for 24 hours. The contents of the wells were gently inverted to remove the suspension and then carefully washed with 250µl of PBS.

Two hundred microlitres of BHI was inoculated into each well. The biofilm was physically removed using the method described in section 5.1h. The suspension was gently removed by pipette and discarded. In microtitre tray column one (eight wells) this method was carried out once. This method was repeated twice in column two and three times for the third column up to a total of six times in order to identify how many times it was necessary to scrape and washes were required to ensure significant biofilm removal.

To determine the effectiveness of the biofilm removal, a sterile naso-pharyngeal swab was inserted into each well and rotated 10 times. This was then rolled across a BHI agar plate and incubated at 37°C in air for 24 hours. The cfu were then enumerated.

5.1.7a Determining the Number of S. epidermidis RP62A CFU/ml in a Biofilm on the Microtitre Well after 24 Hours.

An overnight suspension of the *S. epidermidis RP62A* was prepared (Section 5.1c). The suspension was inoculated into eight wells of the microtitre tray (Section 5.1f) and incubated at 37°C in air for 24 hours. The tray was gently inverted to remove the suspension and then carefully washed with 250µl of PBS. The biofilm was physically removed from each well using method described in Section 5.1h. Enumeration of the cfu in the biofilm was determined (Section 5.1i). The BHI agar plates were then incubated at 37°C in air for 24 hours.

5.1.7b Determining the Number of *S. epidermidis* RP62A CFU in a Biofilm When Enriched with 10% (v/v) Human serum on the Microtitre Well after 24 hours.

This was carried out as above, however the suspension was enriched with 10% (v/v) human serum (Section 5.1g).

5.1.8a Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, at 30 Seconds Contact Time against *S. epidermidis* RP62A in a Biofilm.

An overnight suspension of the *S. epidermidis RP62A* was prepared (Section 5.1c). The suspension was inoculated into 16 wells of the microtitre tray (Section 5.1f) and incubated at 37°C in air for 24 hours. The contents of each well were removed by gentle inversion of the plate and then careful washing with 250µl of PBS. Two hundred µl of the antimicrobial agent was added to each well and allowed to dwell for 30 seconds. The agent was then aspirated and 250µl of neutralising agent was added to each well and left for five minutes. The neutralising agent was removed by inversion of the tray and the microtitre wells washed gently with PBS.

The biofilm was physically removed from each well using the scrape and wash method (Section 5.1g). Enumeration of the cfu was undertaken using the Miles and Misra method (1938) (Section 5.1h).

Control reactions containing no disinfectant were repeated in triplicate.

5.1.8b Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, at 30 Seconds Contact Time against *S. epidermidis* RP62A in a Biofilm Enriched with 10% (v/v) Human Serum using an *In Vitro* Time Kill Carrier Test.

An overnight suspension of the *S. epidermidis RP62A* was prepared (Section 5.1c). The suspension was inoculated into 16 wells of the microtitre tray (Section 5.1g) and incubated at 37°C in air for 24 hours. The contents of each well were removed by gentle inversion of the plate and then careful washing with 250µl of PBS. Two hundred µl of the antimicrobial agent was added to each well for 30 seconds. The agent was then aspirated and 250µl of neutralising agent was added to each well and left for five minutes. The neutralising agent was removed by inversion of the tray and the microtitre wells washed gently with PBS.

The biofilm was physically removed from each well using the scrape and wash method (Section 5.1h). Enumeration of the cfu was undertaken using the Miles and Misra method (1938) (Section 5.1i).

Control reactions containing no disinfectant were repeated in triplicate.

5.2 Results.

5.2.1 Determination of the Efficacy of the Neutralising Agent and the Antimicrobial Agents.

The Efficacy and Non Toxicity of the Neutralising Agent.

There was no reduction of *S. epidermidis* RP62A in the suspension containing the neutralising agent and antimicrobial agent, compared with the initial inoculum of *S. epidermidis* RP62A (initial inoculum of *S. epidermidis* RP62A = $1x10^8$cfu/ml; viable count of *S. epidermidis* RP62 following exposure to neutraliser and antimicrobial agents = $1x10^8$cfu/ml). Confirming that the neutralising agent was non toxic to the challenge microorganism and effective against the antimicrobial agents:

IPA; 30% (v/v), 40% (v/v), 50% (v/v), 60% (v/v) and 70% (v/v).

GHG aqueous; 0.5% (w/v), and 2% (w/v) (Figure 5.2).

0.5% (w/v) CHG in 70% (v/v) IPA.

2% (w/v) CHG in 70% (v/v) IPA.

10% (w/v) PI.

The Efficacy of; 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A.

The efficacy of each antimicrobial agent against the challenge microorganism was demonstrated by zones of bacterial inhibition on each inoculated plate (Figure 5.2).

Figure 5.2: Antimicrobial Effectiveness of 70% (v/v) Isopropyl Alcohol is demonstrated by Zone of Growth Inhibition of *S. epidermidis* RP62A.

5.2.2 Determination of the Effectiveness of; 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A using *In Vitro* Time Kill Suspension Studies.

The following antimicrobial agents were effective in achieving a five Log_{10} (>99.999%) reduction in microbial population of *S. epidermidis* RP62A at 15 and 30 seconds contact time (Figure 5.3 and Table 5.1).

- IPA (v/v); 50%, 60% and 70%.
- CHG aqueous (w/v); 0.5% and 2%.
- CHG (w/v) in 70 % (v/v) IPA; 0.5% and 2%.
- PI (w/v); 10%.

40% (v/v) IPA did not achieve a five Log_{10} reduction at 15 seconds but did at 30 seconds and 30% (v/v) IPA did not achieve disinfection, even at 30 seconds.

Controls containing no disinfectants resulted in complete recovery ($3.5x10^6$ cfu/ml) of the initial inocula.

Figure 5.3: *In Vitro* Time Kill Suspension Tests at 15 and 30 Seconds to Evaluate the Efficacy of; 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) Aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI against *S. epidermidis* RP62A.

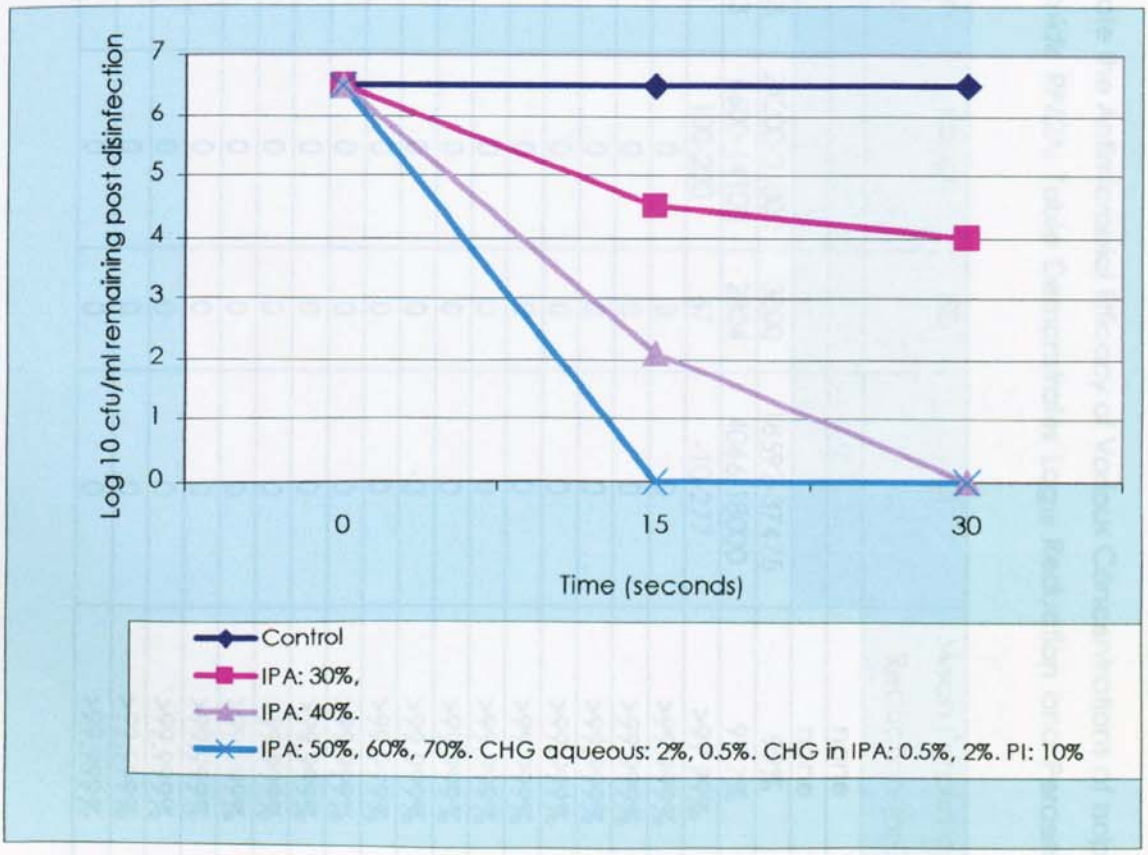


Table 5.1: *In Vitro* Time Kill Suspension Studies at 15 and 30 Seconds to Evaluate the Antimicrobial Efficacy of Various Concentrations of Isopropyl Alcohol, Chlorhexidine Gluconate and Povidone Iodine against *S. epidermidis* RP62A; Table Demonstrates Log_{10} Reduction and Percentage Reduction for Each Product.

Antimicrobial	Exposure Time (seconds)	Mean Log_{10} Reduction (n=3)	Mean cfu/ml	Range	SD	CI	Mean Percentage Reduction (n=3)
Control (Log_{10} 6.5)	15	none					none
	30	none					none
30% (v/v) IPA	15	**2.0**	28033	24200-31800	3800	18592-37475	99%
	30	**2.5**	11033	8600-14100	2804	4066-18000	99.7%
40% (v/v) IPA	15	**4.4**	133	100-200	57	-10-277	>99.99%
	30	6.5	0	0	0	0	>99.999%
50% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
60% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
0.5% (w/v) aqueous CHG	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
2% (w/v) aqueous CHG	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
0.5% (w/v) CHG in 70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
2% (w/v) CHG in 70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
10% (w/v) PI	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%

Figures in bold indicate a failure to achieve a 5 Log_{10} reduction.

5.2.3 Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A in the Presence of Human Serum against using *In Vitro* Time Kill Suspension Tests.

Seventy percent (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70% (v/v) IPA and 2% (w/v) CHG in 70% (v/v) IPA were effective in achieving a five Log_{10} reduction of *S. epidermidis* RP62A after both 15 and 30 seconds contact time in the presence of 10% (v/v) human serum (Figure 5.4 and Table 5.2). However, a five Log_{10} reduction was not achieved with 10% (w/v) PI until 30 seconds contact.

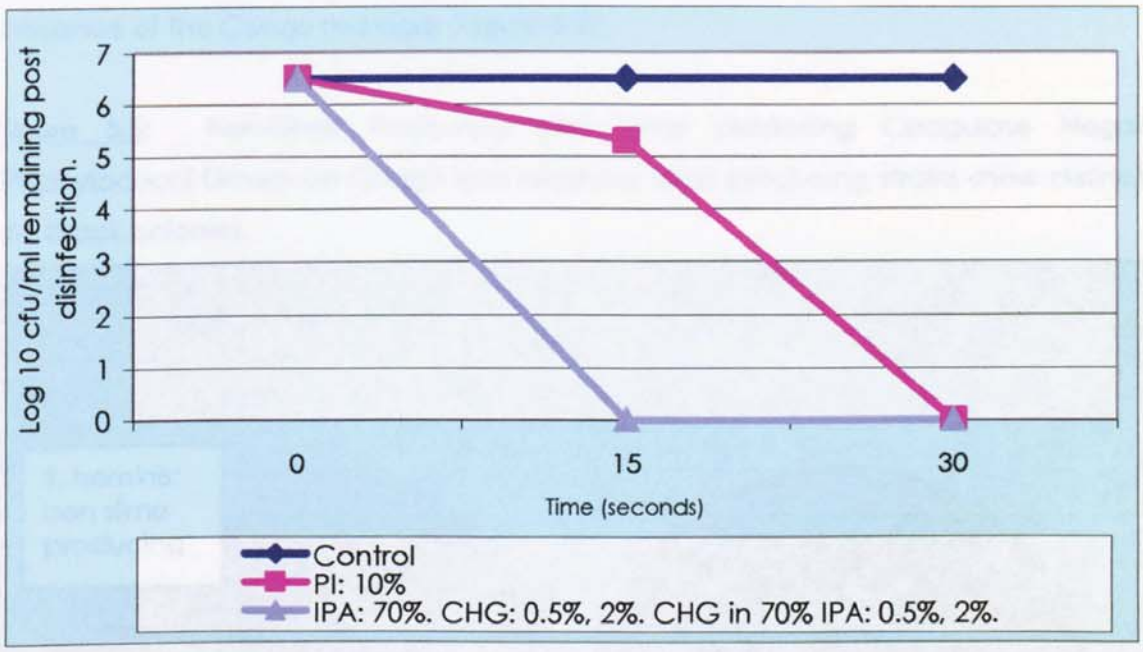
Controls containing no disinfectants resulted in complete recovery ($3.1x10^6$ cfu/ml) of the initial inocula of *S. epidermidis* RP62A.

Table 5.2: *In Vitro* Time Kill Suspension Studies at 15 and 30 Seconds to Evaluate the Efficacy of 30%, 40%, 50%, 60% and 70% (v/v) IPA; 0.5% and 2% (w/v) Aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A in the Presence of 10% (v/v) Human Serum; Table Demonstrates Log_{10} Reduction and Percentage Reduction for Each Product.

Antimicrobial	Exposure Time (seconds)	Mean Log_{10} Reduction (n=3)	Mean cfu/ml	Range cfu/ml	SD	CI	Mean Percentage Reduction (n=3)
Control (log_{10} 6.5)	15	none					none
	30	none					none
70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
0.5% (w/v) aqueous CHG	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
2% (w/v) aqueous CHG	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
0.5% (w/v) CHG in 70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
2% (w/v) CHG in 70% (v/v) IPA	15	6.5	0	0	0	0	>99.999%
	30	6.5	0	0	0	0	>99.999%
10% (w/v) PI	15	**1.2**	208400	179200-229200	26037	179200-229200	<1%
	30	6.5	0	0	0	0	>99.999%

Figures in bold indicate a failure to achieve a 5 Log_{10} reduction.

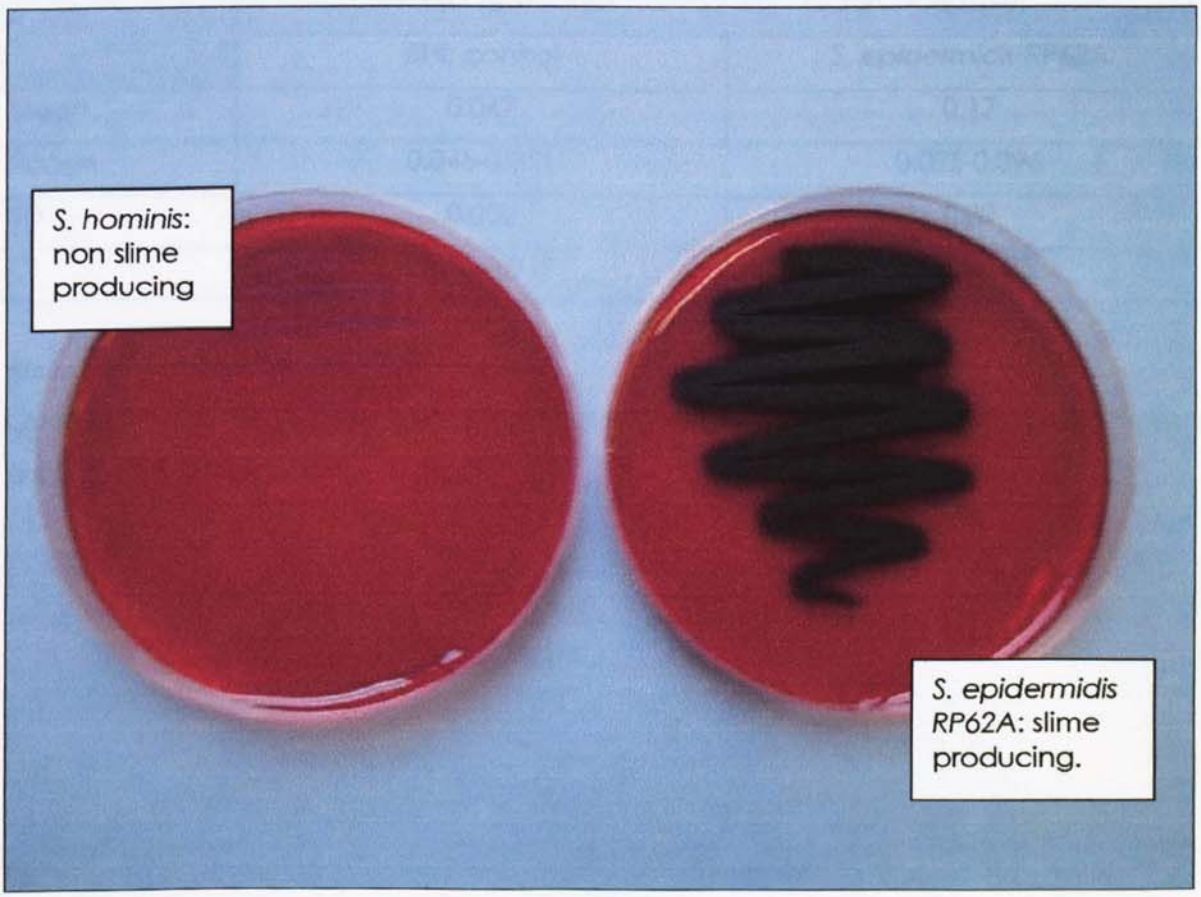
Figure 5.4: *In Vitro* Time Kill Suspension Tests at 15 and 30 Seconds to Evaluate the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) Aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, in the Presence of 10% (v/v) Human Serum against *S. epidermidis* RP62A.



5.2.4 Determination of the Ability *S. epidermidis* RP62A to Produce Slime.

Confirmation of the slime production by *S. epidermidis* RP62A was achieved by the presence of characteristic black colonies on the Congo red agar plate. *S. hominis* was confirmed as a non-slime producer as the colonies did not change colour in the presence of the Congo red agar (Figure 5.5).

Figure 5.5: Non-Slime Producing and Slime producing Coagulase Negative Staphylococci Grown on Congo Red Medium: Slime producing strains show distinctive dry black colonies.



5.2.5a Assessment of Biofilm Production by *S. epidermidis* RP62A (Christenson *et al.*, 1982; O'Toole *et al.*, 1999).

The findings demonstrated that a biofilm of *S. epidermidis* RP62A was adherent to microtitre tray carrier system (Table 5.3).

Table 5.3: A Comparison of the Optical Densities Obtained from the Control (Brain Heart Infusion) and *S. epidermidis* RP62A to Confirm Biofilm Formation.

	OD (570) after staining with Alcian blue (n=8)	
	BHI; control	*S. epidermidis* RP62A
Mean	0.047	0.17
Range	0.045-0.051	0.095-0.396
SD	0.002	0.09
CI	0.045-0.049	0.084-0.25

Statistical Analysis; Independent *t*-test.
Comparing OD for the two groups (control (BHI) with the *S. epidermidis*) demonstrated a significant difference. (p= 0.0113).

5.2.5b Assessment of Biofilm Production by *S. epidermidis* RP62A in the Presence of 10% (v/v) Human Serum (O'Toole and Kolter, 1998).

The findings demonstrated that *S. epidermidis* RP62A continued to produce a biofilm when enriched with 10% (v/v) human serum which was adherent to the microtitre tray carrier system (Table 5.4).

Table 5.4: A Comparison of the Optical Densities Obtained from the Control (Brain Heart Infusion) and *S. epidermidis* RP62A Enriched with 10% (v/v) Human Serum to Confirm Biofilm Formation.

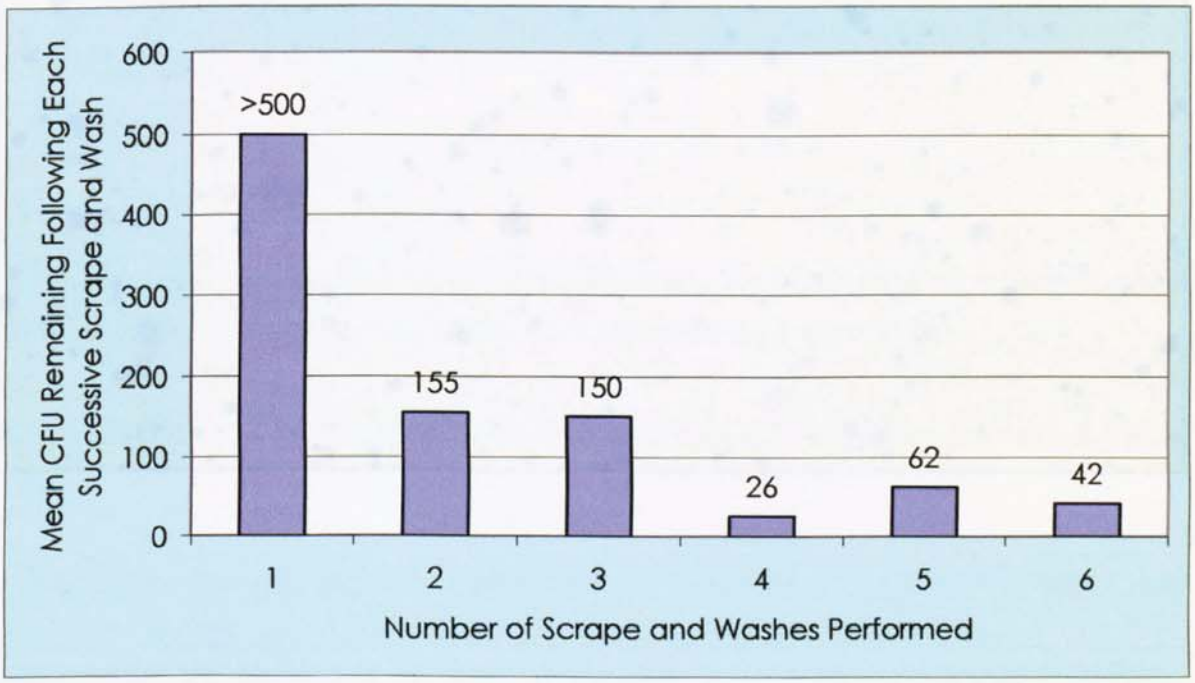
	OD (570) after staining with Alcian blue (n=6)	
	BHI; control	*S. epidermidis* RP62A
Mean	1.649	2.304
Range	1.067-2.409	1.63-2.63
SD	0.514	0.389
CI	1.11-2.189	1.895-2.713

Statistical Analysis; Independent *t*-test.
Comparing OD for the two groups (control (BHI) with the *S. epidermidis*) demonstrated a significant difference (p= 0.035).

5.2.6 Development of an Effective Method of Biofilm Removal Prior to Determining the Efficacy of the Antimicrobial Agents Using an *In Vitro* Carrier Test.

The findings demonstrated that four consecutive scrape and washes (Section 5.1h) were required to remove >99% of the microorganisms in a biofilm attached to the microtitre well. Successive scrape and washes failed to reduce this number (Figure 5.6). Confirmation that the cells were released as single cfu was undertaken by viewing under x1000 magnification following Gram staining the dried films (Figure 5.7). Direct observation under phase contrast gave too few cells to photograph.

Figure 5.6: CFU Remaining on the Wall of the Microtitre Well Carrier System Following Repeated Scrapes and Washes of the Biofilm of *S. epidermidis* RP62A.



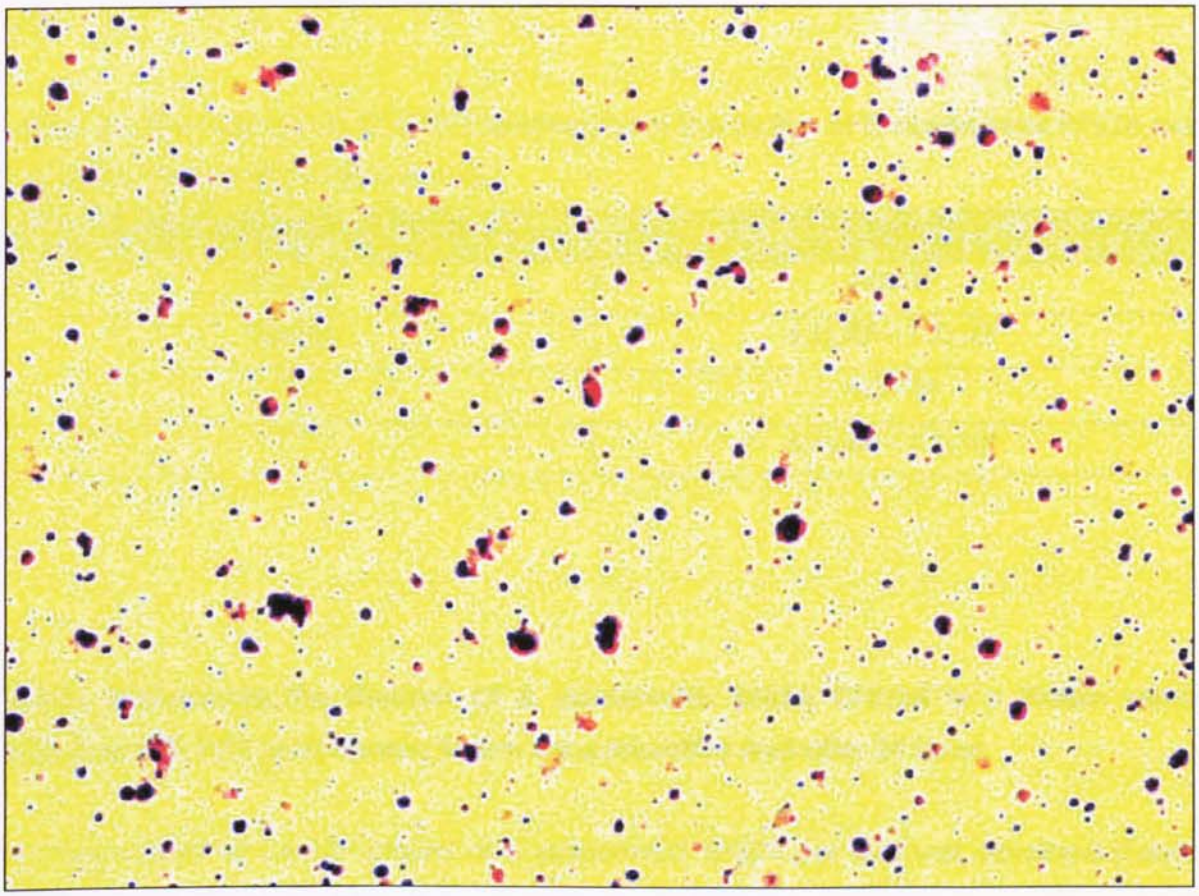
Statistical analysis: Independent *t*-test.

There was no statistical difference in the number of cfu removed between washes 2 and 3 (p=0.91)

A significant difference in the number of cfu removed between wash 3 and 4 was obtained (p=0.001)

No statistical difference in the number of cfu removed between wash 4 and 5 (p=0.12), and 5 and 6 was observed (p=0.71).

Figure 5.7: Confirmation of the Effectiveness of Removing Biofilm from Microtitre Wells as Single CFU; undertaken by viewing the repeated scrape and washes of *S. epidermidis* RP62A under x1000 magnification following Gram staining of the dried films.



5.2.7a Determining the Number of *S. epidermidis* RP62A CFU/ml in a Biofilm On a Microtitre Well Carrier System after 24 Hours.

A mean count of $1.0x10^9$ cfu/ml of *S. epidermidis* RP62A per well was obtained (Table 5.5).

Table 5.5: The Number of CFU/ml Obtained from the Biofilm of *S. epidermidis* RP62A per Microtitre Well after 24 Hours (n=16).

Basic Statistics Tests (n=16)	CFU/ml
Mean	$1.0x10^9$
Range	$6.6x10^8 - 1.7x10^9$
SD	$4.2x10^8$
CI	$6.7x10^8 - 1.7x10^9$

5.2.7b Determining the Number Of *S. epidermidis* RP62A CFU/ml in a Biofilm when Enriched with 10% (v/v) Human Serum On a Microtitre Well after 24 Hours.

A mean count of $1.6x10^{10}$ cfu/ml of *S. epidermidis* RP62A per well was obtained (Table 5.6).

Table 5.6: The Number of CFU/ml Obtained from the Biofilm of *S. epidermidis* RP62A and Enriched with 10% (v/v) Human Serum per Microtitre Well after 24 Hours (n=16).

Basic Statistics Tests (n=16)	CFU/ml
Mean	$2.7x10^8$
Range	$1.3x10^8$-$39x10^8$
SD	$1.1x10^8$
CI	$6.7x10^7$-$4.1x10^8$

5.2.8a Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% IPA and 10% (w/v) PI, against *S. epidermidis* RP62A in a Biofilm, using an *In Vitro* Time Kill Carrier Test at 30 Seconds.

Analysis of the results obtained from the time kill carrier studies of the various antimicrobial agents against a biofilm of *S. epidermidis* RP62A, demonstrated four out of the six disinfectants achieved a five Log_{10} reduction in microbial population of *S. epidermidis* RP62A after 30 seconds contact time.

1. 10% (w/v) PI (Log_{10} reduction factor = 5.9)
2. 0.5% (w/v) CHG in 70% (v/v) IPA (Log_{10} reduction factor = 5.8)
3. 70% (v/v) IPA (Log_{10} reduction factor = 5.4)
4. 2% (w/v) CHG in 70% (v/v) IPA (Log_{10} reduction factor = 5.3)

However, 0.5% (w/v) aqueous CHG and 2% (w/v) aqueous CHG only achieved a >4 to <5 Log_{10} reduction, in the presence of a biofilm (Figure 5.8 and Table 5.8).

All control reactions containing no disinfectants resulted in complete recovery ($1x10^9$ cfu/ml) of the initial inocula.

Statistical Analysis: Independent *t*-test.

Statistically comparing the efficacy of 2% (w/v) CHG in IPA with the remaining antimicrobial agents demonstrated the following results (Table 5.7).

Table 5.7: Statistical Comparison of the Efficacy of Five Traditional Disinfectants Compared to 2% CHG in 70% (v/v) IPA, against *S. epidermidis* RP62A in a Biofilm at 30 Seconds Contact Time, utilizing a Carrier Study.

Disinfectant	Two tailed *p* value	Statistical significance
2% (w/v) CHG in IPA	–	–
70% (v/v) IPA	0.728	Not significant
0.5% (w/v) aqueous CHG	0.069	Not significant
2% (w/v) aqueous CHG	<0.0001	Significant
0.5% (w/v) CHG in IPA	0.0036	Significant
10% (w/v) PI	0.0019	Significant

Figure 5.8: Evaluation of the Efficacy of 70% (v/v) IPA; 0.5% and 2% (w/v) Aqueous CHG; 0.5% and 2% (w/v) in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A in a Biofilm, using an *In Vitro* Time Kill Carrier Test. Exposure time; 30 Seconds.

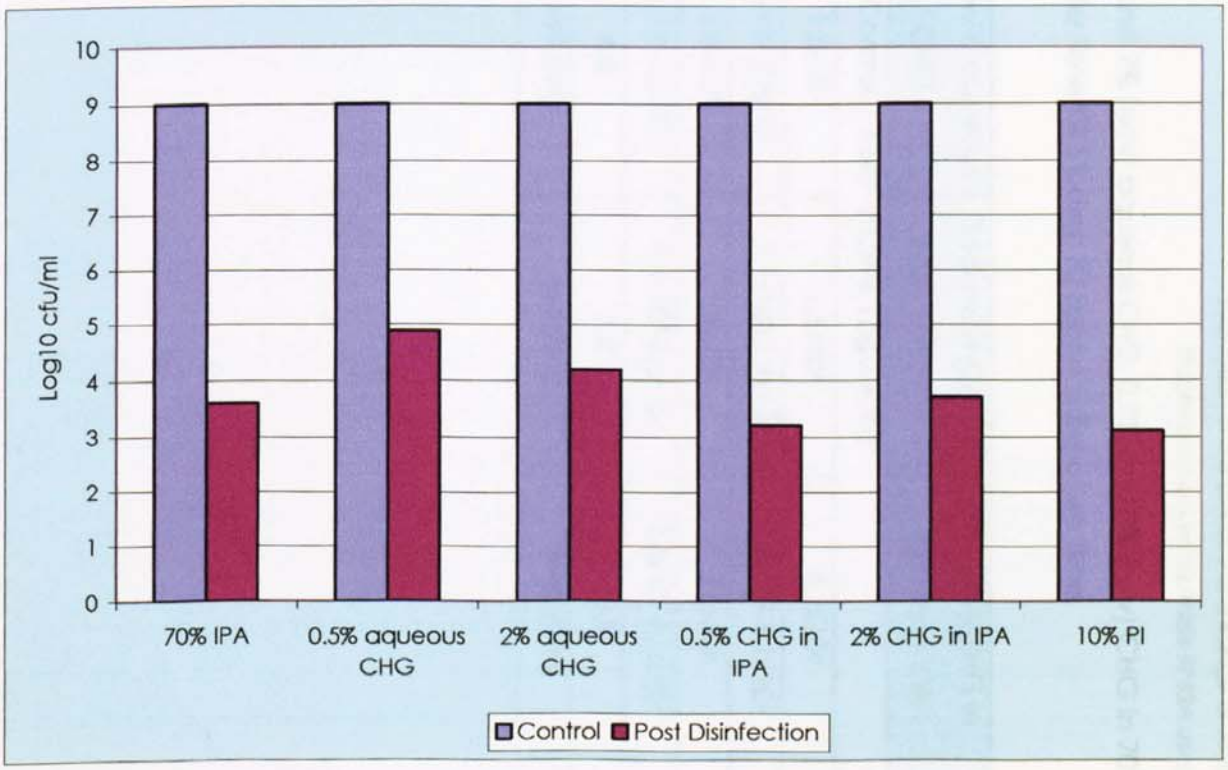


Table 5.8: Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI, against *S. epidermidis* RP62A in a Biofilm; Utilizing *In Vitro* Carrier Time Kill Studies; 30 Seconds Exposure Time.

	70% (v/v) IPA	0.5% (w/v) aqueous CHG	2% (w/v) aqueous CHG	0.5% (w/v) CHG in 70% (v/v) IPA	2% (w/v) CHG in 70% (v/v) IPA	10% (w/v) PI
	Control = $1x10^9$ cfu/ml. $Log_{10} = 9.0$					
Mean cfu/ml	$4.1x10^3$	$7.3x10^4$	$1.5x10^4$	$1.5x10^3$	$4.7x10^3$	$1.4x10^3$
Range (n=16)	$5.4x10^2$-$2.4x10^4$	$2.0x10^3$-$3.6x10^5$	$6.2x10^3$-$2.8x10^4$	$1.1x10^3$-$7.9x10^3$	$9.8x10^2$-$1.1x10^4$	$3.5x10^2$-$2.8x10^3$
SD	$6.0x10^3$	$1.4x10^5$	$5.6x10^3$	$1.9x10^3$	$3.5x10^3$	$6.5x10^2$
CI	$8.6x10^2$-$7.3x10^3$	$1.5x10^3$-$1.5x10^5$	$1.2x10^4$-$1.8x10^4$	$4.4x10^2$-$2.5x10^3$	$2.8x10^3$-$6.6x10^3$	$1.0x10^3$-$1.7x10^3$
Log_{10} Reduction	5.4	**4.1**	**4.8**	5.8	5.3	5.9
% Reduction	>99.999%	>99.99%	>99.99%	>99.999%	>99.999%	>99.999%

Figures in bold indicate a failure to achieve a 5 Log_{10} reduction.

5.2.8b Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI, against *S. epidermidis* RP62A in a Biofilm Enriched with 10% (v/v) Human Serum, using an *In Vitro* Time Kill Carrier Test at 30 Seconds.

Analysis of the results obtained from the time kill carrier studies of the various antimicrobial agents at 30 seconds against a biofilm of *S. epidermidis* enriched with 10% (v/v) human serum, demonstrated that none of the disinfectants; 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in IPA, 2% (w/v) CHG in IPA and 10% PI, were effective in achieving a five Log_{10} and >99% reduction in microbial population of *S. epidermidis* RP62A after 30 seconds contact time (Figure 5.9 and Table 5.9). However, rating them in order of effectiveness demonstrates that 2% (w/v) CHG in IPA achieved the best Log_{10} reduction:

1. 2% (w/v) CHG in 70% (v/v) IPA (Log_{10} reduction factor = 4.7)
2. 10% (w/v) PI (Log_{10} reduction factor = 4.4)
3. 0.5% (w/v) CHG in 70% (v/v) IPA (Log_{10} reduction factor = 3.6)
4. 70% (v/v) IPA (Log_{10} reduction factor = 2.8)
5. 2% (w/v) aqueous CHG (Log_{10} reduction factor = 2.8)
6. 0.5% (w/v) aqueous CHG (Log_{10} reduction factor = 2.8)

Controls containing no antimicrobial agents resulted in complete recovery of the initial inocula.

Statistical Analysis: Independent *t*-test.

When evaluating the effectiveness of the six disinfectants against a *S. epidermidis* RP62A in a biofilm enriched with 10% (v/v) human serum, 70% (v/v) IPA; 0.5% (w/v) aqueous CHG; 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA achieved a Log_{10} reduction factor between 2 and 4, at 30 seconds. In comparison, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) aqueous PI achieved a Log_{10} reduction factor of between 4 and 5. There was no statistical difference between these two disinfectants on analysis. (p= 0.16). (Table 5.10)

Figure 5.9: *In Vitro* Time Kill Carrier Test at 30 Seconds to Evaluate the Efficacy of 70% (v/v) IPA; 0.5% and 2% (w/v) Aqueous CHG; 0.5% and 2% (w/v) in 70% (v/v) IPA and 10% (w/v) PI, against a Biofilm of *S. epidermidis* RP62A Enriched with 10% (v/v) Human Serum.

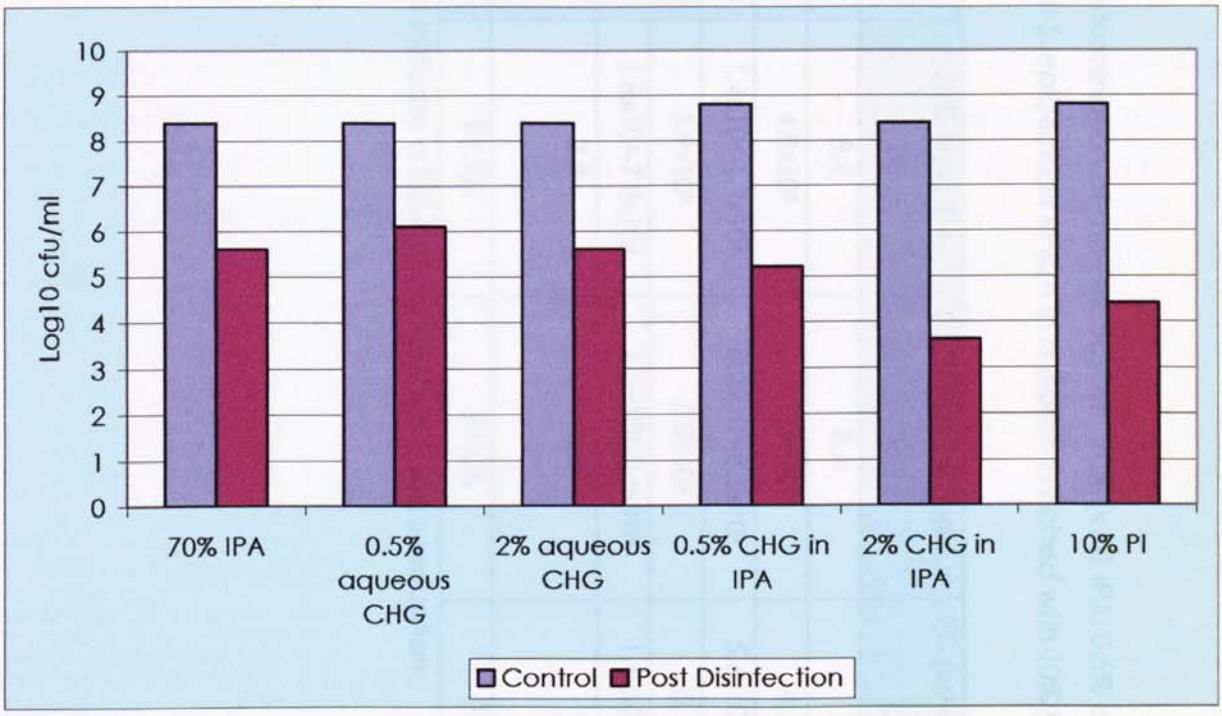


Table 5.9: Statistical Comparison of the Efficacy of Five Traditional Disinfectants Compared to 2% CHG in 70% (v/v) IPA, against *S. epidermidis* RP62A in a Biofilm Enriched with 10% (v/v) Human Serum, at 30 Seconds Contact Time Utilizing a Carrier Study.

Disinfectant	Two tailed *p* value	Statistical significance
2% (w/v) CHG in 70% (v/v) IPA	–	–
70% (v/v) IPA	0.0001	Significant
0.5% (w/v) aqueous CHG	0.0001	Significant
2% (w/v) aqueous CHG	0.0058	Significant
0.5% (w/v) CHG in 70% (v/v) IPA	0.0001	Significant
10% (w/v) PI	0.16	Not significant

Table 5.10: Determination of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI, against *S. epidermidis* RP62A in a Biofilm Enriched with 10% (v/v) Human Serum; Utilizing *In Vitro* Carrier Time Kill Studies at 30 Seconds.

	70% (v/v) IPA	0.5% (w/v) aqueous CHG	2% (w/v) aqueous CHG	0.5% (w/v) CHG in 70% (v/v) IPA	2% CHG in 70% (v/v) IPA	10% (w/v) PI
Control	8.4	8.4	8.4	8.8	8.4	8.8
Mean cfu/ml	$4.8x10^5$	$1.3x10^6$	$4.1x10^5$	$1.4x10^5$	$5.0x10^3$	$2.3x10^4$
Range (n=16)	$1.4x10^4$-$1.7x10^6$	$8.2x10^4$-$8.5x10^6$	$5.6x10^4$-$1.7x10^6$	$7x10^3$-$2.8x10^5$	$1.1x10^3$-$1.0x10^4$	$2.0x10^3$-$1.1x10^5$
SD	$5.9x10^5$	$2.2x10^6$	$5.1x10^5$	$7.5x10^4$	$2.7x10^3$	$2.5x10^4$
CI	$1.8x10^5$-$7.8x10^5$	$1.6x10^5$-$2.5x10^6$	$1.4x10^5$-$6.8x10^5$	$1.0x10^5$-$1.8x10^5$	$3.6x10^3$-$6.4x10^3$	$9.4x10^3$-$3.6x10^4$
Log_{10} Reduction	**2.8**	**2.3**	**2.8**	**3.6**	**4.7**	**4.4**
% Reduction	99.9%	99.5%	99.8%	>99.9%	>99.99%	>99.99%

Figures in bold indicate a failure to achieve a 5 Log_{10} reduction.

5.2.9 A Comparison of the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI against *S. epidermidis* RP62A, Using *In Vitro* Time Kill Quantitative Suspension Tests and Carrier Tests at 30 Seconds.

Comparing the antimicrobial efficacy of 2% (w/v) CHG in 70% (v/v) IPA with traditional skin disinfectants: 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, against *S. epidermidis* RP62A both in the presence and absence of protein demonstrated that overall 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI was more effective than the remaining disinfectants across the range of challenges they were tested against (Figure 5.10 and Table 5.11).

Figure 5.10: A Summary of Results Obtained from *In Vitro* Time Kill Suspension and Carrier Tests (with and without 10% (v/v) Human Serum) at 30 Seconds to Evaluate the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI, against *S. epidermidis* RP62A.

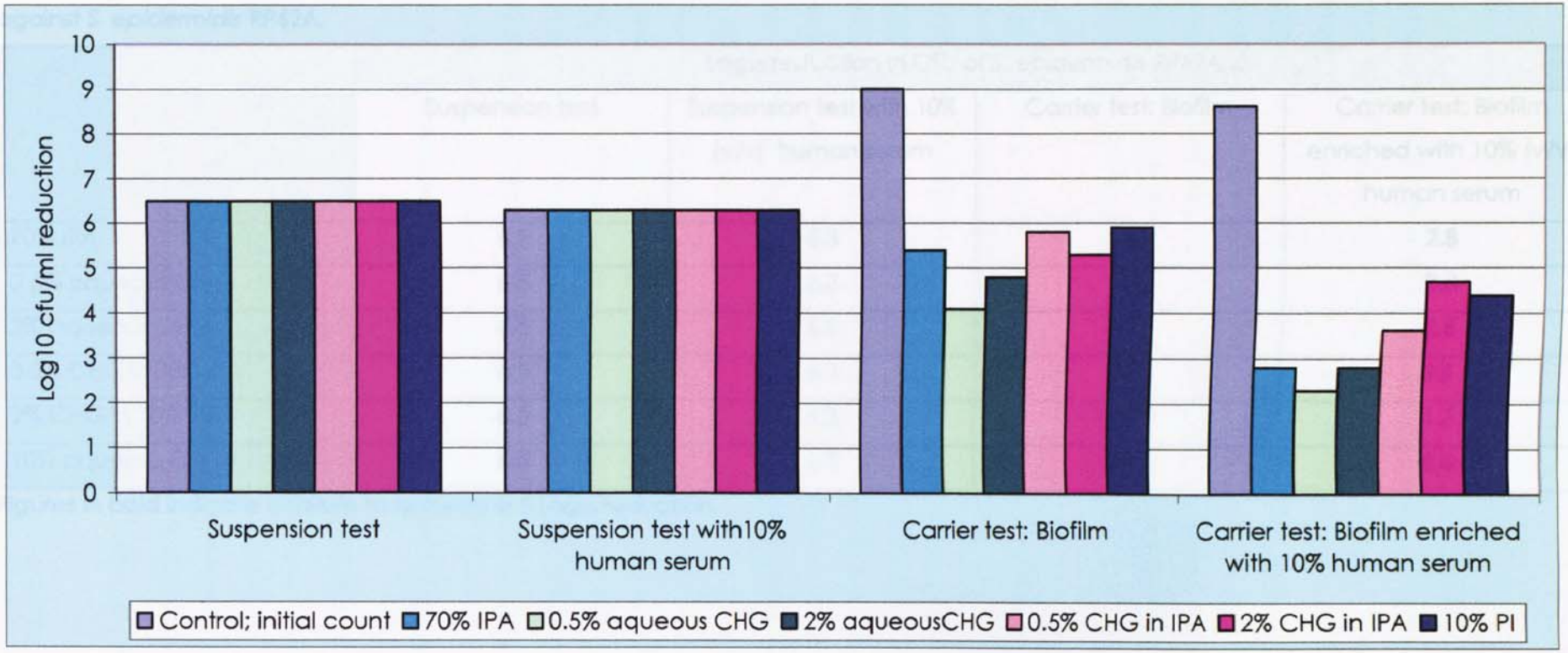


Table 5.11: A Summary of Results Obtained from *In Vitro* Time Kill Suspension and Carrier Tests (with and without 10% (v/v) Human Serum) at 30 Seconds to Evaluate the Efficacy of; 70% (v/v) IPA; 0.5% and 2% (w/v) aqueous CHG; 0.5% and 2% (w/v) CHG in 70% (v/v) IPA and 10% PI, against *S. epidermidis* RP62A.

	Log_{10} reduction in CFU of *S. epidermidis* RP62A...			
	Suspension test	Suspension test with 10% (v/v) human serum	Carrier test: Biofilm	Carrier test: Biofilm enriched with 10% (v/v) human serum
70% IPA	6.5	6.3	5.4	**2.8**
0.5% aqueous CHG	6.5	6.3	**4.1**	**2.3**
2% aqueous CHG	6.5	6.3	**4.8**	**2.8**
0.5% CHG in 70% IPA	6.5	6.3	5.8	**3.6**
2% CHG in 70% IPA	6.5	6.3	5.3	**4.7**
10% aqueous PI	6.5	6.3	5.9	**4.4**

Figures in bold indicate a failure to achieve a 5 Log_{10} reduction.

5.3Conclusion.

Skin antisepsis is the removal or reduction of normal flora or contaminating microorganisms by the topical application of an antimicrobial agent (Crabtree *et al.*, 2000). This is recommended prior to the insertion of a PVC (RCN, 2003) to reduce the risk of infection associated with the procedure. To achieve satisfactory disinfection, a five Log_{10} reduction in the total number of exposed microorganisms is required when assessing the disinfectants activity *in vitro* (Cremieux *et al.*, 2000).

The aim of the study was to compare the antimicrobial efficacy of an innovative disinfectant, 2% (w/v) CHG in 70% (v/v) IPA (ChloraPrep®) with traditional skin disinfectants: 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70% (v/v) IPA and 10% (w/v), utilizing quantitative time kill suspension and carrier tests against *S. epidermidis* RP62A both in the presence and absence of serum. *S. epidermidis* was chosen as it is commonly associated with CRI (Parker, 2002) and the culture RP62A is a reference biofilm-positive strain and known slime producer. Therefore *S. epidermidis* RP62A was representative of the type of opportunistic pathogen that is associated with infections of implanted medical devices due their ability to adhere to, and colonise surfaces of biomaterials. In this study the time chosen for the time kill analysis was 30 seconds. This time is recommended for skin antisepsis prior to PVC insertion (RCN, 2003) and therefore reflects healthcare workers clinical practices. It is acknowledged that in certain cases antimicrobial effect is transitory (Cremieux *et al.*, 2000), however, PVC insertion requires fast acting antisepsis as the procedure is achieved very quickly.

The quantitative *in vitro* time kill suspension test demonstrated no detectable *S. epidermidis* RP62A following 30 seconds contact time with all six antimicrobial agents: 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70 % (v/v) IPA, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI. The findings related to ChloraPrep® support *in vivo* results reported by Hibbard (2002). When *S. epidermidis* RP62A was exposed to aqueous solutions of IPA of less than 40% for 30 seconds a five Log_{10} reduction factor was not achieved. This concurs with previous reports where IPA solutions of between 60% and 95% offer the most effective reduction in microbial counts (Crabtree *et al.*, 2000).

The presence of organic matter can both reduce the availability of the disinfectant for the microorganism (Best *et al.*, 1990) and reduce the antimicrobial properties (Ayliffe *et al.*, 1993). In the clinical setting organic matter in the form of blood and serum from the open wound is often present following invasive procedures such as; line insertion. To evaluate the effect of organic matter on the disinfection properties of the six antimicrobial agents investigated in this study, 10% (v/v) human serum was added to the suspension of *S. epidermidis* RP62A. All six antimicrobial agents: 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70 % (v/v) IPA, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI, achieved a five Log_{10} reduction factor in the presence of human serum.

Biofilm formation can be secreted as early as 24 hours (Annaissie *et al.*, 1995). Whilst this study determined the effectiveness of skin decontamination, chlorhexidine is known to have residual properties. Therefore, to replicate the potential complications of bacterial biofilm formation around implanted medical devices, the effectiveness of the six antimicrobial agents was tested against *S. epidermidis* RP62A growing in a biofilm. The presence of a biofilm reduces antimicrobial action by two mechanisms; the presence of the glycocalyx reduces the accessibility of the disinfectant to the microorganism and the physiological state of the cells can change depending up on their level within the structure (Cremieux *et al.*, 2000). Indeed, Vidal *et al.* (1997) noted that bacteria are 10 to 100 times more resistant to antiseptics in a biofilm compared to those cells in suspension.

Results of the efficacy of the six antimicrobial agents tested against *S. epidermidis* RP62A in a biofilm demonstrated that only four achieved a five Log_{10} reduction factor; 70% (v/v) IPA, 0.5% (w/v) CHG in IPA, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI. 0.5% (w/v) aqueous CHG and 2% (w/v) aqueous CHG only achieved a >4 to <5 Log_{10} reduction factor. Therefore, as with other commonly used skin disinfectants, the antimicrobial action of 2% (w/v) CHG in 70% (v/v) IPA is also reduced in the presence of a biofilm (Cremieux *et al.*, 2000).

A limitation of the *in vitro* carrier studies are that they only examine the effect the antimicrobial agent has by direct contact with the microorganism. This may not accurately reflect the procedures in a working clinical environment; for example, the healthcare worker wipes the antimicrobial agent on to the skin which would mechanically disrupt any biofilm present, therefore, potentially enhancing the antimicrobial properties of the disinfectant which is applied. Perhaps a two stage

disinfection procedure is necessary; especially if there is visible blood, protein and potentially biofilm present. For example the first disinfection would reduce levels of organic matter and biofilm after which a second disinfection step is undertaken. However, further work is required to undertake this hypothesis.

In both the suspension and carrier time kill studies, the antimicrobial agents were in contact with the microorganism for 30 seconds; which is the recommended antisepsis time for skin disinfection prior to the insertion of a PVC (ICNA, 2001). The carrier tests performed with *S. epidermidis* RP62A in a biofilm demonstrated that at 30 seconds aqueous CHG did not achieve a five Log_{10} reduction factor. It has been reported that the uptake of CHG by bacteria occurs within 20 seconds (Fitzgerald et al., 1989) which would explain its effectiveness in the *in vitro* suspension studies. However, in the presence of a biofilm these findings suggest that the combined antimicrobial properties of CHG in IPA are required. Therefore, for the rapid disinfection of skin prior to PVC insertion, where biofilms may be present, aqueous CHG would not be recommended.

The formation of bacterial biofilms around implanted medical devices may also include organic matter such as serum/blood, therefore 10% (v/v) human serum was added to the *S. epidermidis* RP62A prior to testing the antimicrobial agents against biofilm on a carrier. The results demonstrated that following a contact time of 30 seconds none of the six antimicrobial agents achieved a five Log_{10} reduction. However, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) PI achieved a 4 to 5 Log_{10} reduction factor. This was statistically significantly better than the remaining disinfectants (p= >0.0001): 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA.

In conclusion, these studies have demonstrated that the six antimicrobial agents were effective in achieving a five Log_{10} reduction factor of *S. epidermidis* RP62A in a standard suspension test both in the presence and absence of protein. However, as Vidal *et al.* (1997) noted, the same concentration of antimicrobial agent did not achieve the same level of results in the presence of a biofilm and additionally in the presence of one enriched with 10% (v/v) human serum. Nonetheless, the suspension and carrier tests have demonstrated that overall, 2% (w/v) CHG in 70% (v/v) IPA and 10% PI were the most effective antimicrobial agents when challenged with *S. epidermidis* RP62A.

The application of an effective skin antiseptic is essential in the strategy to reduce catheter related sepsis. CDC (2002) recommends the use of a 2% CHG preparation for skin decontamination prior to line insertion, but does not specify the use of either an aqueous solution or one in 70% IPA. Pratt *et al.* (2001) and NICE (2003) recommend an alcoholic chlorhexidine solution but do not specify a concentration. This present study supports the recommendation of utilizing an alcoholic CHG solution, as the *in vitro* results suggest that 2% (w/v) CHG in 70% (v/v) IPA offers an improved antimicrobial effect compared to the three standard preparations of CHG currently available in the UK: 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA, when challenged with *S. epidermidis* RP62A in a biofilm in the presence of 10% (v/v) human serum (p=>0.0001).

Future Recommendations.

Further *in vitro* studies are required to assess the effectiveness of 2% (w/v) CHG in 70% (v/v) IPA against other microbial pathogens such as Gram negative bacteria, mycobacterium, spores, viruses and fungal infections such as Candida sp. In addition, a wider range of time kill analysis would assess the residual activity compared to other commercially available antimicrobial agents. Finally, *in vivo* studies are required to assess the clinical effectiveness of 2% (w/v) CHG in 70% (v/v) IPA.

Chapter Six:

Determination of the Microbial Inhibitory Concentration and Microbial Bactericidal Concentration of Chlorhexidine Gluconate Against a Range of Clinical Isolates; *Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa and Candida albicans.*

6 Introduction.

Chlorhexidine is a biguanide compound which has a rapid, broad spectrum of antibacterial activity against Gram positive and Gram negative bacteria, yeasts and moulds but not spores (Fitzgerald *et al.*, 1989; Hugo and Russell, 1982; Nicoletti *et al.*, 1993). Disinfectants are required to be bactericidal as well as bacteriostatic. At low concentrations, up to 200µg/ml, chlorhexidine damages the cytoplasmic membrane, inhibiting membrane enzymes and promoting leakage of cellular constituents. This action is probably associated with bacteriostasis (Hugo and Russell, 1982). As the concentration increases a bactericidal effect is seen caused by coagulation of intracellular constituents, which leads to congealing of the cytoplasm and therefore a reduction in leakage (McDonnell and Russell, 1999).

Pratt *et al.* (2001), CDC (2002) and National Institute for Clinical Excellence (NICE, 2003) recommend that a chlorhexidine solution is utilized to disinfect the skin, prior to the insertion of vascular lines. In this current study, determination of the effectiveness of chlorhexidine against the five commonly identified pathogens which infect and colonise peripheral vascular catheters (PVC); *Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa* and *Candida albicans* (Elliott *et al.*, 1984; Mermel *et al.*, 2001; Graninger *et al.*, 2002; Parker, 2002), was evaluated utilizing tests to determine the minimum inhibitory concentration (MIC) and the microbial bactericidal concentration (MBC).

The bacteriostatic activity of a disinfectant is determined by an evaluation of its MIC. This test measures the inhibition of bacterial growth. The composition of the test medium is important when determining the sensitivity of organisms to bactericides. MIC values can be inconsistent, depending upon the agar/broth used. Baillie (1989) noted that the MIC of clinical isolates of *Pseudomonas aeruginosa* were considerably higher when

utilizing blood agar (Oxoid) compared to those for the same strains with Iso-Sensitest Agar (Oxoid). Chlorhexidine is a cationic molecule and a reaction can occur between the counter ion of another cationic molecule, resulting in the formation of a less soluble cationic salt, which may precipitate (Denton, 2000). Therefore, sensitivity test media is recommended for sensitivity testing as they are formulated to reduce the antagonistic effect of cations, whereas, the cation content of other media, such as, nutrient agar is not so well controlled (Baillie, 1989).

In addition, the MIC and MBC values for specific microorganisms may be inconsistent due to the emerging resistance patterns, such as methicillin resistant *Staphylococcus aureus* (MRSA). Contradicting results have been published comparing the bacteriostatic and bactericidal properties of chlorhexidine for methicillin sensitive *Staphylococcus aureus* (MSSA) and MRSA. Al-Masaudi *et al.* (1988) and Barry *et al.* (1999) reported no difference in sensitivity towards chlorhexidine for MSSA and MRSA. However, contradicting results were reported by Irizarry *et al.* (1996) and Suller *and* Russell (1999) who determined that MSSA strains were more susceptible to chlorhexidine than MRSA strains.

Information regarding the bacteriostatic and bactericidal activity of disinfectants is important for developing future clinical practice in light of emerging resistance among microorganisms. Chlorhexidine may be used in low concentrations (0.05% to 0.2% w/v) for dental procedures. Whilst this is higher than the reported MBC against a range of pathogens *in vitro* in the presence of blood, biofilm and other organic matter this may reduce its activity *in vivo*.

Aims of the study:

To determine antimicrobial activity for chlorhexidine utilizing MIC (microdilution technique) and MBC studies against; *S. epidermidis, S. aureus, P. aeruginosa and C. albicans.*

6.1 Materials and Methods.

a). Standardised solutions.

- Brain Heart Infusion (BHI) Agar Plates.

  One litre of BHI agar was prepared containing:

  - 37g BHI (Oxoid; Basingstoke, UK)
  - 1% Agar No1 (Oxoid; Basingstoke, UK)
  - 1000ml distilled water

The BHI agar was autoclaved at 121°C for 15 minutes, allowed to cool to 55°C and then 20ml aliquots were poured into sterile Petri dishes and allowed to set at room temperature. When set, the plates were stored at 4°C until required.

- Brain Heart Infusion Broth.

  One litre of BHI broth was prepared containing:

  - 37g BHI (Oxoid; Basingstoke, UK)
  - 1000ml distilled water

The BHI broth was autoclaved at 121°C for 15 minutes, allowed to cool and then stored at 4°C until required.

- Congo Red Agar Plates (Freeman *et al.*, 1989).

  Solution 1:

  - 15g Tryptone Soya broth (Oxoid; Basingstoke, UK),
  - 5g glucose (Sigma; St Louis, USA),
  - 7.5g Agar No1 (Oxoid; Basingstoke, UK)
  - 400ml distilled water.

  Solution 2:

  - 0.4g Congo red (Hopkin and Williams Ltd: Essex, UK)
  - 100ml distilled water.

The solutions were autoclaved separately at 121°C for 15 minutes, allowed to cool to 55°C and then mixed together. The Congo red solution was then poured into sterile Petri dishes and allowed to set.

- Iso-Sensitest Broth.

  One litre of Iso-Sensitest broth was prepared containing:

  - 23.4g Iso-Sensitest Broth (Oxoid; Basingstoke, UK)
  - 1000ml distilled water

The Iso-Sensitest broth was autoclaved at 121°C for 15 minutes and allowed to cool. This was then stored at 4°C until required.

- Letheen Agar Plates.

  One litre of Letheen agar was prepared containing:

  - 59.1g Difco™ Letheen Agar Modified (Becton Dickinson; Sparks, USA)
  - 1000ml distilled water

The Letheen agar was autoclaved at 121°C for 15 minutes, allowed to cool to 55°C and then 20ml aliquots were poured into sterile Petri dishes and allowed to set at room temperature. When set, the plates were stored at 4°C until required.

- Malt Extract Agar Plates.

  One litre of Malt Extract agar was prepared containing:

  - 50g Malt Extract Agar (Oxoid; Basingstoke, UK)
  - 1000ml distilled water

The Malt Extract agar was autoclaved at 121°C for 15 minutes, allowed to cool to 55°C and then 20ml aliquots were poured into sterile Petri dishes and allowed to set at room temperature. When set, the plates were stored at 4°C until required.

- Neutralising Solution.

  One litre of neutralising solution was prepared containing:

  - 2% (v/v) Tween 80 (BDH; Poole, UK)
  - 1.17% (w/v) Lecithin (Fisher Scientific; Loughborough, UK)
  - 0.1% (v/v) Triton X-100 (Sigma; St Louis, USA)
  - 0.5% (w/v) Sodium Thiosulphate (BDH; Poole, UK)
  - 1000ml distilled water (adapted from Sheikh 1981).

The neutralising agent was autoclaved at 121°C for 15 minutes and allowed to cool. This was then stored at 4°C until required.

- Sabouraud Broth.

  One litre of Sabouraud broth was prepared containing:

  - 30g Sabouraud Liquid Medium (Oxoid; Basingstoke, UK)
  - 1000ml distilled water

The Sabouraud broth was autoclaved at 121°C for 15 minutes and allowed to cool. This was then stored at 4°C until required.

b). Antimicrobial Agent:

- Test dilutions of chlorhexidine were prepared by diluting 20% (w/v) Chlorhexidine Digluconate (Sigma; St Louis, USA) in sterile Iso-Sensitest Broth (Oxoid) (Section 6.1a).

c). Challenge Microorganisms:

S. epidermidis.

- *S. epidermidis* RP62A (ATCC 35984) a reference biofilm-positive strain (Sadovaskaya *et al.*, 2004).
- Ten clinical isolates of *S. epidermidis* were obtained from blood cultures taken from bone marrow transplant patients who had central venous catheter related sepsis (UHB NHS Foundation Trust, UK).

S. aureus.

- *S. aureus* NCTC; 6571, 10788 and 8325.
- Seven clinical isolates of MSSA which were obtained from patients with orthopaedic bone infections at the UHB NHS Foundation Trust (stored at Aston University; Department of Pharmaceutical and Biological Sciences).
- Eleven clinical isolates of MRSA which were obtained from patients with blood stream infections at the UHB NHS Foundation Trust (stored at Aston University; Department of Pharmaceutical and Biological Sciences).

P. aeruginosa.

- *P. aeruginosa* PA01.
- Eight clinical isolates of *P. aeruginosa* which were obtained from patients with cystic fibrosis respiratory tract infections at the Birmingham Children's Hospital NHS Trust (stored at Aston University; Department of Pharmaceutical and Biological Sciences).

Bacterial isolates stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) were revived by placing one bead in 3ml of BHI broth (Oxoid; Basingstoke, UK) and incubating at 37°C in air for 24 hours. The suspension containing approximately $1x10^9$cfu/ml was confirmed using the Miles and Misra technique (1938).

C. albicans.

- C. *albicans* MYC1 (obtained as the reference strain from UHB NHS Foundation Trust; Microbiology Laboratory).
- Eight clinical isolates of C. *albicans* which were obtained from patients with blood stream infections at the UHB NHS Foundation Trust (stored at Aston University; Department of Pharmaceutical and Biological Sciences).

C. *albicans* isolates stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) were revived by placing one bead in 3ml of Sabouraud broth (Oxoid; Basingstoke, UK) and incubating at 37°C in air for 24 hours. The suspension containing approximately $1x10^8$cfu/ml was confirmed using the Miles and Misra technique (1938).

d). Determination of the minimum inhibitory concentration (MIC) by tube dilution technique.

A sterile microtitre tray (Appleton Woods; Birmingham, UK) was prepared containing 10 columns of a two fold dilution series of 100µl chlorhexidine concentrations in µg/ml (150; 75; 37.5; 18.8; 9.4; 4.7; 2.34; 1.2; 0.6; 0.3) and two columns of Iso-Sensitest broth (Oxoid) for controls. Five µl aliquots of the overnight suspension (Section 6.1c) diluted to approximately $1x10^7$ in BHI* were inoculated into each of the 10 wells containing the dilution series of CHG and the one positive control. The MIC determinant was repeated twice for each challenge microorganisms. The microtitre tray was then covered with a microplate sealer (Greiner-Bio-One. Gloucester, UK) and incubated at 37°C in air for 24 hours. After incubation the microtitre wells were inspected for turbidity. The MIC was regarded as the lowest concentration showing no turbidity.

* Sabouraud broth (Section 6.1a) was used to dilute C. *albicans* isolates.

e). Determination of the minimum bactericidal concentration (MBC).

Following determination of the MIC, 100µl of neutralising solution (Section 6.1a) was inoculated into each of the wells containing clear suspensions and left for 10 minutes. The 200µl suspension was then sub-cultured on to Letheen Agar plates* (Section 6.1a) to determine the minimum concentration required to kill the organism (MBC). The agar plates were incubated at 37°C in air for 24 hours and then examined for bacterial growth for each concentration of CHG. The lowest concentration which produced a reduction of 99.9% (3 logarithm cycles) of viable cfu was determined as the MBC

(EUCAST: European Committee for Antimicrobial Susceptibility Testing, 2000). Each MBC was repeated twice.

* Malt Extract Agar plates (Section 6.1a) were used to sub-culture C. *albicans* strains.

6.1.1 Determination of the Ability of the *S. epidermidis* Clinical Isolates to Produce Slime.

Confirmation of the 10 *S. epidermidis* isolates ability to produce slime was undertaken using the Congo red agar plate (Section 6.1a) method described by Freeman *et al.* (1989). The isolates were inoculated onto the Congo red agar plates and incubated at 37°C in air for 24 hours. Slime producing strains of staphylococci were characterised by the development of dry, crystalline, black colonies. Non slime producing strains remained pink.

Controls were performed using RP62A; a slime-positive strain and *S. hominis;* a slime negative species.

6.1.2 Determination of the Efficacy of the Neutralising Agent and the Antimicrobial Agent.

To determine whether the neutralising solution had a bactericidal effect on the *S. epidermidis* RP62A an overnight suspension of *S. epidermidis* RP62A was adjusted to $1x10^7$cfu/ml in BHI broth (Oxoid) and 10µl inoculated into 300µl of the neutralising solution (Section 6.1a). This suspension was spread over the surface of BHI agar plate (Oxoid) and incubated at 37°C in air for 24 hours. The cfu were enumerated and compared with the original inoculum count. Each test was performed in triplicate.

To determine the effectiveness of the neutralising agent (section 6.1a) against CHG, 150µl of the 0.5% (w/v) CHG solution (Section 6.1a) was dispensed into 150µl of neutralising solution and left for 10 minutes. Ten µl of *S. epidermidis* RP62A at a concentration of $1x10^7$cfu/ml was then added and mixed thoroughly for 60 seconds. The suspension was spread over the surface of a BHI agar (Oxoid) plate. All plates were incubated at 37°C in air for 24 hours and were then inspected for bacterial growth. Each test was performed in triplicate.

To confirm the bactericidal effectiveness of CHG, an overnight suspension of *S. epidermidis* spp was adjusted to $1x10^7$cfu/ml in BHI broth (Oxoid) and 10µl inoculated into 300µl of the 0.5% (w/v) CHG (Section 6.1a). This suspension was spread over the surface of BHI agar plate (Oxoid) and incubated at 37°C in air for 24 hours. The cfu were enumerated and compared with the original inoculum count. Each test was performed in triplicate.

6.1.3 Determination of the Bacteriostatic and Bactericidal Activity of Chlorhexidine Gluconate against Bacterial Clinical Isolates of *S. epidermidis* and *S. aureus*.

To determine the bacteriostatic and bactericidal activity of CHG an evaluation of the MIC (Section 6.1d) and MBC (Section 6.1e) against a range of challenge microorganisms; *S. epidermidis; S. aureus; P. aeruginosa and C. albicans*, using the microdilution method was undertaken.

The range of concentration of CHG used for determining the MIC and MBC was performed in doubling dilution steps from 150µg/ml to 0.03µg/ml. Precipitation of CHG in Iso-Sensitest (Oxoid) broth occurred at concentrations >150µg/ml, which supported previous reports by Nicoletti *et al.* (1993) who also found precipitation of CHG occurred in Tryptone Soya broth and Muller Hinton Broth in concentrations > 256µg/ml.

If an isolate continued to grow at its highest test concentration of 150µg/ml this was reported as MBC >150µg/ml.

6.2 Results.

6.2.1 Determination of the Ability of the *S. epidermidis* Clinical Isolates to Produce Slime.

Confirmation of the ability of *S. epidermidis* to produce slime was undertaken using the Congo red agar plate method (Freeman *et al.,* 1989). The positive result produced by slime producing strains of coagulase negative staphylococci is demonstrated by the development of dry, crystalline, black colonies. Non slime producing strains remain pink (Figure 6.1). Five out of nine clinical isolates of *S. epidermidis* were confirmed as slime producers (Table 6.1).

Figure 6.1: Non Slime-Producing and Slime-Producing Coagulase Negative Staphylococci Grown on Congo Red Medium: Slime producing strains show distinctive dry black colonies.

Table 6.1: Identification of which Isolates of *S. epidermidis* Produced Slime (n=11).

S. epidermidis spp Clinical Isolate number	Slime Production
Positive Control: *S. epidermidis* RP62A	Yes
Negative Control: *S. hominis*	No
1	No
3	Yes
4a	Yes
4b	Yes
7a	No
7b	No
7c	No
8a	Yes
8b	Yes

6.2.2 Determination of the Efficacy of the Neutralising Agent and the Antimicrobial Agent.

Confirmation of the non bactericidal effect of the neutralising agent against *S. epidermidis* and the neutralising effect against CHG was undertaken. No reduction in cfu/ml was detected following suspension of *S. epidermidis* in the neutralising agent ($1x10^7$cfu/ml) compared to the original overnight broth ($1x10^7$cfu/ml). In addition, no reduction in cfu/ml was observed following suspension of *S. epidermidis* spp in CHG and neutralising agent ($1x10^7$cfu/ml). Therefore, the neutralising agent was non bactericidal and effective in neutralising CHG.

Verification of the bactericidal effect of the CHG was confirmed by no growth on the overnight plates inoculated with *S. epidermidis* following suspension in 0.5% (w/v) CHG.

6.2.3 Determination of the Bacteriostatic and Bactericidal Activity of Chlorhexidine Gluconate against Bacterial Clinical Isolates of *S. epidermidis, S. aureus. P. aeruginosa* and *C. albicans.*

Analysis of the results obtained from the MIC and MBC studies for CHG against the clinical isolates of *S. epidermidis, S. aureus. P. aeruginosa* and *C. albicans* are shown in Table 6.2, 6.3 and Figure 6.2, 6.3 and 6.4.

All negative controls remained clear.

Figure 6.2: Letheen Agar Plates Illustrating the Determination of the Minimum Bactericidal Concentration for Chlorhexidine Gluconate Concentrations against *S. epidermidis* isolate 7a (range 2.3µg/ml to 18.8µg/ml).

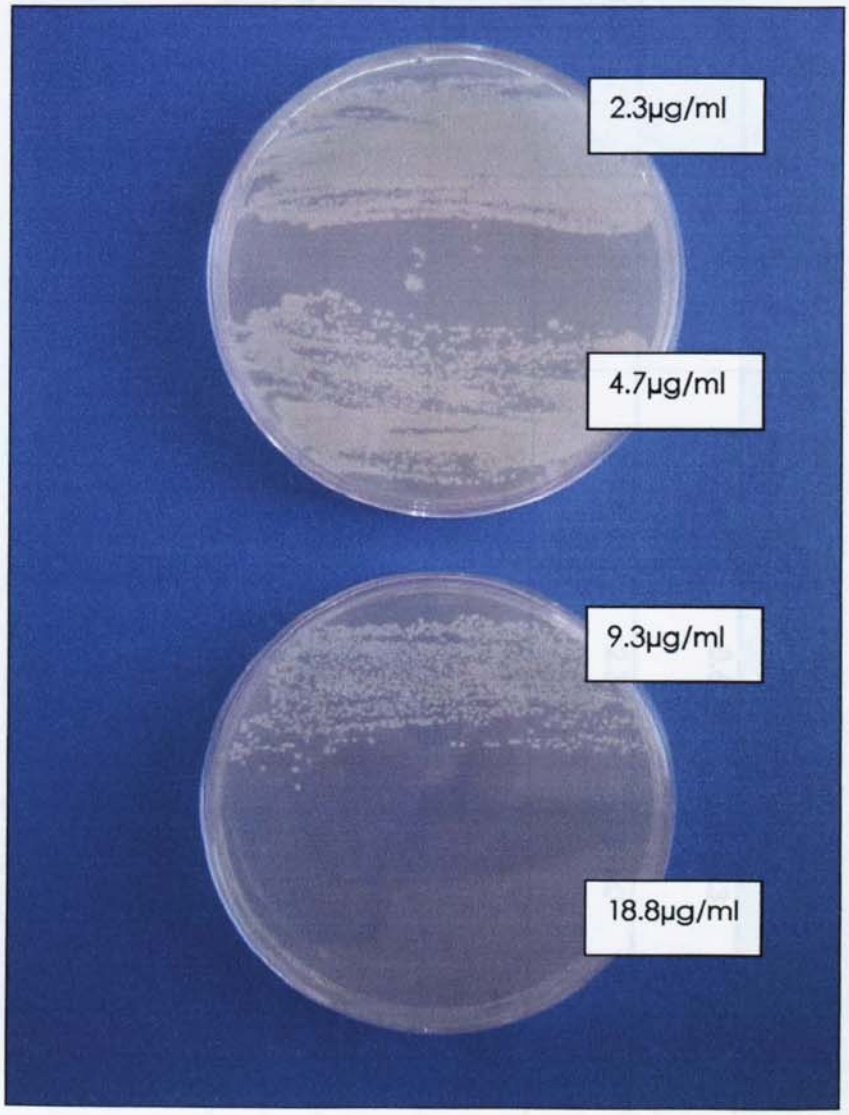


Table 6.2: A Comparison of the Minimum Inhibitory Concentrations (µg/ml) and Minimum Bactericidal Concentrations (µg/ml) Results for Chlorhexidine Gluconate, against *S. epidermidis, S. aureus, P. aeruginosa* and *C. albicans.*

Microorganism	MIC				MBC			
	Mean µg/ml	Range µg/ml	SD	CI	Mean µg/ml	Range µg/ml	SD	CI
S. epidermidis (n=10)	1.9	1.2-2.3	0.6	1.4-2.3	21.1	4.7-37.5	12.3	12.3-29.9
S. aureus: total (n=21)	3.0	1.2-9.4	2.3	1.9-4.0	30.5	3.4-75	18.7	22-39
S. aureus: MSSA (n=10)	1.9	1.2-2.3	0.6	1.4-2.3	23.5	9.4-37.5	12.7	14.4-32.5
S. aureus: MRSA (n=11)	4.1	2.3-9.4	2.8	2.2-5.9	37.5	18.8-75	20.5	23.7-51.3
P. aeruginosa (n=9)	11.5	9.4-18.8	18.8	9.5-13.5	-	-	-	-
C. albicans (n=8)	11.8	9.4-18.8	4.4	8.1-15.4	31.7	9.4-75	20.1	14.4-48.9

Figure 6.3: Comparison of the Microbial Inhibitory Concentrations (µg/ml) for Chlorhexidine Gluconate against *S. epidermidis, S. aureus, P. aeruginosa* and *C. albicans*.

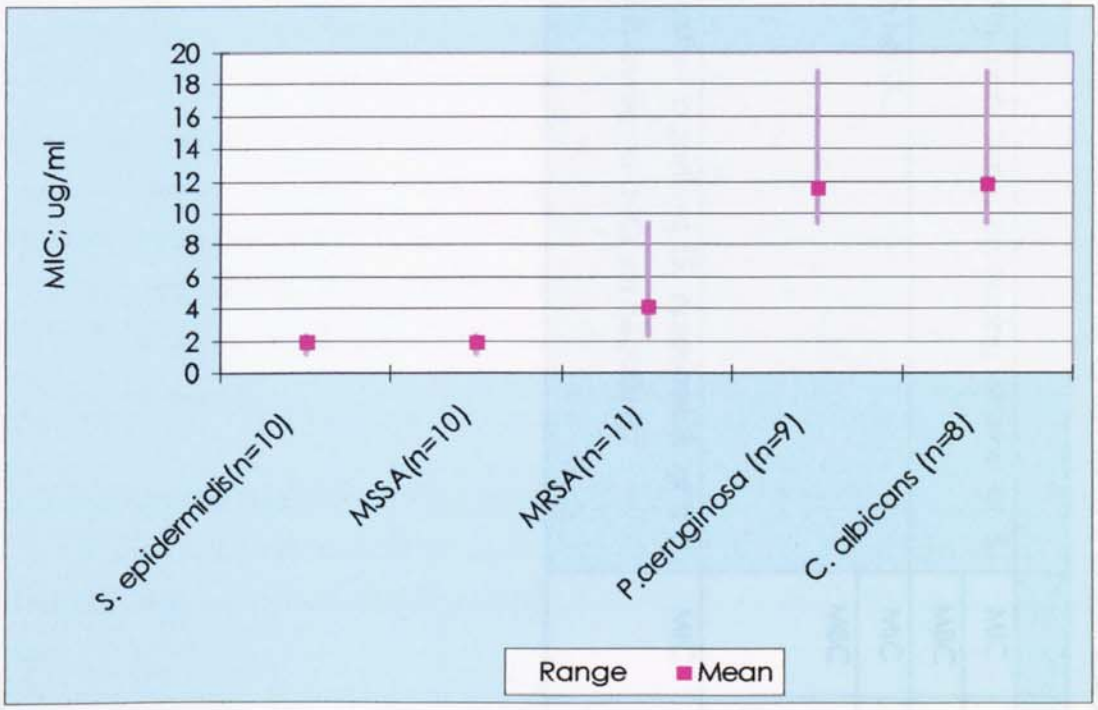


Figure 6.4: Comparison of the Microbial Bactericidal Concentrations (µg/ml) for Chlorhexidine Gluconate against *S. epidermidis, S. aureus, P. aeruginosa* and *C. albicans*.

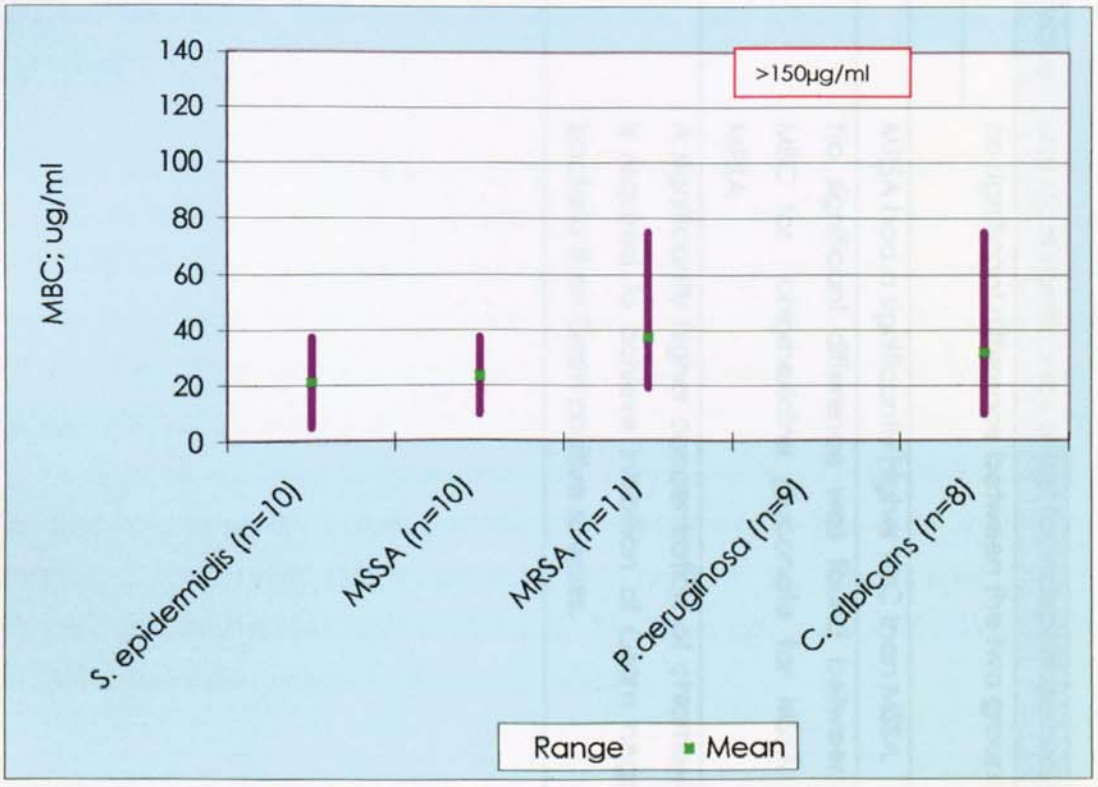


Table 6.3: A Statistical Comparison for Chlorhexidine Gluconate Against.....

		Two tailed *p* value	Statistical significance (*t*-test for independent values)
... slime with non slime producing strains of S. epidermidis.	MIC	0.66	no significant difference between the two groups
	MBC	0.66	
... MSSA with MRSA.	MIC	0.028	MRSA had a significantly higher MIC than MSSA
	MBC	0.075	No significant difference was found between the MBC for chlorhexidine gluconate for MSSA and MRSA
... Gram positive organisms (*S. epidermidis* and *S. aureus*) with *P. aeruginosa* (Gram negative).	MIC	0.0001	A significantly higher concentration of chlorhexidine is required to achieve inhibition of Gram negative bacteria than Gram positive species.

6.3 Conclusion.

Gram negative bacteria tend to be more intrinsically resistant to chlorhexidine than Gram positive strains due to the outer membrane acting as a barrier to limit its entry (McDonnell and Russell, 1999); the results of this study reflect this. The MICs for the Gram positive strains were; *S. epidermidis* 1.2µg/ml to 2.3µg/ml and *S. aureus* 1.2µg/ml to 9.4µg/ml. However, the MICs of the Gram negative bacterium *P. aeruginosa* were significantly higher (p=0.0001), 9.4µg/ml to 18.8µg/ml, supporting the findings of Nicoletti *et al.* (1993) and Kõljalg *et al.* (2002). In addition, chlorhexidine has good fungicidal activity (Ayliffe *et al.*, 1993), MICs for *C. albicans* were achieved at concentrations of 9.4µg/ml to 18.8µg/ml.

Comparing the MIC results of MSSA and MRSA in this study, demonstrated a significantly higher MIC was required to achieve bacteriostasis with MRSA compared to MSSA (p = 0.0286). This was consistent with the findings of Irizarry *et al.* (1996) and Suller *et al.* (1999).

Determination of the ability of the 10 strains of *S. epidermidis* to produce slime was examined. Six out of the 10 strains were found to be slime producers. When the effect of slime-producing and non slime-producing on the MIC and MBC was evaluated, no significant association was noted between the two groups (p=0.66 and 0.66 respectively).

There is not a standard methodology used for undertaking the MBC for chlorhexidine gluconate in the published data. Nicoletti *et al.* (1993) measured the MBC by sub-culturing all the MIC concentrations showing no visible growth into a neutralizer and then inoculated onto Columbia agar plates, Kõljalg *et al.* (2002) used the same method cited by Smith (2004) where sub-culturing the tubes showing no inhibition of growth onto agar plates was carried out; relying on dilution of the residual antimicrobial agent over the agar. In addition to these variables, Baillie (1989) and Nicoletti *et al.* (1993) noted that MIC and MBC values can be inconsistent depending upon the agar and broth used. Cookson *et al.* (1991) also noted that to obtain reproducible MIC and MBC results for chlorhexidine tests had to be run on the same day, by the same operator. All these variables make comparisons of MBC difficult.

This study demonstrates that the MIC and MBC for CHG are below the recommended concentration of 2% (w/v) for skin disinfection prior to vascular line insertion (CDC, 2002)

for the four microorganisms which are most frequently associated with vascular line infections; *S. epidermidis, S. aureus, P. aeruginosa* and *C. albicans* (Elliott *et al.*, 1984; Mermel *et al.*, 2001; Graninger *et al.*, 2002; Parker, 2002). Therefore, 2% (w/v) CHG should achieve *in vitro* disinfection. However, various factors may affect the efficacy of disinfectants such as organic matter; blood, serum, pus and dirt (Russell *et al.*, 1982). In addition, it is recommended that skin disinfection prior to PVC insertion requires a skin contact time of 30 seconds (RCN, 2003) and therefore disinfectant activity is also reliant on correct application by healthcare workers. Further *in vivo* studies are required to confirm that skin disinfection prior to PVC insertion, can be achieved in the much shorter time of 30 seconds (RCN, 2003) than that undertaken in the MIC and MBC studies.

Chapter Seven:

Determining the Potential Microbial Contamination Risk Associated with 2% (w/v) Chlorhexidine Gluconate in 70% (v/v) Isopropyl Alcohol Compared with 70% (v/v) Isopropyl Alcohol on Peripheral Vascular Catheters.

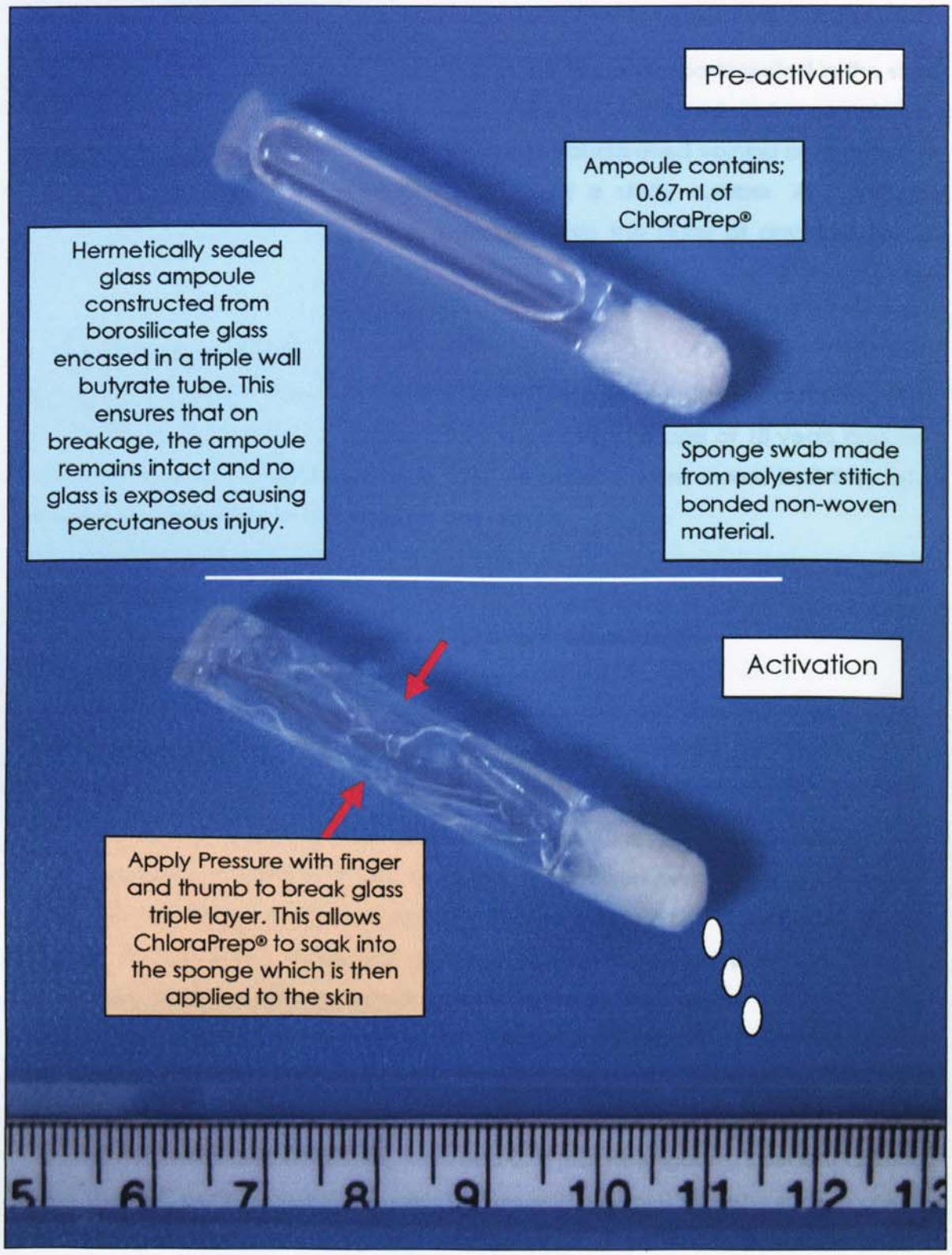
7 Introduction.

Patients who require a peripheral venous catheter (PVC) as part of their clinical management are at risk of developing a catheter related infection (CRI). The four routes by which organisms may gain access to intravenous (IV) catheters are extraluminal, intraluminal, by haematogenous seeding or via contaminated infusate (Elliott, 1993). Extraluminal colonisation occurs when microorganisms are impacted on the distal tip of the catheter during insertion or following ingress from the skin surface (Elliott and Tebbs, 1998). In order to reduce the risk of colonisation of the tip of the PVC on insertion, it is recommended that the intended site should be cleansed with an antimicrobial solution for at least 30 seconds and allowed to dry before the cannula is inserted (Royal College of Nursing; RCN, 2003). The antimicrobial solution recommended by the Evidence Based Guidelines for Preventing Healthcare Associated Infections in Primary and Community Care in England (EPIC) project for line insertion was 2% (w/v) aqueous chlorhexidine gluconate (CHG) (Pellowe *et al.*, 2004). Recently Medi-Flex® International (Kansas, USA) have developed ChloraPrep® (Figure 7.1); a 2% (w/v) CHG in 70% (v/v) isopropyl alcohol (IPA) solution for skin decontamination prior to insertion of PVC, therefore, potentially reducing the risk of phlebitis.

Aims of the Study.

1. Evaluation of the rate of phlebitis associated with PVC entry sites following skin decontamination with ChloraPrep® (Medi-Flex®) compared with Sterets® (70% IPA swab. Seton Healthcare; Oldham, UK)
2. Evaluation of the microbial contamination rates of PVC tips following skin decontamination with ChloraPrep® (Medi-Flex®) compared with Sterets ® (Seton Healthcare).

Figure 7.1: ChloraPrep® (Medi-Flex®) Antimicrobial Skin Agent for PVC Insertion Site Decontamination (scale in cm).



7.1 Materials and Methods.

a). Healthcare Worker Inclusion Criteria.

Healthcare workers who regularly insert PVC in the trial areas participated in the study. Written consent (Appendix 9) was obtained, and each healthcare worker completed a demographic questionnaire (Appendix 10) and a standardised training programme. To maintain anonymity each participant was issued a study number. All healthcare workers were aware that they could withdraw from the study at any time for any reason.

b). Patient Inclusion Criteria.

All patients included in the study required a PVC as part of their clinical management for a minimum of 24 hours. In addition, they were over the age of 18 years and were competent to give consent (Appendix 11). All patients were aware that they could withdraw from the study at any time, for any reason.

c). Antimicrobial Skin Agents:

- 2% (w/v) CHG in 70% (v/v) IPA (ChloraPrep®; Medi-Flex®)
- 70% (v/v) IPA (Sterets®; Seton Healthcare).

d). Peripheral Vascular Catheter Insertion.

Standard practices were followed to insert the PVC.

- Healthcare worker hand decontamination was performed utilizing either alcohol hand sanitizer (Purell. Gojo Industries; Milton Keynes, UK) or 4% aqueous chlorhexidine gluconate (Hibiscrub®; Regent Medical Ltd; Manchester, UK) prior to PVC insertion. Protective clothing (gloves, disposable plastic aprons) was worn by the healthcare worker as determined by themselves.
- The type of PVC utilized on the trial wards was standardised to Optiva 2 (Medex Medical Ltd; Rossendale, UK).
- Antimicrobial skin agent; chosen by randomization.
- All PVC were dressed utilizing the Veca-C™ (BD; Helsingborg, Sweden) dressing.
- The PVC ports were flushed post insertion with 5mls of 0.9% (w/v) sodium chloride (Antigen Pharmaceuticals; Tipperary, Ireland).
- All entry ports to the PVC were disinfected prior to, and after use utilizing, 70% (v/v) IPA; Sterets (Seton Healthcare).
- Following insertion of the PVC, the healthcare worker completed a clinical report form (Appendix 12) detailing information relating to the procedure which

included; patient demographic details and condition of the vein where the PVC was inserted.

e). Determination of Whether Any Residual Effect of ChloraPrep® Remained in the Vortexed Fluid Following Quantitative Tip Analysis (Brun-Buisson et al, 1987) of the Peripheral Vascular Catheter Tips Obtained from Patients who had Received Skin Disinfection Utilizing ChloraPrep®.

- Determination of the Efficacy of the ChloraPrep® (Medi-Flex®).

An overnight suspension of *S. epidermidis* RP62A was adjusted to $1x10^6$ cfu/ml and 100µl inoculated over the surface of a Nutrient Agar plate (BioMerieux; Basingstoke, UK) which was allowed to dry at room temperature for 30 minutes. To demonstrate antimicrobial activity, 10µl of ChloraPrep® was placed onto the centre of an inoculated agar plate and allowed to dry at room temperature. Each test was performed in triplicate. All plates were incubated at 37°C in air for 24 hours and were then inspected for zones of bacterial inhibition.

- Challenge Microorganism: *S. epidermidis* RP62A (ATCC; American Type Culture Collection 35984).

Microorganisms stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) were revived by placing one bead in 3ml of brain heart infusion (BHI) broth (Oxoid; Basingstoke, UK) and incubating at 37°C in air for 24 hours. The suspension was adjusted to the required concentration by dilution in 0.9% (w/v) sterile phosphate buffered saline (PBS) and confirmed using the Miles and Misra technique (1938).

- Determination of Residual Effect.

An overnight suspension of *S. epidermidis* RP62A was adjusted to $1x10^6$ cfu/ml and 100µl inoculated over the surface of a Nutrient Agar plate (BioMerieux; Basingstoke, UK) which was allowed to dry at room temperature for 30 minutes. To demonstrate antimicrobial activity, 10µl of the vortexed fluid obtained following quantitative tip analysis (Brun-Buisson *et al.*, 1987) of the PVC tips obtained from patients who had received skin disinfection with ChloraPrep® (Medi-Flex®) was placed onto the centre of an inoculated nutrient agar plate (BioMerieux) and allowed to dry at room temperature. Each test was performed in triplicate. All plates were incubated at 37°C in air for 24 hours and were then inspected for zones of bacterial inhibition. Negative controls utilizing 10µl of 0.9% (w/v) sodium chloride (BBraun; Melsungen, Germany) were also performed in triplicate.

f). Sampling of Peripheral Venous Catheter Tips for Microbial Contamination:

The PVC was removed from the patient as per routine clinical practice. On removal the catheter tip was removed from the hub using a sterile blade, placed into a sterile

container and transported to the laboratory. The external and internal surfaces of the catheter were cultured for microorganisms using the quantitative tip culture method (Brun-Buisson *et al.*, 1987).

g). Identification of Microorganisms by Utilization of Standard Laboratory Techniques Including:

- Gram stain (Shanson, 1982).

- Catalase test (Lennette *et al.*, 1985).
  This test differentiates whether a Gram positive bacterium is a staphylococcus species (sp, catalase positive) or a streptococcus sp (catalase negative).

- Coagulase test (Shanson, 1982).
  This differentiates whether the Gram positive bacterium is a *Staphylococcus aureus*; (coagulase positive) or a coagulase negative staphylococci (CNS) sp including *S. epidermidis.*

- Oxidase test (Lennette *et al.*, 1985).
  This is a differential test to distinguish oxidase positive pseudomonads from other Gram negative bacteria.

h). Daily Clinical Evaluation of the Peripheral Vascular Catheter Insertion Site:

The study patients were reviewed daily. A standardised tool (Appendix 13) was used to assess key features, which included;

- Insertion site observation; erythema, induration, palpable venous cord, signs of blood, swelling around the site and intact dressing.
- Pain; patient scoring of pain associated with catheter use, touch and manipulation.
- Phlebitis scoring tool; (Jackson, 1998). A score of none indicated no signs of phlebitis; one, the possible first stages of phlebitis; two to five indicated advancing stages of severity of phlebitis (Appendix 14).
- Intravenous medications.
- Reasons for PVC removal.

i). Sample Size.

Current evidence suggests a phlebitis rate of between 7% and 14% associated with PVC. Assuming a phlebitis rate of 10%, 95% confidence intervals, 80% power and a reduction in phlebitis rate of 50%, a population sample size of 900 patients who required a PVC was needed. The sample size was as follows:

- 450 patients received skin disinfection prior to PVC insertion with 70% (v/v) isopropyl alcohol (IPA); Sterets® (Seton Healthcare).
- 450 patients received skin disinfection prior to PVC insertion with 2% (w/v) CHG in 70% (v/v) IPA; ChloraPrep® (Medi-Flex®).
- Length of study was estimated to last 12 to 18 months.

j). Ethical Approval.

Ethical approval was obtained from South Birmingham Research Ethics Committee prior to commencing the study (Appendix 15) in the clinical areas.

k). Laboratory Risk Assessment: Low Risk.

Laboratory risk assessment was undertaken utilizing risk UHB NHS Foundation Trust and Aston University assessment forms.

7.2 Results; interim.

An interim analysis of the first 107 patients of 900 who were eligible for recruitment into the study are detailed below.

7.2.1 Epidemiology of Healthcare Workers who Cannulated Patients for the Trial.

Insertion of PVC on the clinical trial areas was undertaken by both nurses and doctors. A total of 40 healthcare workers consented to be included in the trial following training in the study protocol and product use. Table 7.1 demonstrates the epidemiology of the healthcare workers recruited and shows both the wide range of experience in PVC insertion and the numbers of PVC they estimate they insert per week.

Table 7.1: Epidemiology of Healthcare Workers who Consented to Take Part in the Clinical Trial of ChloraPrep® versus Sterets®.

	Nurses (n=34)	Doctors (n=6)
Length of Experience Inserting PVC.		
0 – 6 months	2	0
6.1 – 12 months	4	2
1 - 3 years	8	4
3.1 – 6 years	13	0
6.1 – 9 years	0	0
9.1 – 12 years	1	0
12.1 – 15 years	2	0
>15 years	4	0
Average Number of PVC Inserted/Week.		
1 - 5	15	1
6 - 10	10	2
11 – 15	2	3
16 – 20	4	0
20 – 25	1	0
>25	2	0

7.2.2 Epidemiology of Patients Who Consented to Be Included in the Trial.

A total of 107 patients, from five clinical trial wards, consented to be included in the trial and met the inclusion criteria. Table 7.2 compares the epidemiological data from patients who were computer randomised to receive ChloraPrep® (Medi-Flex®) skin disinfection with those who received Sterets® (Seton Healthcare). The higher number of male patients was reflective of the ward populations in the trial wards.

Table 7.2: A Comparison of the Epidemiology of the Patients who Consented to be Included in the Trial which Compares ChloraPrep® and Sterets® Skin Disinfectants on the Rate of Peripheral Vascular Catheter Associated Phlebitis.

	ChloraPrep® (n=57)	Sterets® (n=50)
Clinical Wards:		
E3LU	6	4
W3LU	0	2
E1A	15	12
E2A	31	31
Coronary care	5	1
Male (n=71)	36	35
Female (n=36)	21	15

7.2.3 Time (days) Peripheral Vascular Catheter Remained *In Situ*.

No significant difference was determined between the length of time the PVC was left *in situ* when comparing ChloraPrep® (Medi-Flex®. 2.4 days) with Sterets® (Seton Healthcare. 2.3 days) utilized to disinfect the skin prior to PVC insertion ($p = 0.45$. Mann-Whitney U test) (Table 7.3).

Table 7.3: A Comparison of the Length of Time (days) the Peripheral Vascular Catheters Remained *In Situ* for Patients who Received Skin Preparation with ChloraPrep® and Sterets®.

	ChloraPrep®	Sterets®
Number of Days Cannulated (n=107):		
Range	1 to 8	1 to 8
SD	1.2	1.2
Mean	2.4	2.3
CI	2.1 to 2.7	1.9 to 2.6

7.2.4 Healthcare Worker Evaluation of the Ease of the Patients Vein to Cannulate.

Following insertion of the PVC the healthcare worker scored the patient's vein for ease of cannulation, utilizing a Likert Scale of one to 10 (where one equalled optimum and 10 was very difficult). There was no significant difference in the healthcare workers assessment of ease of cannulation (p = 0.49, Mann-Whitney U test) between the two groups; ChloraPrep® (Medi-Flex®) mean score was 4.9 compared to Sterets® (Seton Healthcare) which was 4.6 (Table 7.4).

Table 7.4: A Comparison the Two Cohort Groups Likert Evaluation Scores (1 = optimum) Given by Healthcare Workers Rating the Patients Vein for Ease of Cannulation.

	ChloraPrep®	Sterets®
Condition of vein (n=101 out of 107; 94%):	n=52 out of 57 (91%)	n=49 out of 50 (98%)
Range	1 to 10	1 to 9
SD	2.35	2.4
Mean	4.9	4.6
CI	4.3 to 5.6	3.9 to 5.3

7.2.5 Phlebitis Score.

Patients who had been recruited in to the study had their PVC site assessed daily by the research nurse, utilizing the Jackson Evaluation Tool (1997). None of the 107 patients in either arm of the study had confirmed signs of phlebitis detected (score two to five).

However, three patients had a phlebitis score of one, which indicated that there was a possible sign of phlebitis developing; one utilized ChloraPrep® (Medi-Flex®) skin disinfection and two utilized Sterets® (Seton Healthcare).

7.2.6 Determination of Whether Any Residual Effect of ChloraPrep® Remained in the Vortexed Fluid Following Quantitative Tip Analysis (Brun-Buisson *et al.*, 1987) of the Peripheral Vascular Catheter Tips Obtained from Patients who had Received Skin Disinfection Utilizing ChloraPrep®.

The efficacy of ChloraPrep® (Medi-Flex®) against the challenge microorganism *S. epidermidis* RP62A was demonstrated by zones of bacterial inhibition on each inoculated Nutrient Agar plate (BioMerieux).

No residual effect of ChloraPrep® remained in the vortexed fluid following quantitative tip analysis (Brun-Buisson *et al.*, 1987) of the PVC tips obtained from patients who had received skin disinfection with ChloraPrep® (Medi-Flex®). This was demonstrated by no visual zones of bacterial inhibition on each inoculated plate.

Negative controls utilizing 0.9% sodium chloride (BBraun) did not show any zones of inhibition.

7.2.7 Microbial Analysis of Peripheral Vascular Catheter Tips.

Following the removal of the PVC by the healthcare worker on completion of clinical need, the tip of the PVC was sent for microbial analysis. Ninety-one out of 107 (85%) PVC tips were received; 49 from the patients who had received ChloraPrep® (Medi-Flex®) and 42 from those who had received Sterets® (Seton Healthcare). There was a significantly higher microbial tip contamination rate when Sterets® (Seton Healthcare) were utilized to decontaminate the skin prior to PVC insertion compared to that when ChloraPrep® (Medi-Flex®) was used ($p = 0.042$. Fisher's Exact Test). Seventeen out of 42 (40%) tips from PVC which had been inserted following skin preparation with Sterets® (Seton Healthcare) were found to be positive, compared to only 10 out of 49 (20%) tips from patients who had received ChloraPrep® (Medi-Flex®) (Table 7.5).

Table 7.5: A Comparison of the Peripheral Vascular Catheter Tip Microbial Contamination Identified Following Removal of Cannula from Patients who had Received either ChloraPrep® or Sterets® Skin Decontamination.

	ChloraPrep®	Sterets®
PVC tips received for microbial analysis (n=91 out of 107; 85%).	49	42
Number of PVC tips with Positive Microbiology (n=27 out of 91; 30%).	10 out of 49 (20%)	17 out of 42 (40%)
Bacteria isolated:		
Streptococcus sp	5	3
CNS	1	12
Pseudomonas sp	1	5
S. aureus	2	3
Bacillus sp	1	0
Neisseria sp	0	4

7.3 Conclusion.

Interim analysis of 107 clinical trial patients suggests that when the PVC remained *in situ* for an average time of 2.4 days there was no difference in PVC associated phlebitis, irrespective of whether ChloraPrep® or Sterets® skin disinfection was utilized. However, microbial contamination of the PVC tip was significantly lower when ChloraPrep® was utilized compared to Sterets® ($p = 0.042$). The CDC (2002) recommends that PVC may be left *in situ* for up to 96 hours. Therefore, ChloraPrep® may reduce the risk of phlebitis for patients who require longer periods of PVC access than patients in this current study required.

7.4 Recommendations.

So far this study has largely recruited patients who have been admitted for cardiac investigations following an acute cardiac episode. Therefore, PVC are only required for short duration. To compare the reduction in PVC associated phlebitis between ChloraPrep® and Sterets® skin disinfection, it is advisable that future patients are recruited from a wider range of specialities which include patients with chronic illnesses such as a general medical ward.

This work was undertaken in conjunction with Heather Small (Clinical Research Nurse; UHB NHS Foundation Trust).

Chapter Eight:

Studies to Assess the Potential Infection Risk Associated with Nexiva™ (BD) Peripheral Vascular Catheter and Q-Syte™ (BD) Needleless Connector.

8 Introduction.

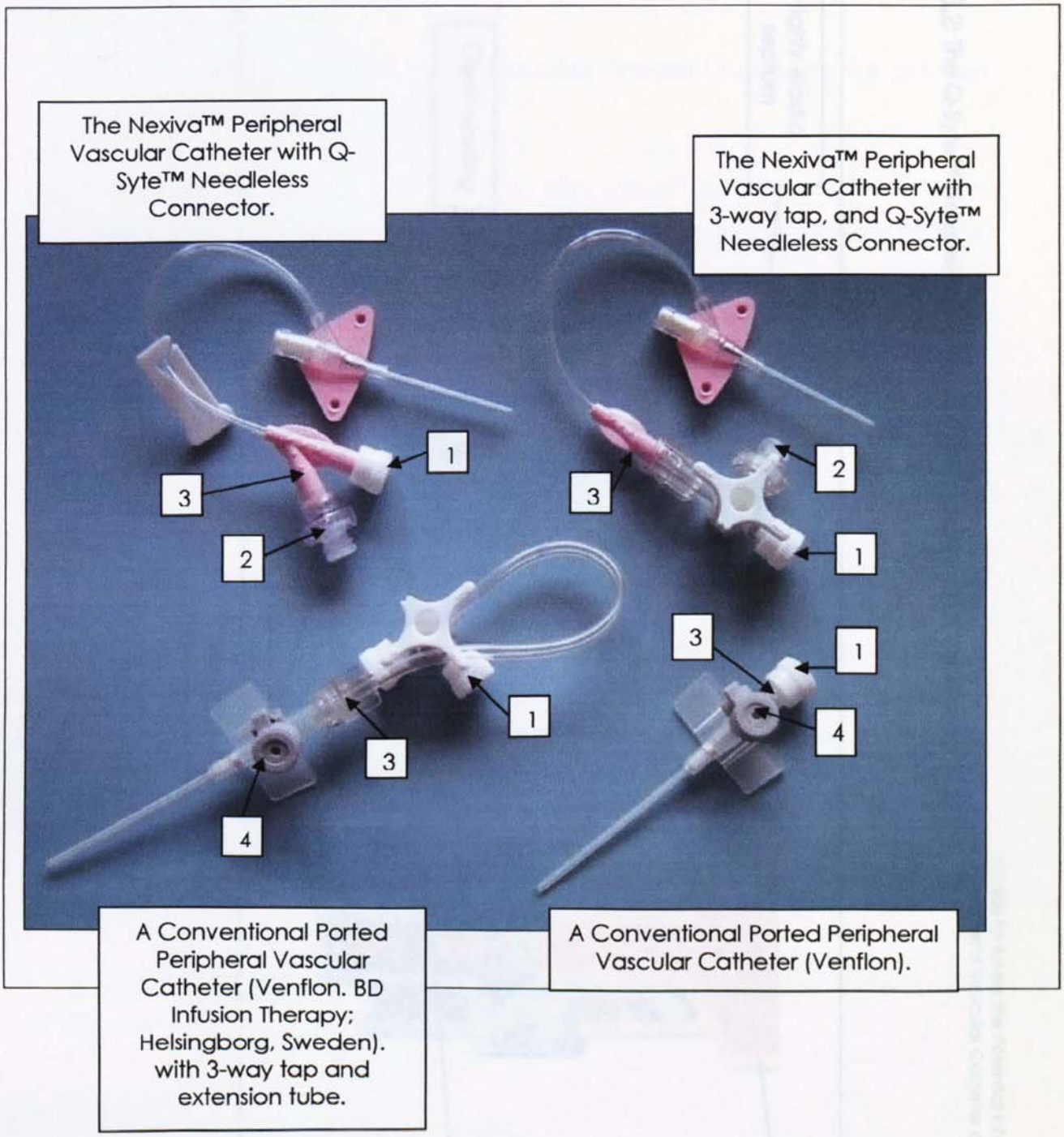
Microorganisms may contaminate an intravenous (IV) catheter via several routes. However, the most frequent mechanism is via the intraluminal and extraluminal pathways (Elliott, 1993); commonly due to contamination of the catheter hub from manipulation (Sitges-Serra *et al.*, 1985; Linares *et al.*, 1985). Tebbs *et al.* (1996) demonstrated that the rate of microbial contamination in stopcocks attached to IV catheters can be as high as 22%. Furthermore, the study demonstrated that there was a clear correlation between the microbial contamination rate and the frequencies of manipulation of the port. In comparison, Brown *et al.* (1997) showed that Connecta Clave (Ohmeda, UK), a needleless connector which was designed to keep the external surface apart from the channel for injection, reduced the risk of microbial contamination to 2%, despite 72% of the external compression seals still having microorganisms on their surface following disinfection with 70% (v/v) isopropyl alcohol (IPA). More recently, Casey *et al.* (2003) compared the microbial contamination rates of standard luer ports with those which had a needleless connector (PosiFlow®, Becton Dickinson, USA). Following 72 hours of clinical use, 18% of the standard luer connectors were microbially contaminated compared to only 6.6% of the needleless connectors.

Aims of the Study:

To determine the microbial contamination risk associated with the Q-Syte™ needleless connector (Becton Dickinson. BD; Utah, USA), utilizing *in vitro* studies.

To compare the microbial contamination risk associated with four peripheral vascular catheter (PVC) configurations (Figure 8.1); Nexiva™ PVC with a Q-Syte™ needleless connector (BD; Utah, USA); Nexiva™ PVC with 3-way tap and Q-Syte™ needleless connector (BD; Utah, USA); conventional ported PVC and conventional ported PVC with 3-way tap, following the preparation and infusion via the access port of 10ml, 0.9% (w/v) sterile saline by 50 nurses in their clinical setting.

Figure 8.1: The Nexiva™ Peripheral Vascular Catheter (BD) and Conventional Ported Peripheral Vascular Catheters (with and without three way taps).



Legend:

1. Hub with male Luer connector
2. Q-Syte™ needleless connector (Figure 8.2)
3. Luer
4. Side port

Figure 8.2: The Q-Syte™ Needleless Connector (graphic supplied courtesy of BD).

8.1 Materials and Methods.

a). Standardised solutions:

- Saline flush: Saline XS (BD, Le Pont-de-Claix, France); a sterile syringe pre-filled with 10 ml, 0.9% (w/v) sterile saline.

b). Challenge Microorganism:

- *Staphylococcus epidermidis*: *S. epidermidis* NCTC (National Collection of Type Cultures) 9865 stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) stored at -20°C were revived by placing one bead in 3ml of brain heart infusion (BHI) (Oxoid; Basingstoke, UK) and incubated at 37°C for 24 hours in air. The culture was then supplemented with 0.75ml (25%) human blood (Haematology Dept: University Hospital Birmingham (UHB) NHS Foundation Trust, UK).

c). Antimicrobial agent: 70% (v/v) IPA swab (Sterets; Seton Healthcare, Oldham, UK).

d). Estimation of the Number of CFU/ml: The number of viable *S. epidermidis* NCTC 9865 in suspension were enumerated by serial dilutions (10^{-1} to 10^{-6}) followed by inoculation on to Columbia agar plates containing 5% horse blood (BioMerieux; Basingstoke, UK) using the Miles and Misra technique (1938). The plates were then incubated at 37°C for 24 hours in air.

e). Q-Syte™ needleless connector: (BD; Utah, USA).

f). Peripheral Vascular Catheters: Nexiva™ (BD; Utah, USA) and Venflon (BD; Helsingborg, Sweden).

g). Sample Size:

- *In Vitro* Microbial Contamination Rates:

The sample size of 50 Q-Syte™ connectors was chosen to ensure that the width of the 95% CI for the contamination rate would be < 0.3 (whatever the contamination rate in the sample).

- Determining the Microbial Contamination Rates Associated with the Two Catheters:

The sample size of 50 healthcare workers (for each catheter configuration) was chosen so that a difference of 0.3 in contamination rates could be detected with 80% power at a significance level of 0.05.

h). Ethical Approval.

Ethical approval was obtained from South Birmingham Research Ethics Committee prior to commencing the study (Appendix 16) in the clinical areas. All participants were provided with a study information sheet (Appendix 17) and gave written consent (Appendix 18) prior to their inclusion.

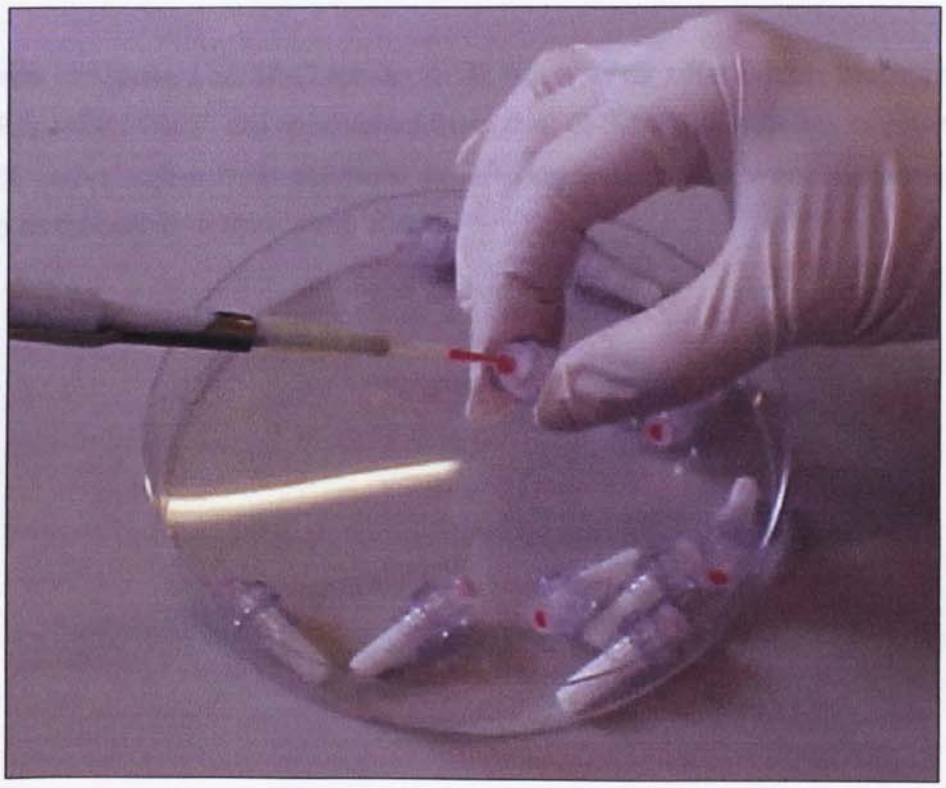
i). Risk Assessment: Low Risk.

Laboratory risk assessment was undertaken utilizing risk UHB NHS Foundation Trust and Aston University assessment forms.

8.1.1 Determination of the Microbial Contamination Associated with the Q-Syte™ Needleless Connector (BD) Following *In Vitro* Contamination and Disinfection with 70% Isopropyl Alcohol.

Sixty Q-Syte™ needleless connectors (BD) were used in the *in vitro* contamination studies; 50 test devices, five positive controls (inoculated with the suspension below) and five negative controls (uninoculated). The compression seals of 55 of the 60 Q-Syte™ needleless connectors (BD) were inoculated with 10µl of a suspension containing 6.5×10^6cfu *S. epidermidis* NCTC 9865 (Section 8.1b) supplemented with 25% (v/v) human blood (UHB) and allowed to dry at 37°C, in air for 30 minutes (Figure 8.3).

Figure 8.3: Inoculation of Q-Syte™ Needleless Connector Compression Seals (BD) with *S. epidermidis* NCTC 9865 Suspension in Brain Heart Infusion (Oxoid) Containing 25% (v/v) Human Blood (UHB).



Fifty test devices and five (uninoculated) negative control devices were then disinfected with Sterets swabs (Seton Healthcare). Disinfection was achieved by firmly applying one swab to the compression seal of each device and rotating five times through 360° and allowing the 70% (v/v) IPA to dry for two minutes in air. Five (inoculated) positive controls were not disinfected.

A pre-filled Saline XS syringe (BD) was then aseptically attached to each Q-Syte™ needleless connector (BD). Each device was flushed through with 10ml, 0.9% sterile saline. The first 5ml of the saline flush solution was collected in one sterile Petri dish and the second 5ml was collected in another sterile Petri dish. Fifteen ml of molten nutrient agar (Oxoid, Basingstoke, UK) cooled to 56°C was added to each plate, mixed thoroughly with the 0.9% (w/v) saline flush and allowed to set at room temperature.

The syringe Luer tip which had been attached to the Q-Syte™ compression seal (BD) was sampled for microbial contamination. Each syringe Luer tip was imprinted 10 times onto the surface of a nutrient agar plate (Oxoid).

The compression seals of each Q-Syte™ needleless connector (BD) were sampled for microbial contamination following the flush procedure, as described previously. Each compression seal was imprinted onto the surface of a nutrient agar plate (Oxoid).

Plates were incubated at 37°C for up to 48 hours in air after which the number of *S. epidermidis* NCTC 9865 cfu recovered from the; Q-Syte™ needleless connector (BD), 10ml 0.9% (w/v) saline flush solutions and syringes Luer tips were determined, and recorded as follows: 0, 1-10, 11-100, >100.

8.1.2 Determination of the Microbial Contamination of 0.9% (w/v) Saline Flush Solutions Following Infusion through a Multiply Activated Q-Syte™ Needleless Connector (BD).

Sixty Q-Syte™ needleless connectors (BD) were analysed; 50 test devices, five positive controls and five negative controls.

Following multiple activations (Table 8.1), the compression seals of 55 Q-Syte™ needleless connectors (BD) were inoculated with 10µl of a suspension containing $1.5x10^7$ cfu *S. epidermidis* NCTC 9865 in BHI (Oxoid), enriched with 25% (v/v) human blood (UHB). This was allowed to dry on the surface of the seal at 37°C in air for 30 min.

Table 8.1: The Multiple Activation Process of the Q-Syte™ Needleless Connectors (BD) with a Pre-Filled Saline XS Syringe (BD).

Number of Q-Syte™ needleless Connectors (BD) activated	Number of times Activated with a sterile Luer-lok™ syringe	Number of Times Activated with a Saline XS Syringe (BD)
5	0	1
5	9	1
5	29	1
5	49	1
5	69	1

The 50 Q-Syte™ test devices and five negative controls were then disinfected with Sterets swabs (Seton Healthcare). This was achieved by firmly applying the swab to the compression seal of each device and rotating five times through 360° and allowing the 70% (v/v) IPA to dry in air for two minutes. One Sterets swab (Seton Healthcare) was used per Q-Syte™ device. The five positive controls were not disinfected.

A pre-filled Saline XS syringe (BD) was aseptically attached to each Q-Syte™ device (BD). Five ml of 0.9% (w/v) saline was flushed through the device and collected in a sterile Petri dish. The remaining 5ml was flushed through into a second sterile Petri dish. Fifteen ml of molten nutrient agar (Oxoid) cooled to 56°C was added to each plate, mixed thoroughly with the 0.9% (w/v) saline flush and allowed to set at room temperature.

The compression seal of each Q-Syte™ device (BD) and syringe Luer tip were sampled for microbial contamination by imprinting onto the surface of a nutrient agar plate (Oxoid).

Plates were incubated at 37°C for up to 48 hours in air after which the number of *S. epidermidis* NCTC 9865 cfu recovered from the; Q-Syte™ compression seal (BD), 10ml 0.9% (w/v) saline flush solutions and syringes Luer tips were determined, and recorded as follows: 0, 1-10, 11-100, >100.

8.1.3 Determination of the Microbial Contamination of 0.9% (w/v) Saline Flush Solutions Following Passage Through a Multiply Activated Q-Syte™ Needleless Connector (BD) with a Syringe Luer Tip Externally Inoculated with a Suspension Containing 30CFU *S. epidermidis* NCTC 9865 in BHI (Oxoid).

Twenty-eight Q-Syte™ needleless connectors (BD) were analysed; 25 acted as test devices and three as negative controls.

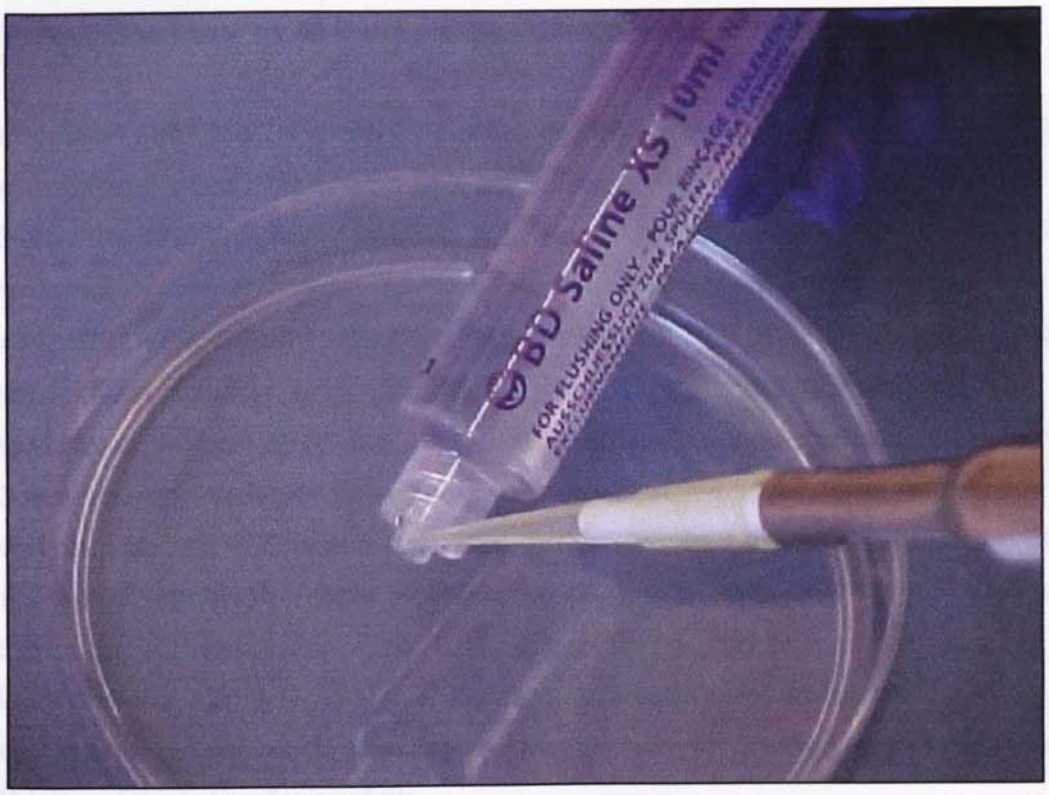
Following the multiple activations (Table 8.2) 25 test connectors and three negative controls were disinfected with Sterets swabs (Seton Healthcare). This was achieved by firmly applying the swab to the compression seal of each device and rotating it five times through 360° and allowing the alcohol to dry in air for two minutes. One Sterets swab (Seton Healthcare) was used per Q-Syte™ device (BD).

Table 8.2: The Multiple Activation Process of the Q-Syte™ Needleless Connectors (BD) with a Pre-Filled Saline XS Syringe (BD), Externally Contaminated with *S. epidermidis* NCTC 9865.

Number of Q-Syte™ needleless Connectors (BD)	Number of times Activated with a sterile Luer-lok™ syringe	Number of Times Activated with a Saline XS Syringe (BD) Externally Contaminated with 30 CFU *S. epidermidis* NCTC 9865
5	0	1
5	9	1
5	29	1
5	49	1
5	69	1

The external Luer of 25 pre-filled Saline XS syringes (BD) were inoculated with 5µl of an overnight suspension containing 30 cfu *S. epidermidis* NCTC 9865 in BHI (Oxoid) and allowed to dry at 37°C in air for 30 min (Figure 8.4). Each inoculated Saline XS syringe (BD) was then attached to the multiply activated Q-Syte™ device (BD). Three uninoculated pre-filled Saline XS syringes (BD) were utilized as negative controls. Five ml of 0.9% (w/v) saline was then flushed through the Q-Syte™ device (BD) and collected in a sterile Petri dish. The remaining 5ml was flushed through into a second sterile Petri dish. Fifteen ml of molten nutrient agar (Oxoid) cooled to 56°C was added to each plate, mixed thoroughly with the 0.9% (w/v) saline flush by rotation and allowed to set at room temperature.

Figure 8.4: Inoculation of Pre-Filled Saline XS syringe (BD) with Five µl (30CFU) *S. epidermidis* NCTC 9865 Suspension in Brain Heart Infusion (Oxoid).



The compression seals of the 25 test connectors and three negative controls of each Q-Syte™ device (BD) were imprinted onto the surface of a nutrient agar plate (Oxoid) once and then disinfected with Sterets swab (Seton Healthcare) as above and imprinted again on to the nutrient agar plate (Oxoid). In addition, each syringe Luer tip was imprinted onto the surface of a nutrient agar plate (Oxoid).

Plates were incubated at 37°C for up to 48 hours in air after which the number of *S. epidermidis* NCTC 9865 cfu were determined per; 10ml of flush solution, syringe Luer tip and Q-Syte™ compression seal (BD); both before and after disinfection with a Sterets swab (Seton Healthcare). Ranges of cfu recovered were recorded as follows: 0, 1-10, 11-100, >100.

8.1.4 Determining the Microbial Contamination Rates Associated with Four Catheter Configurations; Nexiva™ PVC with Q-Syte™ Needleless Connector (BD); Nexiva™ PVC with 3-way Tap and Q-Syte™ Needleless Connector (BD); Conventional Ported PVC and Conventional Ported PVC with 3-way Tap, Following Preparation and Administration of a 0.9% (w/v) Saline Flush, by 50 Nurses in their Clinical Area.

Determination of the microbial contamination rate comparing four catheter configurations; Nexiva™ PVC with Q-Syte™ needleless connector (BD); Nexiva™ PVC with 3-way tap and Q-Syte™ needleless connector (BD); conventional ported PVC and conventional ported PVC with 3-way tap, was undertaken. Fifty nurses in their own clinical setting were asked to prepare four syringes of 0.9% (w/v) sterile saline (B Braun, Germany) flush solution and administer it via the access port of the four PVC configurations; Nexiva™ PVC with Q-Syte™ needleless connector (BD); Nexiva™ PVC with 3-way tap and Q-Syte™ needleless connector (BD); conventional ported PVC and conventional ported PVC with 3-way tap, as they would if the PVC was *in situ*, utilizing their normal practices. The order in which the nurse flushed each PVC was designated by computer randomisation. The 0.9% (w/v) saline flushes were collected after administration via the PVC, in sterile, labelled, universal containers and the PVC were placed in sterile, labelled, specimen bags, prior to being transported to the microbiology laboratory for analysis.

A standardised study questionnaire was completed by the researcher for each nurse (Appendix 18). The questionnaire evaluated whether the nurse decontaminated their hands before the procedures were carried out; which skin disinfectant was used to decontaminate their hands; whether protective clothing was worn; whether the saline ampoule was decontaminated prior to aspiration and whether the access port was decontaminated prior to accessing it with the syringe

8.1.4.1 Sampling for microbial contamination.

The 10ml, 0.9% (w/v) saline flush was mixed thoroughly; 1ml of the flush was cultured by spreading two X 500µl aliquots over the surface of two Columbia agar plates containing 5% horse blood (BioMerieux). Plates were incubated at 37°C in air for 48 hours. Five ml of the 0.9% (w/v) saline flush was further cultured through enrichment by inoculation into 15ml of BHI (Oxoid) broth and incubated at 37°C in air for up to 48 hours. Broths were examined for turbidity after 48 hours and positive samples were

further sub-cultured onto Columbia agar plates containing 5% horse blood (BioMerieux) and incubated at 37°C in air for 48 hours.

The Q-Syte™ compression seals (BD) was cultured by impression onto Columbia agar plates containing 5% horse blood (BioMerieux), followed by incubation at 37°C in air for up to 48 hours.

The access Luer, hubs and side port were sampled with a nasopharyngeal swab moistened in 0.9% (w/v) sterile saline (B Braun). The swab was rotated 10 times, through 360°C in the internal Luer and cultured by impression onto Columbia agar plates containing 5% horse blood (BioMerieux) followed by incubation at 37°C in air for 48 hours.

8.1.4.2 Identification of Microorganisms Recovered from the PVC.

- Gram stain (Shanson, 1982).

- Catalase test (Lennette *et al.*, 1985).
  This test differentiates whether a Gram positive bacterial is a staphylococci sp (catalase positive) or a streptococci sp (catalase negative).

- Coagulase test (Shanson, 1982).
  This differentiates whether the Gram positive bacteria is a *Staphylococcus (S.) aureus*; coagulase positive or a coagulase negative staphylococci (CNS) sp including *S. epidermidis.*

- Methicillin resistant *S. aureus* (MRSA) plates; to differentiate an MRSA from a Methicillin sensitive *S. aureus* (MSSA) a selective media plate containing mannitol salt agar with Oxacillin (Oxoid, Basingstoke, UK) was used.

- Oxidase test (Lennette *et al.*, 1985).
  This is a differential test to distinguish oxidase positive pseudomonads from other Gram negative bacteria.

8.2 Results.

8.2.1 Determination of the Microbial Contamination Associated with the Q-Syte™ Compression Seal (BD) Following *In Vitro* Contamination and Disinfection with 70% (v/v) Isopropyl Alcohol.

Fifty Q-Syte™ needleless connectors (BD) were flushed with pre-filled Saline XS syringes (BD) following *in vitro* contamination and subsequent disinfection with Sterets swabs (Seton Healthcare); all flushes (50 out of 50; 100%) remained sterile. However, the surface of one Q-Syte™ compression seal (BD) and the associated syringe Luer tip subsequently yielded contamination with *S. epidermidis* NCTC 9865 (Table 8.3).

Table 8.3: Determination of the Microbial Contamination Associated with Q-Syte™ Compression Seal (BD) Following Inoculation with *S. epidermidis* NCTC 9865 (6.5×10^6) in BHI (Oxoid) Supplemented with 25% (v/v) Human Blood (UHB) and Followed by Disinfection with 70% (v/v) IPA. The Fluid Flushed after Disinfection, Syringe Luer Tip and Q-Syte™ Compression Seal (BD) were Sampled for Contamination.

		10 ml Fluid Flush			Syringe Tip			Q-Syte™ Compression Seal		
		N° of Flushes Contaminated	Percentage	Range of cfu	N° of Syringe Tips Contaminated	Percentage	Range of cfu	N° of Connectors Contaminated (device number) Percentage	Percentage	Range of cfu
Q-Syte™ needleless connector.	Test devices (n=50)	0	0%	0	**1**	**2%**	**11-100**	**1**	**2%**	**11-100**
	Positive control (n=5)	5	100%	>100	5	100%	11-100	5	100%	11-100
	Negative control (n=5)	0	0%	0	0	0%	0	0	0%	0

Bold type face indicates microbial contamination with *S. epidermidis* NCTC 9865.

8.2.2 Determination of the Microbial Contamination of 0.9% (w/v) Saline Flush Solutions following Infusion through a Q-Syte™ Needleless Connector (BD) which has undergone Multiple Activations.

Forty-eight out of the 50 (96%) flush solutions obtained through Q-Syte™ connectors (BD) which had been inoculated with $1.5x10^7$cfu *S. epidermidis* NCTC 9865, subsequently disinfected with Sterets swabs (Seton Healthcare), flushed with pre-filled Saline XS syringes (BD) and activated between one and 70 times, remained sterile. However two Q-Syte™ devices (BD) which had only been activated 10 times yielded flush solutions contaminated with *S. epidermidis* NCTC 9865 (Table 8.4).

Table 8.4: Determination of the Microbial Contamination Associated with Multiple Activations of the Q-Syte™ Needleless Connectors (BD) Following *In Vitro* Contamination with 10µl *S. epidermidis* NCTC 9865 Containing $1.5x10^7$ CFU in BHI (Oxoid) Supplemented with 25% (v/v) Human Blood (UHB) and Subsequent Disinfection with 70% (v/v) IPA Swab. The Fluid Flushed after Disinfection, Syringe Luer Tip and Q-Syte™ Compression Seal (BD) were Sampled for Contamination.

Test Devices		10ml Flush Fluid			Syringe Luer Tip			Q-Syte™ Compression Seal		
Times Activated	Number Tested	N° of Flushes Contaminated	Percentage	Range of cfu	N° of Tips Contaminated	Percentage	Range of cfu	N° of Connectors Contaminated	Percentage	Range of cfu
1	10	0	0%	0	0	0%	0	0	0%	0
10	10	**2**	**20%**	**>100; 11-100**	0	0%	0	0	0%	0
30	10	0	0%	0	0	0%	0	0	0%	0
50	10	0	0%	0	0	0%	0	0	0%	0
70	10	0	0%	0	0	0%	0	0	0%	0
Positive control	5	5 (all)	100%	>100	5 (all)	100%	11-100	5 (all)	100%	11-100
Negative control	5	0	0%	0	0	0%	0	0	0%	0

Bold type face indicates microbial contamination with *S. epidermidis* NCTC 9865.

8.2.3 Determination of the Microbial Contamination of 0.9% (w/v) Saline Flush Solutions Following Infusion Through a Multiple Activated Q-Syte™ Needleless Connector (BD) with a Syringe Luer Tip, Externally Inoculated with a Suspension Containing 30 CFU of *S. epidermidis* NCTC 9865 in BHI (Oxoid).

None of the 0.9% (w/v) saline solutions flushed through the Q-Syte™ needleless connectors (BD) which had been activated up to a total of 70 times, contained detectable numbers of *S. epidermidis* NCTC 9865 (0 out of 50; 100%), following flushing with a pre-filled Saline XS syringe (BD), externally contaminated with 30cfu *S. epidermidis* NCTC 9865 (Table 8.5).

Table 8.5: Determination of the Microbial Contamination of 0.9% (w/v) Saline Flush Solutions Following Infusion Through a Multiple Activated Q-Syte™ Needleless Connector (BD) with a Syringe Luer Tip Externally Inoculated with a Suspension Containing 30CFU of *S. epidermidis* NCTC 9865 in BHI (Oxoid). The Fluid Flushed after Disinfection, Syringe Luer Tip and Q-Syte™ Compression Seals (BD) were Sampled for Contamination.

Test devices		10ml Flush Fluid			Syringe Tip			Q-Syte™ Compression Seal			
Times Activated	Number Tested	N° of Flushes Contaminated	Percentage	Range of cfu	N° of Tips Contaminated	Percentage	Range of cfu	N° of Connectors Contaminated Pre disinfection	Percentage	Range of cfu	Number of Post Decontamination Percentage
1	5	0	0%	0	**5**	**100%**	**1-10**	0	0%	0	0
10	5	0	0%	0	**5**	**100%**	**1-10**	**2**	**40%**	**1-10**	0
30	5	0	0%	0	**4**	**80%**	**1-10**	**2**	**40%**	**1-10**	0
50	5	0	0%	0	**4**	**80%**	**1-10**	**3**	**60%**	**1-10**	0
70	5	0	0%	0	**5**	**100%**	**1-10**	**4**	**80%**	**1-10**	0
Negative Control	3	0	0%	0	0	0%	0	0	0%	0	0

Bold type face indicates microbial contamination with *S. epidermidis* NCTC 9865.

8.2.4 Determining the Microbial Contamination Rates Associated with Four Catheter Configurations; Nexiva™ PVC with Q-Syte™ Needleless Connector (BD); Nexiva™ PVC with 3-way Tap and Q-Syte™ Needleless Connector (BD); Conventional Ported PVC and Conventional Ported PVC with 3-way Tap Following Preparation and Administration of a 0.9% (w/v) Saline Flush, by 50 Nurses in their Clinical Area.

A total of 50 nurses, who have been assessed as competent by UHB NHS Foundation Trust to administer IV medication via PVC completed the study. The nursing grades ranged from:

D grade (junior staff nurse) = 10%
E grade (staff nurse) = 54%
F grade (junior sister) = 26%
G grade (sister) = 10%

8.2.4.1 Standardised Questionnaire Results.

a) How Many Nursing Staff Washed their Hands Before Preparing the Saline Flush for Infusion through the PVC Devices?

All nurses (50 out of 50; 100%) washed their hands prior to preparing the saline flush for infusion through a PVC device. However, four out of 50 (8%) did not then decontaminate their hands between subsequent PVC manipulations. This did not statistically affect the outcome with regards to contamination of the catheter (Fishers Exact test $p=0.64$).

b) Which Skin Disinfectant Solution did Nurses Use Prior to Accessing Peripheral Vascular Catheters?

Four % (w/v) aqueous CHG was most frequently used (31 out of 50; 62%), followed by 70% (v/v) IPA (11 out of 50; 22%) and lastly liquid soap (Leverline Mild: Diversey Lever, UK) (eight out of 50; 16%).

c) Did Nurses Wear Protective Clothing When Accessing Peripheral Vascular Catheters?

Forty-three out of 50 (86%) of nurses wore gloves to access the PVC. This did not statistically affect the outcome of catheter contamination (Fishers Exact test, $p=1.0$). Of

these 100% (n=50) changed them between subsequent catheter manipulations. All of the staff (n=50) wore disposable plastic aprons.

d) Which Surface Disinfectant Did Nurses Use to Disinfect the Hub, Luer and Side Port of the Peripheral Vascular Catheters?

During this study 200 hubs, Luer and side ports were accessed. 166 out of 200 (83%) were disinfected prior to use. All nurses used 70% (v/v) IPA (166 out of 166; 100%).

e) Did Nurses Disinfect the Hubs, Luer and Side Ports on the Peripheral Vascular Catheter Prior to Each Flushing Procedure?

A comparison of the disinfection practices associated with the four PVC configurations: Nexiva™ PVC and Q-Syte™ needleless connector (BD); Nexiva™ PVC with 3-way tap and Q-Syte™ needleless connector (BD); conventional PVC and conventional PVC with 3-way tap is shown in Table 8.6.

Table 8.6: A Comparison of Decontamination Practices Prior to Activation, Associated with the Nexiva™ Peripheral Vascular Catheter and Q-Syte™ Needleless Connector (BD) and the Conventional Ported Peripheral Vascular Catheter.

Peripheral Vascular Catheter Configuration	Number of Nurses Who Disinfected the Access Port Prior to the Flush Procedure (n=50).	
	Number	Percentage
Nexiva™ catheter with Q-Syte™ needleless connector (BD).	47	94%
Nexiva™ catheter with 3 way tap and Q-Syte™ needleless connector (BD).	47	94%
Ported PVC	35	70%
Ported PVC with 3 way tap.	37	74%

A significantly greater number of nurses disinfected the Nexiva™ PVC with Q-Syte™ needleless connector (BD) prior to accessing the device for infusion (47 out of 50; 94%) compared to the conventional ported PVC (35 out of 50; 70%) (McNemar test; nominal data, non parametric, paired results. p=0.0015). Similar results were also found when comparing the Nexiva™ PVC with 3-way tap and Q-Syte™ needleless connector (BD) (47 out of 50; 94%) with the conventional PVC with 3-way tap (37 out of 50; 74%)

(McNemar test; nominal data, non parametric, paired results. p=0.0094). Indicating that nurses disinfected the Q-Syte™ needleless connector more frequently than they did traditional side ports and hubs.

All nurses who disinfected the Q-Syte™ device on the Nexiva™ PVC also disinfected the Q-Syte™ device on the Nexiva™ PVC with 3-way tap. In addition, there was no significant difference between the disinfection rates of the hubs and side ports of the conventional ported PVC and conventional ported PVC with 3 way tap (McNemar test; nominal data, non parametric, paired results p=0.479).

8.2.4.2 Determining the Microbial Contamination Associated with the Nexiva™ Peripheral Vascular Catheters (BD) Compared with Conventional Peripheral Vascular Catheters in the Clinical Setting.

A total of 900 specimens were obtained for microbial analysis from this study:

- The 0.9% (w/v) saline flush: 600 specimens were analysed for microbial contamination.
- The Q-Syte™ needleless connector (BD): 100 compression seals were analysed for microbial contamination.
- The hub, Luer and side ports: 200 access ports were analysed for microbial contamination.

Thirty-one out of 900 cultures (3.4%) obtained from 50 nurses manipulating the four catheter configurations (n=200) were found to be microbially contaminated (Table 8.7, 8.8 and 8.9).

Statistical analysis: McNamar test (non parametric, paired results for nominal data).
Comparing the microbial contamination rates between the two configurations of Nexiva™ PVC (BD) demonstrated that there was no significant difference for the two devices (p= 0.58). In addition, no significant difference in microbial contamination rates were observed between the two configurations of conventional catheters (p=0.11).

Comparing Nexiva™ PVC (BD) with conventional PVC and Nexiva™ PVC with 3-way tap (BD) and conventional PVC with 3-way tap, also demonstrated no significant

difference in microbial contamination rates between the two PVC configurations (p=0.18; p=0.39).

Standard laboratory techniques were used to identify the 31 positive cultures obtained from the 900 specimens collected in this study (Table 8.7, 8.8 and 8.9). These included; colony morphology, Gram stain, coagulase test, catalase test, oxidase test and specific culture media for MRSA. The organisms and numbers (percentages) isolated included:

S. aureus: 18 out of 31(48%). Three out of 18 (17%) were MRSA.

Pseudomonas spp: six out of 31(19%).

Non haemolytic *Streptococcus* spp: three out of 31(10%).

Gram negative cocci: two out of 31(7%).

S. epidermidis: one out of 31 (3%).

Bacillus spp: one out of 31(3%).

Table 8.7: Identification of the Site and the Microbial Contamination Associated with the Simulated Use of Nexiva™ Peripheral Vascular Catheters (BD) by 50 Healthcare Workers in the Clinical Setting.

HCW Number	Contamination of Nexiva™ with Q-Syte™ needleless connector (BD): bacteria (number of cfu)				Contamination of Nexiva™ with 3way Q-Syte™ needleless connector: bacteria (number of cfu)			
	Internal			External	Internal			External
	BHI	10 ml Flush	Luer	Q-Syte ™	BHI	10 ml Flush	Luer	Q-Syte™
2						B(31)		
3		G-ve(1)						MRSA(1)
5								SA(3)
9								SA(1)
18						S (1); G -ve(1)		
19						SE(1)		
24		SA(1)						
27							SA(1)	
29					SA			
30		SA(4); *P*(1)						
33		SA(1)						
35		SA(1)						
46						SA(9)		
47	S							
Total	1	6	0	0	1	4	1	3

Legend: SA= S. *aureus*. SE= *S. epidermidis*. *P=Pseudomonas* spp. G -ve= Gram negative cocci. S= *Streptococcus* spp (non haemolytic). B = *Bacillus* spp. MRSA= Methicillin Resistant *Staphylococcus aureus*. BHI = brain heart infusion. HCW= healthcare worker.

Table 8.8: Identification of the Site and the Microbial Contamination Associated with the Simulated Use of Conventional Peripheral Vascular Catheters by 50 Healthcare Workers in the Clinical Setting.

HCW Number	Contamination of Ported PVC: bacteria (number of cfu)			Contamination of Ported PVC with 3 way tap: bacteria (number of cfu)		
	Internal		External	Internal		External
	BHI	10ml Flush	Luer	BHI	10ml Flush	Luer
3		SA(1)				
4	S				SA(2)	
5	S				*P* (3) and SA(3)	
11	MRSA					
16						G-ve(1)
21	MRSA					
29		SA(2)				
33	SA					
35		*P*(1)				
39				*P*(1)		
42		SA(6)				
47		SA(1)			*P*(1)	
48		*P*(1)				
Total	5	6	0	1	3	1

Legend: SA= S. *aureus*. SE= S. *epidermidis*. *P*=*Pseudomonas* spp. G -ve= Gram negative cocci. S= *Streptococcus* spp (non haemolytic). B = *Bacillus* spp. MRSA= Methicillin Resistant *Staphylococcus aureus*. BHI = brain heart infusion. HCW= healthcare worker

Table 8.9: Summary of the Sites of Microbial Contamination Associated with the Simulated Use of Nexiva™ Peripheral Vascular Catheters (BD) (n=100) Compared with Conventional Peripheral Vascular Catheters (n=100) by 50 Healthcare Workers in the Clinical Setting.

Catheter Configuration	Internal Contamination	External Contamination
Nexiva™ PVC with a Q-Syte™ needleless connector attached (n=50).	6	0
Nexiva™ PVC with 3-way tap to which a Q-Syte™ needleless connector is attached (n=50).	6	3
Total	12	3
Mean Number of Contaminated Sites per Nexiva™ Device (n=50).	6	1.5
% of Nexiva™ PVC contaminated catheters.	15%	
Conventional ported PVC (n=50).	11	0
Conventional ported PVC with 3-way tap and extension tube attached (n=50).	4	1
Total	15	1
Mean Number of Contaminated Sites per Conventional ported PVC (n=50).	7.5	0.5
% of Conventional contaminated catheters.	16%	

8.3 Conclusion.

Needleless connectors are widely used within the healthcare setting. They were first introduced in order to reduce the risk of occupationally acquired NSI (Orenstein, 1995; Steinberg, 1995). However, the potential risk of microbial contamination and subsequent infection remains unclear (Brown *et al.*, 1995; Steinberg, 1995; Cookson *et al.*, 1998; Seymour *et al.*, 2000; Casey *et al.*, 2003).

In vitro studies demonstrated that when the Q-Syte™ compression seal (BD) was inoculated with a high number of microorganisms ($1x10^7$ cfu) to that observed on devices in the clinical arena (<16 cfu) (Brown *et al.*, 1997) and subsequently disinfected with 70% (v/v) IPA swab, only two devices out of 100 (2%) (Section 8.2.1 and 8.2.2) allowed the passage of organisms. These findings support those of Brown *et al.* (1997). Therefore, in the clinical environment, where a lower risk of contamination is expected, the Q-Syte™ needleless connector (BD) would be a negligible risk of contamination for IV devices.

In addition, these studies demonstrated that effective disinfection of the Q-Syte™ needleless connector (BD) can be achieved when utilizing a 70% (v/v) IPA swab. Brown *et al.* (1997) recommended that a two stage disinfection program for needleless connectors may be more effective. However, this would negate one of the benefits of needleless connectors; that of being more time efficient. Casey *et al.*, (2003) demonstrated that 70% (v/v) IPA was not the most effective device disinfectant and that both 10% (w/v) povidone iodine and 0.5% (w/v) CHG in 70% (v/v) IPA were more effective. However, at present 70% (v/v) IPA continues to be commonly used method of disinfection for hubs and ports. Future studies, evaluating a range of disinfecting agents on the Q-Syte™ needleless connector (BD) would be required to test evaluate other methods of disinfection.

The CDC (2002) and RCN (2003) recommended that PVC can remain *in situ* for up to 72 to 96 hours. However, there are no guidelines as to how many times needleless devices may be accessed. In order to determine whether multiple activations of the Q-Syte™ needleless connector (BD) increased the risk of microbial contamination of the fluid pathway, the devices were activated in incremental steps up to a total of 70 times. Findings demonstrated that multiple activations of the device did not increase the potential risk of microbial contamination of the flush solution. Again however, two out of 50 devices (4%) which were activated only 10 times did deliver flushes contaminated with *S. epidermidis*, even though the Q-Syte™ needleless connectors (BD) were disinfected and showed no contamination on microbial analysis. These

results were probably due to experimental contamination as increase multiple activations demonstrated no increase in contamination risk.

Furthermore, a multiply activated Q-Syte™ needleless connector (BD) with a syringe Luer tip, externally contaminated with 30 cfu of *S. epidermidis* NCTC 9865, demonstrated that there were no detectable numbers of *S. epidermidis* NCTC 9865 passing through the device in the flush fluid. *S. epidermidis* NCTC 9865 was detected on the syringe Luer tip and on the external septum of the connector after activation (Section 8.2.3). These findings suggest that the compression seal septum wipes the external surface of the Luer syringe tip as it passes through, leaving any bacterial pathogens on the exterior face of the compression seal. These findings re-enforce the need for decontamination of the Q-Syte™ compressions seal (BD) both pre and post activation to ensure the removal of pathogenic bacteria before the device is activated.

In the clinical setting, nurses used standard techniques to prepare 0.9% (w/v) sterile saline (B Braun) flushes to infuse through the four catheter configurations. Fifteen out of 100 (15%) of the Nexiva™ PVC configurations (BD) subsequently demonstrated contaminated samples compared with 16 out of 100 (16%) of the conventional ported PVC configurations (Section 8.2.4.2). Of the 15% Nexiva™ PVC (BD) which showed contamination, only one out of 100 (1%) showed the corresponding Q-Syte™ needleless connector (BD) to be contaminated. Therefore, the use of the Q-Syte™ needleless connector (BD) does not increase the risk of microbial contamination via the internal lumen, compared to standard ports on PVC. This supports previous findings by Seymour *et al.* (2000).

Worthington *et al.* (2001) demonstrated that manually prepared 0.9% (w/v) saline flushes had a higher risk of microbial contamination (2% to 8%) compared to pre-filled syringes (0%); due to the extra manipulation required drawing up the saline. In addition, both in the study carried out by Worthington *et al.* (2001) and this current study, nurses did not disinfect the ampoule prior to aspirating the saline. However, recommendations for the disinfection of the 0.9% (w/v) saline ampoules before use are not included in the product information supplied by the manufacturer (Mini-Plasco. B-Braun, Germany). Therefore, manually drawn up 0.9% (w/v) saline is a potential risk of contamination associated with this study.

In Section 8.2.4.2, three out of the 100 (3%) Q-Syte™ needleless connectors (BD) and one out of 100 (1%) ported PVC Luer loks™ showed contamination. However none of the corresponding samples yielded contamination. Thirty out of 900 (3%) internal

samples obtained from the range of PVC configurations yielded contamination, none were associated with external contamination. This supports previous findings by Seymour *et al.*, (2000) and Worthington *et al.*, (2001), who concluded that contaminated infusates from manually drawn up fluids may pose a significant risk of internal contamination. Disinfecting the ampoules prior to use or utilizing pre-filled ampoules may reduce the risk of microbial contamination in future studies in the clinical setting.

Eighteen out of 31 (58%) contaminated specimens obtained from the clinical evaluation were identified as *S. aureus*. It is estimated that 10% of healthy adults are colonised with *S. aureus* which can then be spread via skin scales to bed linen and other environmental surfaces (Elliott *et al.*, 1997). This may lead to a high environmental load in clinical areas (Shiomori *et al.*, 2002), which unless aseptic precautions are followed can lead to contaminated hands. This may be a contributing factor to these findings and should be considered when undertaking future *in vivo* evaluations.

The findings demonstrated that there was a significant difference between the numbers of nurses who disinfected the Q-Syte™ needleless connector (BD) (94 out of 100; 94%) compared with the ports of a conventional PVC (72 out of 100; 72%) (McNemar's Test, p=0.0019). Therefore, patients who have a PVC with a needleless connector would appear to have a higher standard of aseptic care than patients who have PVC with standard access ports.

In conclusion, this study demonstrated that the Q-Syte™ needleless connector (BD) can be activated multiple times with out an associated increased risk of fluid pathway contamination, compared to conventional ported PVC. In addition, healthcare workers are more likely to disinfect the Q-Syte™ needleless connector (BD) compared to conventional ports.

Chapter Nine:

General Discussion.

Medical devices such as hypodermic needles and peripheral vascular catheters (PVC) are widely used in the healthcare setting. However, these devices are associated with a risk of complications for both the healthcare worker and the patient. The current study focussed on two main themes; determining the effectiveness of two strategies aimed at protecting healthcare workers from needlestick injuries (NSI) and evaluating two innovations targeted at the reducing the risk of PVC associated phlebitis.

Reducing the Risk of Needlestick Injury and Potential Blood Borne Virus Transmission to the Healthcare Worker from Hypodermic Needle Devices.

Healthcare workers are at risk from transmission of blood borne pathogens resulting from exposure to blood through NSI (Centre for Disease Control and Prevention: CDC, 1997). The average volume of blood inoculated via a 22 gauge needle is approximately 1.0µl, which may therefore contain an infectious dose of a blood borne virus (Napoli and McGowan, 1987). This has been confirmed; between July 2003 to July 2004, six seroconversions to hepatitis C following occupational percutaneous exposure from hollow bore needles were reported to the Health Protection Agency (HPA, 2005).

Several studies have demonstrated that healthcare knowledge related to inoculation injuries is poor (Fasbinder, 1992; Parks *et al.*, 1998; Duff, 1999; Diprose *et al.*, 2000; Scoular *et al.*, 2000). The results in Chapter 2 support these findings. However, as the results in Chapter 4 demonstrated, the number of NSI reported in 2002 by healthcare workers was reduced by 18% following an enhanced educational strategy specifically directed towards NSI awareness. What was also highlighted was that awareness needs to be constantly reinforced as the number of NSI increased by 30% the following year, when training returned to the standard mandatory update.

In the United States of America (USA), the issue of occupationally acquired NSI has been addressed by the "Needle Stick Safety and Prevention Act, 2000" (House of Representatives; 5178) which requires that all health care facilities provide needle protective devices in order to reduce the risk of staff acquiring a blood borne virus. In

the United Kingdom (UK), specific legislation on safer devices has not yet been introduced and the current approach centres on risk assessment and control.

Several studies have attributed a reduction in NSI to innovative technologies which have produced needle protective devices (Younger *et al.*, 1992; Wolfrum, 1994; DeBaun *et al.*, 1995a; Yassi *et al.*, 1995; Orenstein *et al.*, 1995; Siddharta *et al.*, 2001; Mendelson *et al.*, 2003). In comparison, L'Ecuyer *et al.* (1996) and Mulherin *et al.* (1996) noted no corresponding reduction in NSI reports following the introduction of the safety devices. In both studies the healthcare workers did not readily accept the devices and had not correctly used them. This supports the recommendations of the Occupational Safety and Health Administration (OSHA, 1997) who highlighted that a comprehensive training programme is required before needle protective devices are introduced, to ensure that they are accepted by healthcare staff.

Following an evaluation of a range of safety needle devices manufactured by Becton Dickinson (BD) in the Trust during 2002 (Chapter 3) the SafetyGlide™ needle range were introduced in 2003 (Chapter 4). Healthcare workers in the trial areas were trained on how to use, activate and dispose of the devices safely. The results in the study demonstrated a significant 70% reduction in reported NSI ($p=0.045$) following the introduction of safety needles. In addition, the healthcare worker user evaluation questionnaire which examined three key features associated with the devices demonstrated that the devices were safe, usable and compatible with most clinical situations. Also, visual determination of the safety device following use showed that the majority of the SafetyGlide™ needles had been activated prior to disposal.

The National Institute for Clinical Excellence (NICE, 2003) guidelines state that "needle safety devices must be used where there are clear indications that they will provide safer systems of working for healthcare personnel". However, the cost analysis showed a six to 15 fold increase in costs may be associated with the acquisition of the safety needle device range. Although not applicable to the NHS, in England and Wales a recent ruling in the Scottish court has deemed that any decision by employers not to provide safety equipment cannot be undertaken on cost alone (Skinner versus the Scottish Ambulance Service, 2004). Therefore, following the excellent results obtained in this trial a recommendation for their use has been made to the Trust.

Reducing the Risk of Transmission of Infection to the Patient, Associated with Practices and Procedures Related to Peripheral Vascular Catheters.

In 2000, National Health Service (NHS) logistics reportedly sold over 18.6 million peripheral venous catheters (PVC). Due to the wide variation in classifying intravascular (IV) catheter infections it is difficult to determine the rate of phlebitis associated with these devices. However, rates have been reported from as low as 0% (Elliott, 1993) up to 50% (Cornely *et al.*, 2002).

The most frequently associated routes of transmission of infection for IV catheters are from the extraluminal and intraluminal route (Elliott, 1993). Bjornson *et al.* (1982) demonstrated that cutaneous microorganisms can contaminate the IV catheter during insertion, or can migrate along the catheter post insertion. Therefore, skin antisepsis prior to IV catheter insertion is fundamental to reducing the risk of catheter related infection (CRI) from impaction and extraluminal migration.

Previous studies have demonstrated that cutaneous antisepsis with 2% (w/v) aqueous chlorhexidine gluconate (CHG) is more efficacious than both 70% (v/v) isopropyl alcohol (IPA) and 10% (w/v) povidone iodine (PI) in the reduction of CRI (Maki *et al.*, 1991). In a meta analysis of eight studies by Chaiyakunapruk *et al.* (2002) they identified that CHG significantly reduced the risk of blood stream infections compared to PI by approximately 50% in hospitalised patients requiring short term IV cannulation.

The efficacy of a new skin disinfectant, 2% (w/v) CHG in 70% (v/v) IPA (ChloraPrep®), was compared to five commonly used skin disinfectants against *Staphylococcus epidermidis* RP62A in the presence or absence of protein, utilizing quantitative time kill suspension and carrier tests (Chapter 5). All six disinfectants: 70% (v/v) IPA; 0.5% (w/v) aqueous CHG; 2% (w/v) aqueous CHG; 0.5% (w/v) CHG in 70% (v/v) IPA; and 10% (w/v) aqueous povidone iodine (PI), achieved a Log_{10} reduction factor of five, in cfu/ml, in a suspension test (exposure time; 30 seconds) in the presence and absence of 10% human serum. However, subsequent challenges of *S. epidermidis* RP62A in a biofilm (with and without human serum) demonstrated reduced bactericidal activity with each agent. Overall, the most effective skin disinfectants tested against *S. epidermidis* RP62A, were ChloraPrep® and 10% (w/v) PI. These results suggest that enhanced skin antisepsis may be achieved with ChloraPrep® compared to the three commonly used CHG preparations: 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA.

In vivo analysis determining the efficacy of ChloraPrep® compared to 70% (v/v) IPA on the reduction of PVC associated phlebitis was undertaken (Chapter 7). Interim analysis suggests that when the PVC remained *in situ* for an average time of 2.4 days there was no difference in PVC associated phlebitis, irrespective of whether ChloraPrep® or Sterets® skin disinfection was utilized. However, microbial contamination of the PVC tip was significantly lower when ChloraPrep® was utilized compared to Sterets® ($p= 0.042$). Therefore, 2% (w/v) CHG in 70% (v/v) IPA may reduce the risk of IV catheter contamination on insertion, compared to catheters inserted following skin decontamination with 70% (v/v) IPA.

The most common cause of CRI is believed to be due to contamination of the catheter hub (Sitges-Serra *et al.*, 1985; Linares *et al.*, 1985). Studies have demonstrated that the microbial contamination rate of IV catheter hubs, are as high as 31% and that there is a clear correlation between the contamination rate and the frequency of manipulation (Tebbs *et al.*, 1996). Evaluation of the microbial contamination associated with these needleless connectors has however produced conflicting results. Cookson *et al.* (1998) found a significant increase in blood stream infection rates associated with the introduction of a needleless connector, which was attributed to unfamiliarity with the device and practices differing from the manufacturer's recommendations. Conversely, several studies have demonstrated no statistically significant difference in the rate of fluid pathway contamination when comparing standard access hubs with needleless access devices (Rodriguez ,1993; Larson *et al.*, 1993; Arduino *et al.*, 1997; Leubke *et al.*, 1998; Seymour et al., 2000). However, Brown *et al.* (1997) and Casey *et al.* (2003) reported that when needleless systems were effectively decontaminated, the risk of microbial contamination of the IV catheter via the internal lumen was reduced.

The potential for microbial contamination associated with a recently developed needleless closed luer access device (CLAD) (Q-Syte™; Becton Dickinson, UK), was evaluated *in vitro* (Chapter 8). Compression seals of 50 multiply activated Q-Syte™ devices were inoculated with *S. epidermidis* NCTC 9865 in 25% (v/v) human blood and then disinfected with 70% (v/v) IPA followed by flushing with 0.9% (w/v) sterile saline. Forty eight out of 50 (96%) saline flushes passed through devices which had been activated up to a maximum of 70 times, remained sterile compared to standard entry ports which have had a reported microbial contamination rate of 22% (Tebbs *et al.*, 1995). A further 25 Q-Syte™ CLAD which had undergone multiple activations were challenged with pre-filled 0.9% (w/v) sterile saline syringes whose external luer tip had

been inoculated with *S. epidermidis* NCTC 9865 prior to accessing the devices. None of the devices which had been accessed up to 70 times allowed passage of microorganisms, despite challenge microorganisms being detected on both the syringe tip after activation and the compression seals before decontamination.

These findings suggest that the Q-Syte™ CLAD may be activated up to 70 times with no increased risk of microbial contamination within the fluid pathway. The device may also offer protection from external surface of syringe tips contaminated with microorganisms.

Future Work.

Reducing the Risk of Needlestick Injury and Potential Blood Borne Virus Transmission to the Healthcare Worker from Hypodermic Needle Devices.

Improving Healthcare Worker Awareness of Inoculation Injuries.

The results from these studies demonstrated that Healthcare Workers' knowledge associated with inoculation injuries is both poor (Chapter 2) and requires regular reinforcement (Chapter 4). Further studies are required to determine the most effective educational strategies which will maintain healthcare workers awareness of risk associated with NSI and the frequency with which this needs to be undertaken.

The Use of Safety Needle Devices to Reduce Occupational Acquired Needlestick Injuries.

The introduction the SafetyGlide™ needle range into four clinical areas at the UHB NHS Foundation Trust in 2004 demonstrated a significant reduction in NSI during its 12 month evaluation (Chapter 4). Further studies are required to assess the longer term effect on NSI to see if the reduction is sustainable. Unfortunately, as this study demonstrated, NSI can still occur with safety devices. Therefore, further developments are required to develop devices which offer even greater healthcare worker protection against NSI. For example, the Nexiva™ PVC (Chapter 8) has been designed to have an automatic activation system which ensures that staff are not exposed to the needle point at any time once the cannulation procedure has commenced. Whilst safety needle devices are a significant step forward in protecting healthcare workers alternative systems which can deliver medications without the need for hypodermic needles, but which ensure effective drug delivery, are required.

Reducing the Risk of Transmission of Infection Patient, Associated with Practices and Procedures Related to Peripheral Vascular Catheters.

Advances in Skin Antisepsis.

Previous studies have demonstrated that cutaneous antisepsis with 2% (w/v) aqueous CHG is more efficacious than both 70% (v/v) IPA and 10% (w/v) PI in the reduction of catheter related sepsis (Maki *et al.*, 1991). The results of the current study (Chapter 5)

found that 2% (w/v) CHG in 70% (v/v) IPA was more effective than 2% (w/v) aqueous CHG against *S. epidermidis* RP62A in the presence of a biofilm enriched with human serum. It would be of interest to determine whether similar findings were likely in the presence of other microorganisms. In addition, further work should concentrate on the development of advanced skin antiseptics which offer prolonged effectiveness following application. Determination of whether the tools of application of the disinfectant can effect the disinfection process, for example a swab which requires direct contact by the user (Sterets®; Seton Healthcare) applicator versus ChloraPrep® (Mediflex) which is enclosed in a delivery applicator. Finally, the development and evaluation of PVC dressings which incorporate an antiseptic agent to reduce the risk of line sepsis.

Advances in the Design of Peripheral Vascular Catheters.

In addition to the safety needle feature incorporated in to the Nexiva™ PVC, the device combined two key characteristics designed to reduce phlebitis; a needleless connector and a cannula manufactured from Vialon™.

- Needleless Connectors.

As cited previously there is conflicting evidence relating the microbial contamination associated with needleless connectors. Results from the *in vitro* studies reported in Chapter 8, demonstrated that the Q-Syte™ needleless connector could be activated up to 70 times without an associated increase in fluid pathway contamination. Further *in vitro* studies utilizing a range of microorganisms are required to determine up to how many times, and for how long these devices can be accessed and still maintain their efficacy.

Intravenous access lines now incorporate antimicrobial agents to reduce the risk of CRI. The development of needleless connectors which also include this technology may further reduce the risk of catheter colonisation and subsequent CRI.

- Cannula Material.

Vialon™ cannula have been shown to significantly reduce the risk of phlebitis compared to those PVC manufactured utilizing Teflon™ (Maki and Ringer, 1991). In addition, studies have shown that they are easier to insert and are more comfortable for the patient (McKee *et al.*, 1989). Recently Becton Dickinson (BD) have developed a

new PVC, Nexiva™ which incorporates; the Q-Syte™ CLAD, a passive needle shielding device designed to reduce of NSI and a cannula manufactured from Vialon™.

Further *in vivo* studies are required to compare the Nexiva™ PVC with standard PVC focusing on; an evaluation of the effectiveness of the device to reduce NSI, determination of the intra-luer microbial contamination rate of the entry ports and an appraisal of the devices when evaluating PVC associated phlebitis.

There is currently controversy regarding how long a PVC should remain *in situ* prior to being replaced. Some studies recommend that PVC should be changed every 72 to 96 hours (Maki and Ringer, 1991; Lai, 1998); however, Bregenzer (1998) and Curran *et al.* (2000) recommend that routine replacement should be re-evaluated. Future developments for PVC design should concentrate on increasing the time the devices may remain *in situ* for without compromising patient safety from risks such as phlebitis. This may be achieved for example by the integration of antimicrobial agents in the cannula material, subsequently reducing the risk of colonization and biofilm development. At present removal of the cannula at 72 to 96 hours is reliant on good documentation of when the device was inserted. A cannula which indicated that it had been *in situ* for a set amount of time, by a change in colour for instance, may enhance compliance with current recommendations (RCN, 2003).

Chapter Ten:

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Chapter Eleven:

Appendices.

1. University Hospital Birmingham NHS Foundation Trust Inoculation Injury Information Sheet.

2. University Hospital Birmingham NHS Foundation Trust Sharps Injury Posters.

3. Healthcare Worker Knowledge Study; Ethical Approval Confirmation Letter.

TC -> JO.

Birmingham and The Black Country NHS

South Birmingham
Research Ethics Committee
Strategic Health Authority
27 Highfield Road, Edgbaston, Birmingham B15 3DP
Tel: 0121 245 2533 & 2534 Fax: 0121 245 2535

Chairman Mr R K Vohra

Our ref: mbt/jb/DD/01
14 February 2003
Please quote: 0813/CA

Professor TS J Elliott
Consultant Microbiologist
Clinical Laboratory Services Directorate
Clinical Microbiology & Infection Control
Queen Elizabeth Hospital
Edgbaston
Birmingham B15 2TH

Dear Professor Elliott

LREC reference number 0813/CA
Evaluation of a sheathed peripheral IV catheter (Safelon® Pro)

Thank you for your letter dated 5 February 2003 enclosing a copy of the Protocol for the above Study.

Having now had an opportunity to review this document we confirm that we are happy to support it.

Yours sincerely

Vice Chairman
Research Ethics Committee

MICROBIOLOGY

PROF. T. ELLIOTT

4. SafetyGlide™ Study; BD Points to Practice Sheet.

BD SafetyGlide™

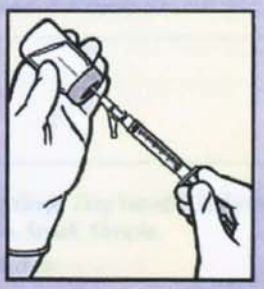
Points to **Practice**

1 Preparation

- Prepare site according to local policy
- Select appropriate Needle & Syringe
- Select Appropriate Drawing up needle

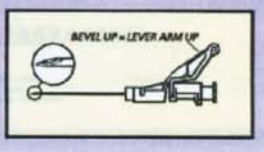
2 Aspiration

- Aspirate Medication into Syringe
- Check for appropriate volume
- Remove drawing up needle
- Attach SafetyGlide needle



3 Injection

- Remove needle guard
- Administer injection according to established technique
- For convenience Needle bevel always up



4 Activation

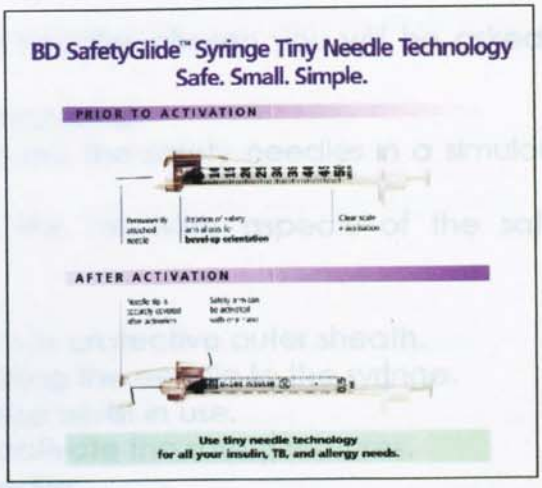
- After injection place finger behind lever arm
- Immediately apply single stroke forward
- The Activation-assist lever arm will activate the mechanism
- Dispose of SafetyGlide needle and syringe into the nearest sharps container.

5 Thing to remember

- Always follow Hospital policy for safe disposal of all medical waste
- Ease of use
- Single handed activation
- Minimal change in technique
- Minimal training
- Secure and visible lock
- Virtually no splatter on activation
- No negative impact on patient
- Aseptic technique and proper skin preparation essential
- When using SafetyGlide be sure to push the needle firmly onto the syringe
- Activate away from yourself and others
- Listen for audible click and visually confirm needle tip is fully covered.

BD
Indispensable to Human Health

5. SafetyGlide™ Study; BD Product Information Leaflets.



6. SafetyGlide™ Clinical Study; Healthcare Worker Information Sheet and Consent Form.

University Hospital Birmingham NHS
NHS Trust

Introduction to SafetyGlide™ insulin and/or Eclipse™, SafetyGlide™ needle protective devices.

Needlestick injuries are a potential hazard for all healthcare workers. Devices which are new to Europe, but which are currently being used in America aims to reduce this problem. With your consent we will be introducing new safer needles into your clinical area in order to evaluate the effect on the number of reported needlestick injuries.

For the purpose of this study you will be introduced to the safety needles SafetyGlide™ insulin and/or Eclipse™/SafetyGlide™. You will not be trained on any technique other than to operate and dispose of the needles safely and according to the manufacturer's guidelines and UHB NHS Trust policy of sharps handling and disposal.

Following the introduction of the safety needles chosen you will be asked to sign to agree to the following:

- You are satisfied with the training provided.
- You have had the opportunity to use the safety needles in a simulated situation, using a practice model.
- You have been introduced to the following aspects of the safety needles:
    - Design packaging.
    - Removal of the needle from its protective outer sheath.
    - Correct technique in attaching the needle to the syringe.
    - Correct position of the device whilst in use.
    - The correct techniques to activate the safety features.
    - Correct disposal of the needles.
- You agree to use the safety needles for the duration of the study (standard needles must always be available on the Cardio-Pulmonary Resuscitation trolley).
- You agree to report any adverse situations experienced.
- You agree to demonstrate how to use the safety needles correctly to any adhoc agency staff etc.

Name _____.

Signature _____.

Ward _____.

Job Title _____.

7. SafetyGlide™ Study; Ethical Approval Confirmation Letter.

Birmingham and The Black Country NHS
Health Authority

South Birmingham Research Ethics Committee
27 Highfield Road, Edgbaston, Birmingham B15 3DP

Tel: 0121 245 2533 & 2534 Fax: 0121 245 2535

Chairmen: Professor C Clifford & Mrs P K Moseley
Administrator: Mrs A P McCullough

Our ref: APM/mbt/DD/01
Please Quote: 2002/085

Professor T S Elliott
Consultant Microbiologist
Queen Elizabeth Hospital
Edgbaston
Birmingham B15 2TH

→ Dr B. Adam.

Dear Professor Elliott

REC reference number 2002/085
A Comparative Study to Evaluate the Effectiveness and Acceptability of a Safety Hypodermic Needle "Eclipse™/Safety Glide™:BD"
Protocol dated 18/6/2002
User Evaluation Data Sheet dated 18/6/2002
Observational Data Collection Sheetdated 18/6/2002
Staff Information Leafle, no date no version & Staff Questionnaire - dated 18/6/2002

South Birmingham Research Ethics Committee are happy to Approve your Study subject to the following:

- Satisfactory Indemnity arrangements being in place.
- Clearance from your Trust or relevant employer.
- That you produce an annual review in line with the Good Clinical Practice Guidelines.
- Active Approval is required until the Study has been completed.
- The Committee would wish to be kept informed of Serious Adverse Events, Amendments and any modifications to Patient Information Leaflets and Consent Forms.

Approval is valid for three years, however, if it is intended to continue the Study after THREE YEARS from the date of this letter South Birmingham Research Ethics Committee would wish to re-examine it.

Would you please communicate this approval immediately to all members of the investigating team and where appropriate the sponsoring commercial company. Please also advise your Research and Development Office of this approval.

Yours sincerely

P K. Moseley

Research Ethics Committee
29 AUG 2002
APPROVED

Chairman
Research Ethics Committee

cc: File
Appropriate Trust

Chairman: Elisabeth Buggins
Chief Executive: Geoff Scaife

8. Healthcare Worker Information Sheet, Consent to Interview Following a Needlestick Injury Form and Needlestick Injury data Collection Tool.

University Hospital Birmingham NHS
NHS Trust

Healthcare Worker Information Sheet:
Analysis of Healthcare Worker Reported Needlestick Injury.

Study: A Comparative Study To Evaluate the Effectiveness and Acceptability of a Safety Hypodermic Needle: SafetyGlide™ systems; BD.
Phase 2; the analysis of occupational needlestick injuries occurring to staff in E3LU, E4A,B, C, W1, W2, W3LU, LOPD using a standardised questionnaire.

Name of Researcher: Professor TSJ Elliott, Consultant Microbiologist and Debra Adams, Infection Control Nurse Specialist; UHB NHS Trust.

Dear Colleague,
This phase of the above study aims to evaluate the risks associated with staff acquiring an occupational needlestick injury (NSI). In order to obtain the most relevant data we would like staff who have reported a NSI via Occupational Health, Risk Management or serology in the above wards to complete a short questionnaire. The questionnaire includes the following:

- Name
- Job category
- Ward
- Date of Injury
- Right/Left handed?
- Device Associated with Injury
- Was the device a "safety device"?
- How many hours worked prior to injury
- How did injury occur?
- Where did the injury occur?
- What procedure was being carried out at the time?
- Which part of the body did the NSI affect?
- Was source patient identifiable?
- Were you the original user of the device?
- Was the device contaminated with: blood or body fluids, drugs, clean, unknown
- What was the original purpose for the device?
- Did the injury occur: before the device was used, during the use of the item, between steps of a multiple procedure, re-sheathing the device, disposing of device, after device had been disposed of or other .

Participation in the study is completely voluntary and any information disclosed will remain CONFIDENTIAL between the research agents and the individual questioned. Published will be anonamised.

Many thanks for your assistance with this study.
Debra Adams
Infection Control Nurse Specialist; UHB NHS Foundation Trust.

University Hospital Birmingham NHS
NHS Trust

Healthcare Worker Consent Form; Interview following Needlestick Injury.

Study: A Comparative Study To Evaluate the Effectiveness andAcceptability of a Safety Hypodermic Needle: SafetyGlide™ systems; BD.Phase 2; The analysis of occupational needlestick injuries occurring tostaff in E3LU, E4A, B, C, W1, W2, W3LU, LOPD using a standardisedquestionnaire.

Name of Researcher: Professor TSJ Elliott, Consultant Microbiologist andDebra Adams, Infection Control Nurse Specialist; UHB NHS Trust.

Healthcare Worker Consent: Please initial or sign section 1, 2 and 3.

1. I confirm that I have read and understood the information sheet for the above part of the study.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time.

3. I agree to take part in this study.

Name _____

Signature _____

Name of person taking consent_____

Signature _____

University Hospital Birmingham NHS
NHS Trust

Healthcare Worker Interview Data Collection Form Following a Needlestick Injury.

- Name:_____. Job category:_____.
- Ward:_____. Date of Injury:_____.
- Right/Left handed? (please circle)

Device Associated with Injury?_____.

Was the device a "safety device"? Yes / no (please circle)

How many hours worked prior to injury?_____.

How did injury occur?

_____

_____

_____

Where did the injury occur?_____.

What procedure was being carried out at the time?

_____.

Which part of the body did the NSI affect?

_____.

Was source patient identifiable? Yes / no (please circle).

Were you the original user of the device? Yes / no (please circle).

Was the device contaminated with?
blood or body fluids/drugs/clean/unknown (please circle one)

What was the original purpose for the device?

_____.

Did the injury occur?
before the device was used/during the use of the item/between steps of a multiple procedure/re-sheathing the device/disposing of device/after device had been disposed of/other (please circle one).

The information provided will remain confidential between the research agents and the individual questioned. Any data published will be anonamised.

Thank you for your help with this study.
Debra Adams: Infection Control Nurse Specialist; UHB NHS Trust.

9. ChloraPrep® *In Vivo* Study; Healthcare Worker Information Sheet and Consent Form.

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: Healthcare Worker Information Sheet.

MEDI-FLEX Medi-Flex, Inc.

Prospective, randomised clinical trial to assess the efficacy of 70% (w/v) isopropyl alcohol and 2% (w/v) chlorhexidine gluconate in 70% (w/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous catheterisation.

Eighteen to 80% of general hospital admissions include peripheral venous therapy (Wilkinson, 1996). In 2000, NHS logistics sold over 18.6 million peripheral venous catheters (PVC) to the UK market (NHS Purchasing and Supply Agency; PASA, 2003) and in 2002 the UHB NHS Trust used a total of 122,943 cannulas (unreported data). Although infections associated with these devices remains relatively low they have the potential to become life threatening, especially in the critically ill and immunocompromised.

Patients who require a peripheral venous catheter as part of their clinical management are at risk of developing a device-related infection. Microorganisms most frequently associated with catheter related bloodstream (BSI) infections include *Staphylococcus aureus*, aerobic Gram-negative bacilli, *Candida albicans* and coagulase negative staphylococci (Parker, 2002. Graninger *et al.* 2002. Mermel *et al.* 2001. Elliott *et al.* 1994). The four routes by which organisms may gain access to intravenous catheters are extraluminal, intraluminal, by haematogenous seeding or via contaminated infusate (Elliott, 1993). Extraluminal colonisation occurs when microorganisms are impacted on the distal tip of the catheter during insertion (Elliott and Tebbs, 1998), or they may migrate along the external catheter track once the catheter is *in situ* (Mermel, 2001; Cook, 1999; Tebbs *et al.* 1995).

Prior to the insertion of a PVC device, the intended site should be cleansed with an antimicrobial solution (RCN, 2003) in order to reduce the risk of colonisation of the tip on insertion. Maki *et al.*, (1991) evaluated the efficacy of three skin disinfectants (10% povidone iodine, 70% isopropyl alcohol and 2% aqueous chlorhexidine gluconate) in preventing infections associated with IV devices. Two percent chlorhexidine was associated with the lowest incidence of catheter related infection. At present 2% chlorhexidine gluconate is not commercially available within the UK. Therefore, the Department of Health (Pratt, 2001), currently recommends the use of an alcoholic

chlorhexidine gluconate solution (no percentage advised) which should be applied for at least 30 seconds and allowed to dry before the cannula is inserted (Saloojee, 2001).

Recently Medi-Flex International (Overland Park, Kansas, USA) have developed ChloraPrep®; a chlorhexidine gluconate 2% solution for skin decontamination prior to insertion of intravascular catheters. Therefore, potentially reducing the risk of phlebitis for patients having PVCs inserted.

Aims of the study

1. Evaluation of the rate of phlebitis associated with entry sites decontaminated with ChloraPrep® compared with conventional 70% isopropyl alcohol.
2. Evaluation of the microbial contamination rates of PVC entry sites following skin decontamination with ChloraPrep® (2% (w/v) chlorhexidine gluconate with 70% (w/v) isopropyl alcohol) compared with the conventional 70% (w/v) isopropyl alcohol (Steret; Seton Healthcare).

If you agree to participate (you are under no obligation to do so), the Clinical Research Nurse will collect your basic demographic data and allocate you a study number to ensure anonymity. You will then complete a training programme to familiarise yourself with the new product. During the trial, you will be asked to decontaminate the skin prior to insertion of a peripheral venous catheter with either ChloraPrep® or 70% isopropyl alcohol, determined by the randomisation table, adhering to study protocol. The Clinical Research Nurse will then review the peripheral vascular catheter insertion site on a daily basis.

This research has been given the approval of the South Birmingham Ethics Committee and the Research & Development department, UHB NHS Trust, are aware of the study. At the end of the study, the data collected will be analysed and published (anonymity and confidentiality will be maintained at all times). For further information, please contact the Clinical Research nurse.

Principal investigator: Professor TSJ Elliott, Consultant Microbiologist, Department of Clinical Microbiology, Queen Elizabeth Hospital, UHB NHS Trust, Edgbaston, Birmingham B15 2TH

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: Healthcare Worker Consent Form.

MEDI-FLEX Medi-Flex, Inc.

Study number:

Title of the research: Prospective, randomised clinical trial to assess the efficacy of 70% (w/v) isopropyl alcohol and 2% (w/v) chlorhexidine gluconate in 70% (w/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous catheterisation.

Name of researcher: Professor TSJ Elliott – Principal Investigator

1. I confirm that I have read and understand the information sheet ☐
2. I understand that my participation is voluntary and that I am free ☐to withdraw at any time.
3. I agree to take part in the study. ☐

Name of participant (please print)	Date	Signature
Name of person taking consent	Date	Signature
Researcher	Date	Signature

10. ChloraPrep® *In Vivo* Study Healthcare Worker Demographic Data Collection Tool.

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: Demographic Data Questionnaire.

MEDI-FLEX Medi-Flex, Inc.

---

1. Name:_____

2. Profession: Nurse ☐ Doctor ☐ Other please state: _____

3. Grade: _____

4. How long have you been inserting peripheral venous catheters?

0-6 months ☐ 6.1-12 months ☐ 1-3 years ☐ 3.1-6 years ☐
6.1-9 years ☐ 9.1-12 years ☐ 12.1-15 years ☐ > 15 years ☐

5. How many peripheral venous catheters on average do you insert per week?

1-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 20-25 ☐ > 25 ☐

6. I have been trained on the proper use of ChloraPrep® skin disinfection?

Yes ☐ No ☐ Not applicable ☐

11. ChloraPrep® *In Vivo* Study Patient Information Sheet and Consent Form.

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: Patient Information Sheet.

MEDI-FLEX Medi-Flex, Inc.

Prospective, randomised clinical trial to assess the efficacy of 70% (w/v) isopropyl alcohol and 2% (w/v) chlorhexidine gluconate in 70% (w/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous catheterisation.

Introduction to the Research and invitation to take part.

As a patient who will receive a peripheral venous catheter (a "drip" which is attached to your bloodstream), you are being invited to take part in our study.

What is the research study about?

In our study, we wish to investigate a new skin cleansing agent which will be used prior to the insertion of your peripheral venous catheter ("drip"). By investigating this new cleansing agent, it may be possible to demonstrate that it helps to reduce bacterial contamination. If we can demonstrate this, it may be beneficial for patients in the future who require a "drip" as part of their clinical care.

What will I have to do?

If you do decide to take part, you will be one of 900 patients. By taking part in the study, you will receive either the new ChloraPrep® cleanser or a 70% alcohol solution (Steret®) which is currently used in this hospital. The majority of "drips" are successfully inserted on the first attempt. If however, this is not the case a maximum of three attempts will be made before exclusion from the study occurs. The "drip" will remain in place for the necessary duration of your treatment (routine practice). There are no additional risks associated with using the cleansing agent. Some clinical information will be recorded when the catheter is inserted and on a daily basis whilst the catheter is in place. Any information recorded will only be used for the purpose of this study. Your doctor is not being paid any additional fees for your participation in this study.

What are the benefits?

We hope to demonstrate that ChloraPrep® helps to reduce bacterial contamination that is occasionally associated with a "drip".

What are the risks?

ChloraPrep® has undergone investigations in other hospitals and there are no additional risks.

What if I do not want to take part?

If you decide not to take part this will not affect your medical care. Also if you do decide to take part and then change your mind, you are also free to withdraw from the study at any time without giving a reason. Again, this will not affect your medical care.

What happens to the information?

The information collected during this study is kept confidential and will be used for the purpose of this study only. Should we publish any material resulting from the study in medical journals the data will be anonymous.

Who else is taking part?

A total of 900 patients who require a catheter as a part of their care will take part.

What if something goes wrong?

As ChloraPrep® has been studied previously in other hospitals we do not anticipate any problems.

What happens at the end of the research study?

When we complete the study, we will evaluate the results. The results may be published in medical journals or presented at scientific conferences.

What happens now if I decide to take part?

If you do decide to take part you will be asked to sign consent form which will be kept with your patient notes. You will also be given a copy of this information sheet to keep.

Contact name and number:

Professor TSJ Elliott Divisional Director (D3) Consultant Microbiologist Clinical Microbiology and Infection Control Queen Elizabeth Hospital UHB NHS Trust 0121 627 2366	Heather Small/Debra Adams Research Nurse: Clinical Microbiology Queen Elizabeth Hospital UHB NHS Trust 0121 627 2366 Pager 07661 035552 (#6619) Extension 3451

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: **Consent Form.**

MEDI-FLEX **Medi-Flex, Inc.**

Prospective, randomised clinical trial to assess the efficacy of 70% (w/v) isopropyl alcohol and 2% (w/v) chlorhexidine gluconate in 70% (w/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous catheterisation.

Name of Researcher: Professor TSJ Elliott, Consultant Microbiologist, Department of Clinical Microbiology and Infection Control, University Hospital Birmingham NHS Trust.

Patient Consent. Please initial or sign sections 1, 2 and 3.

1. I confirm that I have read and understood the information sheet for the above study.

_____

2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.

_____

3. I agree to take part in the study.

_____

Name of patient (print) _____

Signature _____ Date _____

Name of person taking consent (print) _____

Signature _____ Date _____

12. ChloraPrep® *In Vivo* Study; Healthcare Worker Clinical Report Form.

University Hospital Birmingham NHS
NHS Trust

ChloraPrep™ Study: Clinical Report Form.

MEDI-FLEX Medi-Flex, Inc.

Date:

Healthcare worker details

1. Name:_____
2. Skin disinfection: ChloraPrep® / 70% isopropyl alcohol (Steret®)

Patient Details (please complete or fix an addressograph label)

1. Patient identification (reg no + first 2 letters of name):_____
2. Age:
3. Male / Female
4. Ward:
5. Clinical details/underlying medical condition: _____

_____

6. How would you rate the condition of the veins prior to insertion?

   Optimal Normal Very difficult

   1 2 3 4 5 6 7 8 9 10

7. How much pain was felt by the patient on insertion of the device?

   No pain Moderate pain Very painful

   1 2 3 4 5 6 7 8 9 10

8. Comments: _____

_____

_____

_____

13. Daily Assessment Tool for Reviewing the Peripheral Vascular Catheter.

University Hospital Birmingham NHS
NHS Trust

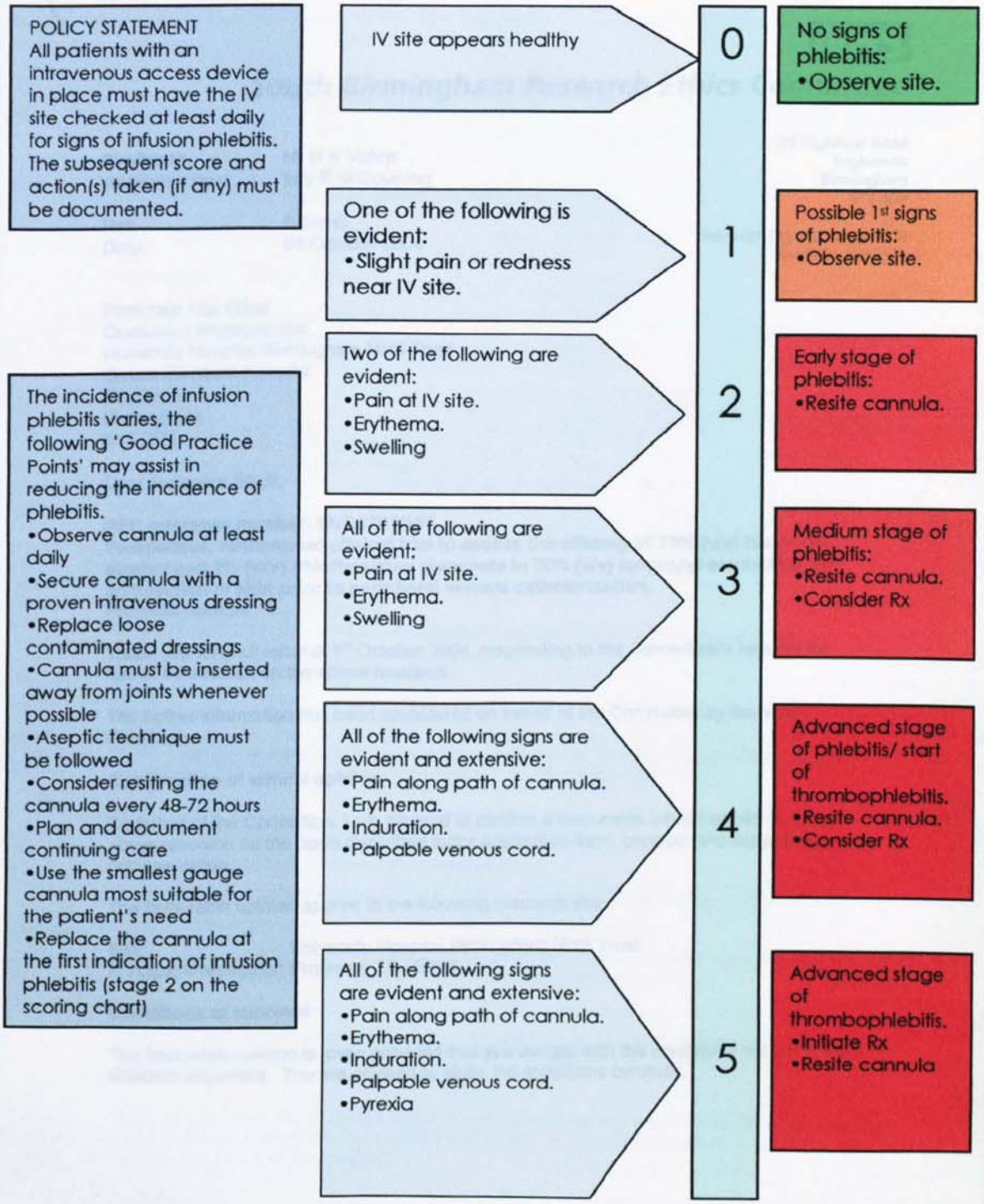
Daily Assessment of Peripheral Venous Cannula.

Trial/Control (please circle). Patient Identification Code: _____

Assessment	Day 1:		Day 2:		Day 3:		Day 4:	
Insertion site assessed								
Is there tunnelling from the edge of the dressing to the insertion site?								
Is the dressing intact all around the insertion site?								
Is the dressing loosely attached causing the cannula to move?								
Blood present at insertion site? (assess in mm's)								
Was the dressing changed? Indication for dressing change? E.g. blood stained, wet								
Are there signs of: Erythema (redness) around insertion site? Size:< 2mm/>2mm-5mm/>5mm								
Can redness along the line of the vein be visualised ('Tracking')?								
Is there evidence of: Pus, Clear fluid, Exudate? < 2mm/>2mm-5mm/>5mm								
Oedema around insertion site? <2mm/>2mm-5mm/>5mm								
Hardness around insertion site? <2mm/>2mm-5mm/>5mm								

Pain:								
None 0, Moderate 2-3, Severe 4								
When the catheter is used is it painful for the patient?								
When the catheter is flushed is it painful for the patient?								
Does the patient find it painful when the catheter is touched?								
Does the patient find it painful when the catheter is manipulated								
Phlebitis score (if applicable)								
Fluids/drips/medications delivered via the cannulae.....								
Crystaloids eg.saline,Ringers								
Cytotoxics eg anticancer drugs Insulin								
Anti-convulsants								
Lipids								
Anaesthetics								
Glucose								
Antibiotics								
Blood								
Cardiovascular e.g. anti-arrhythmic, vasodilators								
Others (please specify)								
Cannula removed on:								
Reason(s) for removal..... Indwell time limit reached								
Evidence of phlebitis /infection								
IV no longer needed								
Infiltration								
Clotting / Obstruction								
Other (specify)								

14. Visual Infusion Phlebitis Score. Adapted from Jackson (1998).



15. ChloraPrep® *In Vivo* Study; Ethical Approval Confirmation Letter.

NHS

South Birmingham Research Ethics Committee

Chairman: Mr R K Vohra
Administrator: Mrs R M Downing

27 Highfield Road
Edgbaston
Birmingham
B15 3DP

Tel: 0121 245 2533/2534/2538
Fax: 0121 245 2535

Ref: BC/rmd
Date: 06 October 2004

Professor TSJ Elliott
Consultant Microbiologist
University Hospital Birmingham NHS Trust
Queen Elizabeth Hospital
Edgbaston
Birmingham
B15 2TH

Dear Professor Elliott,

REC reference number: 04/Q2707/157
Prospective, randomised clinical trial to assess the efficacy of 70% (v/v) isopropyl alcohol and 2% (w/v) chlorhexidine gluconate in 70% (v/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous catheterisation.
Protocol number: 1

Thank you for your letter of 1st October 2004, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Vice-Chairman.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation.

The favourable opinion applies to the following research site:

Site: University Hospital Birmingham NHS Trust
Principal Investigator: Professor TSJ Elliott

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

16. Nexiva™/Q-Syte™ *In Vitro* Study; Ethical Approval Confirmation Letter.

Birmingham and The Black Country NHS
Strategic Health Authority

South Birmingham
Research Ethics Committee
27 Highfield Road, Edgbaston, Birmingham B15 3DP

Tel 0121 243 2533 & 2534 Fax 0121 245 2535

MICROBIOLOGY

Chairman: Mr R K Vohra

Our ref RJ/Dm/2003/207
Please Quote: 2003/207

PROF. T. ELLIOTT

Professor T S J Elliott
Consultant Microbiologist
Clinical Microbiology and Infection Control
Queen Elizabeth Hospital NHS Trust
Edgbaston
Birmingham B15 2TH

Research Ethics Committee
18 SEP 2003
APPROVED

Dear Professor Elliott

REC reference number 2003/207
Potential for BD Nexiva microbial contamination from the Q-shield needleless connector
Protocol Draft 1 dated 30.05.03
Healthcare Worker Information Sheet
Consent Form
Questionnaire

South Birmingham Research Ethics Committee are happy to Approve your Study subject to the following

- Satisfactory indemnity arrangements being in place
- Clearance from your Trust or relevant employer.
- That you produce an annual report in line with the Good Clinical Practice Guidelines.
- Active Approval is required until the Study has been completed
- The Committee would wish to be kept informed of Serious Adverse Events, Amendments and any modifications to Patient Information Leaflets and Consent Forms.

Approval is valid for three years, however, if it is intended to continue the Study after THREE YEARS from the date of this letter South Birmingham Local Research Ethics Committee would wish to re-examine it

Would you please communicate this approval immediately to all members of the investigating team and where appropriate the sponsoring commercial company. Please also advise your Research and Development Office of this approval.

Yours sincerely

Vice Chairman
Research Ethics Committee
cc: Appropriate Trust

Chairman: Elizabeth Budgett
Chief Executive: Geoff Scaife

17. Nexiva™/Q-Syte™ *In Vitro* Study; Healthcare Worker Information Sheet and Consent Form.

University Hospital Birmingham NHS
NHS Trust

Healthcare Worker Information Sheet: Nexiva™ Study.

Prospective, randomised clinical trial to assess the microbial contamination associated with the BD Nexiva™ peripheral venous catheter

As a member of staff who inserts peripheral venous catheters as part of your clinical practice, you are being invited to participate in this clinical investigation.

Peripheral venous therapy is a frequent and essential part of patient's clinical management. On average, the Queen Elizabeth Hospital, University Hospital Birmingham NHS Trust uses 68,000 peripheral venous catheters per year. Phlebitis is diagnosed in an estimated 7 to 14% of patients with a peripheral venous catheter, which is compounded by poor cannulation technique and post insertion care. Microbial contamination may occur during the insertion process, during catheter manipulation by healthcare workers or due to current infection. Previously, preventative strategies have focused on adequate hand hygiene and disinfection prior to and whilst using the device.

Becton Dickinson has a new product, Nexiva™, which is a peripheral venous catheter with an extension tube integral to the catheter. In addition, the product features a needle shielding mechanism, which is activated as part of the insertion procedure which may reduce associated needlestick injuries and blood contamination. It may also reduce microbial contamination whilst the catheter is *in situ*.

The aims of this current study are to:

- Evaluate the microbial contamination rate of the entry Luer port of the Q-Syte™ needleless connector compared with control (BD; Venflon™) hub with male Luer lock connectors in the clinical setting.
- Evaluate the microbial contamination rate of the adjacent Nexiva™ catheter hub with male luer lock connectors with a control side port in the clinical setting.
- Evaluate the rate of phlebitis associated with Nexiva™ catheter compared with control (BD; Venflon™) catheter.

If you agree to participate (you are under **no** obligation to do so), the Clinical Research Nurse will collect your basic demographic data and allocate you a study number to ensure anonymity. You will then complete a training programme to familiarise yourself with the new product. During the trial, you will be asked to either insert a conventional peripheral catheter (BD; Venflon™) or Nexiva™, determined by the randomisation table, adhering to study protocol. The Clinical Research Nurse will then review study catheters on a daily basis and take samples from the stopcock entry ports at either 24 or 72 hours post insertion.

This research has been given the approval of the South Birmingham Ethics Committee and the Research & Development department, UHB NHS Trust, are aware of the study. At the end of the study, the data collected will be analysed and published (anonymity and confidentiality will be maintained at all times). For further information, please contact the Clinical Research nurse.

Principal investigator: Professor TSJ Elliott, Consultant Microbiologist, Department of Clinical Microbiology, Queen Elizabeth Hospital, UHB NHS Trust, Edgbaston, Birmingham B15 2TH

University Hospital Birmingham NHS
NHS Trust

Nexiva™ Study: Healthcare Worker Consent Form

Study number: _____

Title of the research: Prospective, randomised clinical trial to assess the microbial contamination associated with the BD Nexiva™ peripheral catheter

Name of researcher: Professor TSJ Elliott – Principal Investigator

1. I confirm that I have read and understand the information sheet ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time. ☐
3. I agree to take part in the study. ☐

Name of participant (please print)	Date	Signature
Name of person taking consent	Date	Signature
Researcher	Date	Signature

18. Nexiva™/Q-Syte™ *In Vitro* Study; Questionnaire Completed by Researcher whilst Healthcare Worker Completed the Flushing Procedure.

University Hospital Birmingham NHS
NHS Trust

Nexiva™ Study Questionnaire:

Potential for BD Nexiva microbial contamination from the Galahad needleless connector

(A) Staff Demographics:

Randomisation number: HCW ___/50

Job Title/Grade:_____

Ward/Speciality: _____

Number of years of professional experience:_____

Number of intravenous administrations via peripheral catheters per week:_____

(B) Aseptic Technique:

Hands washed: Y / N

Hands washed between catheter configurations: Y / N

Hands washed with:_____

Gloves worn Y / N

Gloves changed between catheter configurations: Y / N

Apron worn Y / N

Other_____

(C) Flush preparation

Saline ampoule disinfected Y / N

(D) Catheter Access

Galahad / Port disinfection

Catheter configuration		Disinfectant
A	Y / N	_____
B	Y / N	_____
C	Y / N	_____
D	Y / N	_____

Chapter Twelve:

Publications and Presentations.

12.1 Publication List.

1. Adams D and Elliott TSJ. Needle Stick Injuries. *E-Hospital.* 2002; 4(2): 58-59.

2. Trim JC, Adams D, Elliott TSJ. Healthcare Workers Knowledge of Inoculation Injuries and Glove Use. *British Journal of Nursing.* 2003; 12(4): 215- 221.

3. Adams D and Elliott TSJ. A Comparative User Evaluation of Three Needle Protective Devices. *British Journal of Nursing.* 2003; 12(8): 470-474.

4. Adams D, Quayum MH, Worthington T, Lambert PA and Elliott TSJ. Evaluation of a 2% Chlorhexidine Gluconate in 70% Isopropyl Alcohol Skin Disinfectant. *Journal of Hospital Infection.* 2005; 61(4): 287-290.

5. Adams D, Karpanen T, Worthington T and Lambert P and Elliott TSJ. Infection Risk Associated with a Closed Luer Access Device. *Journal of Hospital Infection.* 2006; 62: 353-357.

6. Adams D and Elliott TSJ. Impact of Safety Needle Devices on Occupationally Acquired Needlestick Injuries: A four year prospective study. *Journal of Hospital Infection.* Accepted for publication.

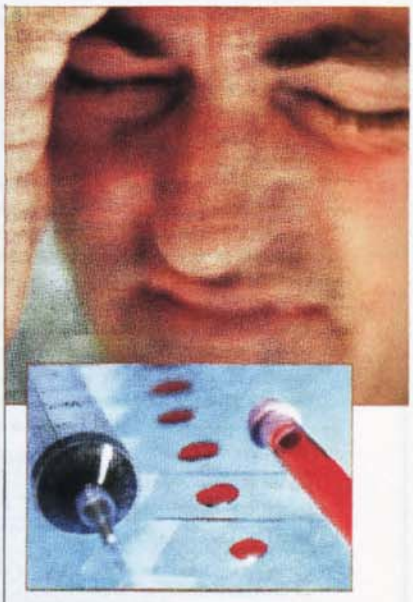
1:

FEATURES

D. ADAMS, TSJ ELLIOTT

Needle Stick Injuries

by D. Adams, TSJ Elliott
Microbiology Department, Queen Elizabeth Hospital, Birmingham (UK)



Needle stick injuries (NSI) pose a significant risk to healthcare workers, with many thousands of injuries occurring each year. In 1996 the National Audit Office reported that one sixth of accidents involving healthcare workers in English NHS Trusts were related to NSI.

Healthcare workers who are most at risk of acquiring an NSI are frontline workers, with nurses accounting for almost 50-63% of reported NSI and medical staff 13-17% (Tan et al, 2001 and NHS Scotland 2001). However, it is interesting to note that in a recent study almost 40% of NSI did not occur to the original user of the device, but to downstream workers such as hotel services staff (May and Churchill, 2001), probably due to inappropriate disposal.

It is important to acknowledge that the number of NSI reported may not accurately indicate the size of the problem. Reports from the USA suggest that there may be up to 90% under-reporting of NSI by physicians (OSHA, 1997) and 32% under-reporting by nurses (CDC, 1997). This is reflected in studies by Burke and Madan (1997) in the UK, who revealed that only 9% of doctors and 46% of midwives questioned had reported occupationally acquired NSI. In another study by our own group of 84 members of healthcare staff, including doctors, nurses and phlebotomists, 65% of those questioned had not reported NSI (unpublished data, 2001). The under-reporting of NSI may be due to several reasons. Burke and Madan (1997) and Haiduven et al (1999) both found that staff felt that the whole reporting procedure was too time consuming, staff were too busy, dissatisfaction was felt with the follow up procedures and staff underestimated the risks associated with a contaminated NSI. Leliopoulou et al (1999) found that nurses working in both high and low risk areas felt that a needle contaminated with blood was an unlikely source of infection. This confirmed previous reports from Burke and Madan (1997) who identified that both nursing and medical staff underestimated the risks of acquiring hepatitis B and HIV following contamination incidents.

The risk of acquiring a blood borne virus from an infected patient via an inoculation injury may be as high as 1 in 3 for hepatitis B if the healthcare worker is non immune, 1 in 30 for hepatitis C and 1 in 300 for HIV (UK Health Departments, 1998). Although all healthcare workers in the UK are offered the hepatitis B immunization, some do not wish to undertake the immunization programme and some staff do not respond to the vaccine and are therefore not immune. Alzahrani et al (2000) demonstrated that in one centre in the UK 10% of staff had not been vaccinated and 27% of those who had received vaccination had no anti-HBs. This leaves 37% of staff unprotected against hepatitis B. Gyawali et al (1998) reported that the overall uptake of hepatitis B vaccine in one UK hospital was 78%, however this fell to 70% in paramedical staff and as low as 45% in domestic staff. To date there are still no immunizations for hepatitis C or HIV. Collins and Kennedy (1987) identified 17 pathogens in addition to Human Immunodeficiency Virus (HIV) and hepatitis B and C which have been transmitted via inoculation injuries.

Studies have shown that the device commonly identified with NSI is the hollow bore needle; this has been responsible for up to 68% of all injuries associated with reported NSI (May and Churchill, 2001 and Tan et al, 2001). It is unfortunate, therefore, that the hollow bore needle has the greatest capacity for inoculating blood (Jeans, 1999) and is therefore also associated with the transmission of blood borne pathogens (IHCWSC, 1999 and Cardo et al, 1997). Hollow bore needles are primarily used in association with syringe and needle, butterfly cannulae, peripheral vascular access catheters and needles and butterfly cannulae used for blood collection.

Recently in the UK, engineered safety needle protective devices have been introduced. In the USA, the issue of occupationally acquired needle stick injuries has already been addressed; on

FEATURES

November 6th 2000 President Clinton signed into law the "Needle Stick Safety and Prevention Act". This act requires that all healthcare facilities in the USA purchase and provide needle protective devices in order to reduce the risk of staff acquiring a blood borne virus (e.g. hepatitis B, C, HIV).

Several studies have evaluated the effect that "safety devices" have made on the incidence of NSI. The CDC (1997) reviewed three types of "safety devices" used for phlebotomy. A 23%-76% reduction in NSI was noted when "safety devices" were used, compared with routine products. However "safety devices" are only as good as the operator using them and it is therefore essential that frontline workers are included in any decision to purchase these devices. OSHA (1997) reported that one reason why these devices failed to reduce NSI was that they were not accepted by healthcare staff because they had not received a comprehensive training programme and that poor implementation of the change process had been incorporated.

Needles are ubiquitous in providing healthcare. Staff, however, should not feel that NSI are an acceptable occupational hazard. It is impossible to provide an environment without hollow bore needles and therefore strategies need to be employed to reduce the risk of healthcare workers acquiring a blood borne virus from an occupational NSI.

No one single strategy will reduce the number of NSI; all healthcare workers need to work together. Firstly, as Alzahrani et al (2000) indicated, Occupational Health Departments need to continually reinforce vaccination policies. Secondly, staff requires regular educational updates on Universal Precautions, handling/disposal of sharps and inoculation injury and reporting policies. However experiences in both the USA and the UK indicate that even adopting these robust strategies to reduce NSI may not be sufficient to significantly reduce the number of NSI. Engineered needle protective devices may be the only available strategy left to explore.

These strategies are supported by the UK Health Department (1998), which recommends a reduction in the use of sharp items wherever possible and "to consider the benefits of introducing new safety devices". In addition the process also falls within the Clinical Governance Guidelines (DOH, 1998), 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) of providing an environment which is safe and healthy for patients, visitors and staff.

In summary, the way forward in the UK appears to be to follow the lead taken by the USA; that of developing a comprehensive, all-inclusive sharps injury prevention programme.
The UK needs to ensure legislation continues to support the use of new strategies to reduce healthcare worker exposure to blood borne pathogens. We need to assess the risks faced by healthcare staff by reviewing what devices are causing NSI in different clinical areas.

Educational strategies to incorporate all healthcare staff need to be continuously reinforced. Clinical evaluations of "safety devices" developed for use in the UK need to be instigated to assess their effectiveness. Finally cost benefit analyses need to be undertaken in order to demonstrate that, although in the short term the cost appears to be prohibitive, in the long term the use of "safety devices" may be both cost effective and prevent healthcare workers going through the physical and emotional traumas associated with acquiring a needle stick injury in the 21st Century.

References

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2.

INFECTION CONTROL

Healthcare workers' knowledge of inoculation injuries and glove use

Joanna C Trim, Debra Adams, TSJ Elliott

Abstract

Healthcare workers' (HCWs') occupational risk of exposure to blood-borne pathogens has been well documented. Subsequent educational programmes, awareness campaigns and policy implementation made limited impact on HCWs' level of knowledge of these risks and compliance with universal precautions. Two hundred HCWs completed a questionnaire to evaluate their level of knowledge. Results demonstrated that despite a comprehensive education programme for nurses and training for medical staff, knowledge of inoculation injuries and associated issues remained inadequate. Indeed, policies and procedures were not followed. Furthermore, gloves were not routinely worn in the clinical setting. Educational programmes are essential to inform HCWs of occupational risk of exposure to blood-borne pathogens and guide practice following an inoculation injury. However, efficacy of such programmes must be reviewed, alternative strategies evaluated, and the cause of HCWs' limited knowledge determined.

Healthcare workers' (HCWs') risk of occupational exposure to blood-borne pathogens from a sharps injury has been well documented since 1984, following the first reported occupational exposure to human immunodeficiency virus (HIV) (Communicable Disease and Surveillance Centre (CDSC), 2000). Consequently, universal precautions (Centre for Disease Control and Prevention (CDC), 1987) were implemented to protect HCWs and minimize the stigma placed upon HIV-infected patients (McCreaddie, 2001). Furthermore, sharps management programmes emerged in an attempt to reduce the risk of sharps injury to HCWs by raising awareness (Gershon et al, 2000).

The implementation of universal precautions and sharps management educational programmes reduced the number of inoculation incidents and improved the awareness of the risks associated with sharp devices and exposure to blood and body fluids (Beekmann et al, 1994; Calabro et al, 1998; Kim et al, 2001). However, the level of knowledge and compliance with universal precautions procedures within the clinical setting was limited (Godin et al, 2000; Scouler et al, 2000). Reasons for this included personal protective clothing interfering with working skill, ill-fitting or unavailable gloves and protective eyewear (Nelsing et al, 1997). Furthermore, personal clinical practice was perceived to be sufficient to ensure safety (Connington, 2002).

Currently, the risk of transmission of hepatitis B (from a hepatitis B 'e' antigen positive source patient to an unvaccinated recipient or a non-responder to the vaccine) is 1:3. The risk of transmission of hepatitis C (from a positive source patient to a negative recipient) is 1:30, and the risk of transmission of HIV (from an infected patient to a negative recipient) is 1:300 (Department of Health (DoH), 1998).

Despite occupational exposure awareness campaigns, e.g. *Be Sharp — Be Safe*, led by the Royal College of Nursing (RCN, 2001), HCWs have demonstrated limited awareness of the actual risk of exposure to blood-borne pathogens from clinical injury.

The risk of transmission of blood-borne pathogens increases in a variety of situations. These include:

- Injury caused by a hollow bore needle
- Any device that directly accesses an artery or vein
- A deep injury
- A large volume of blood
- Source patients with high blood viral loads (Goldmann, 2002).

The majority of inoculation injuries are caused by hollow bore needles, representing a high risk to HCWs (Ippolito et al, 1994; National Institute for Occupational Safety and Health (NIOSH), 1999; CDSC, 2000; Rabaud et al, 2000).

Policy and procedures vary between healthcare institutions with regard to the reporting of inoculation injuries, despite the availability of DoH guidelines (DoH, 1998). There are, however, a number of commonalities. All sharps injuries should be bled and washed under running water,

Joanna C Trim is Clinical Research Nurse, Debra Adams is Infection Control Nurse Specialist and Professor TSJ Elliott is Consultant Microbiologist/Divisional Director, Department of Clinical Microbiology and Infection Control, University Hospital, Birmingham

Accepted for publication: January 2003

the occupational health and safety department contacted (or the out- of-hours alternative), an incident form completed, and the HCW's manager should be informed of the incident.

Despite extensive education and training in the management of inoculation injuries, HCW knowledge and compliance of the reporting policy and procedure is inadequate (Henderson, 2001; May and Brewer, 2001). Indeed, studies have highlighted that as many as 80% of sharps injuries are not reported (Williams et al, 1993; Hettiaratchy et al, 1998; Patterson et al, 1998).

At a teaching hospital in Birmingham, the level of HCW knowledge of the risk of occupational transmission of blood-borne pathogens, inoculation injuries and use of gloves when handling sharp devices was previously unclear. In an attempt to evaluate the level of staff knowledge and the efficacy of current training and education programmes on universal precautions and inoculation injury management, a clinical audit was undertaken.

Table 1. Topics included within the audit questionnaire

Definition of an inoculation injury: Eight potential injuries were listed (a splash of blood or body fluid to the eyes or mouth and an injury caused by a scratch, bite, blade, scalpel, spicule of bone or teeth or a used needle; injury from a clean needle was also included). Healthcare workers (HCWs) were asked to identify which injuries were inoculation injuries. (Answer: all except a clean needle injury)
Incidence of transmission of hepatitis B, hepatitis C and human immunodeficiency virus: For each blood-borne pathogen, a continuum was presented with figures from 1 in 0.3 to 1 in 3000. Participants were asked to identify what they perceived to be the risk of transmission for each blood-borne pathogen
Risk of transmission of blood-borne pathogens associated with sharp devices: Eight sharp devices were listed (peripheral venous catheter, blade, suture needle, subcutaneous butterfly cannula, needle and syringe, blood glucose lancet, vacutainer system, and stitch cutter), from which participants rated each device according to the associated risk of exposure following an injury with the device. (Answer: hollow bore needle devices are the highest risk to HCWs)
'First-aid' action following a percutaneous inoculation injury: Participants were asked to document the first-aid procedure that should be undertaken following a percutaneous inoculation injury. (Answer: bleed and wash the injured site under running water and cover the affected site)
Reporting process following a percutaneous inoculation injury: Participants were asked to document how a percutaneous inoculation injury would be reported. (Answer: contact the occupational health and safety department or the allocated department out of working hours, or ward manager, and complete a risk management incident form)
Serological testing of the source patient: Participants were asked whether the source patient should have blood taken for serological testing following an inoculation injury, and if so, by whom. (Answer: the source patient should be serologically tested, blood being taken by the medical team managing the patient's care or the allocated team during the night)
Use of gloves in the clinical setting when handling sharp devices: Eleven clinical procedures involving a sharp device were listed. Participants recorded whether they wore gloves routinely during each activity undertaken in the clinical setting. (Answer: gloves should have been worn during all the procedures)
Awareness of needle-protective devices: Participants were asked to recall any needle-protective device and if their clinical area was currently using any such device

METHODS

Two hundred HCWs, comprising 135 nurses, 35 doctors, 13 phlebotomists, 10 surgical staff, two healthcare assistants and five 'others', participated in the clinical audit. A standardized questionnaire was devised, in consultation with the trust's consultant microbiologist and virologist, which was validated following its use in a pilot study before implementation. The topics shown in *Table 1* were included in the questionnaire.

The clinical audit was conducted over a 6-month period and questionnaires were completed before educational sessions by the infection control team and clinical research nurse. Doctors were recruited by visiting clinical areas. The trust's statistician was consulted. The sample size of 200 HCWs ensured 95% confidence intervals (CIs) with a range 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). Non-parametric statistical analysis was applied, and CIs were calculated using a binomial CI test.

RESULTS

The 200 HCWs who participated in the clinical audit accounted for 100% of phlebotomists, 12% of nurses and 10% of doctors working within the hospital. Each grade of profession was represented, the majority of nurses were D and E grades (68%) and 71% of doctors were preregistration house officers and registrars (*Figure 1*).

Inoculation injury

Only nine out of the 200 HCWs (5%, 95% CI, 2–8%) accurately defined an inoculation

injury (four preregistration house officers, one registrar, one surgical theatre staff, one D-grade nurse and two E-grade nurses).

One hundred and eighty two (91%) HCWs were aware that an injury involving a used needle was an inoculation injury, compared with an injury caused by a scratch (40%), blade (41%), bite (39%), scalpel (42%), bone or teeth (36%) or splash of body fluid (35%). Eight out of 10 surgical theatre staff were not aware that an injury involving a blade or scalpel was an inoculation injury (95% CI, 44–97%).

Overall, doctors (205/280, 73%, 95% CI, 68–78%) were significantly more knowledgeable regarding inoculation injuries than nurses (489/1080, 45%, 95% CI, 42–48%, $P < 0.0001$ Fisher's exact test). The denominator figure is based on the total number of correct responses each professional group should have made, e.g. 35 doctors and eight correct responses equals 280.

Risk of transmission of blood-borne pathogens

Eight nurses and one junior doctor (5%, 95% CI, 2–8%) correctly identified the risk of transmission of hepatitis B, hepatitis C and HIV from a percutaneous inoculation injury. Forty-two (21%) knew the risk of transmission of hepatitis B following a percutaneous inoculation injury, compared to 59 (30%) for hepatitis C and 53/200 (27%) for HIV (*Figure 2*). Indeed, 54 (27%) believed the risk of transmission of HIV to be 1:3000, 10 times lower than the actual risk. Similarly, more than half of all HCWs believed the risk of exposure to hepatitis B to be 10–1000 times lower than the actual risk, and 68 (34%) believed hepatitis C to be 10–100 times lower than the actual risk. Nine nurses and one phlebotomist (5%) did not know the risk of transmission for any blood-borne pathogen.

Less than a quarter of each professional group were aware of the risk of transmission of hepatitis B, hepatitis C and HIV (*Figure 3*). Indeed, only 12 (34%) doctors knew the risk of transmission of HIV (six preregistration house officers, four registrars, one senior house officer and one clinical lecturer), and only three surgical theatre staff knew the risk of transmission of hepatitis C and HIV.

No statistical significance was reached when junior and senior doctors' and junior and senior nurses' overall and individual levels of knowledge regarding blood-borne pathogens were compared.

Sharp devices and risk of exposure to blood-borne pathogens

HCWs were asked to rate the risk for transmission of blood-borne pathogens for eight

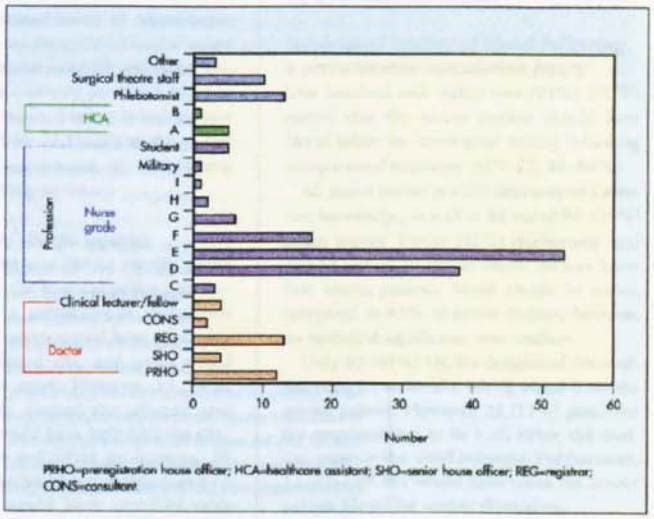

Figure 1. Profession and grade of healthcare workers who participated in the staff knowledge audit.

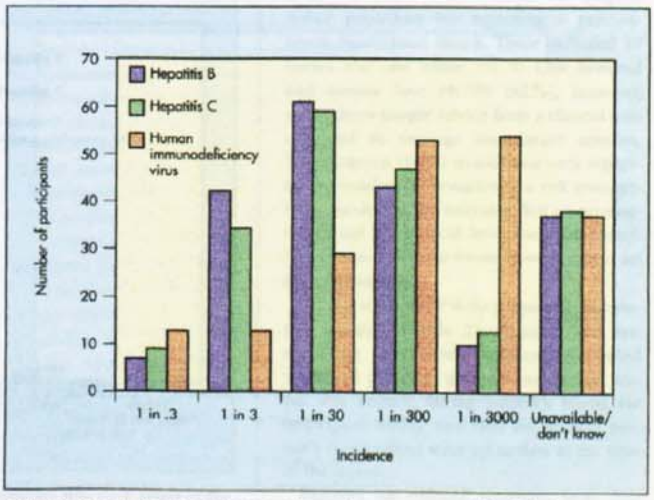

Figure 2. The number of healthcare workers who were aware of the risk of transmission of hepatitis B, hepatitis C and human immunodeficiency virus following a percutaneous inoculation injury.

sharp devices. Twenty nine (15%) HCWs correctly rated a peripheral venous catheter, needle and syringe and vacutainer system (with needle) as a high-risk device. The HCWs who were correct in their risk assessment of sharp devices comprised 21 nurses, six doctors, one phlebotomist and one 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 correctly perceived to be of lower risk. An injury from a blood glucose lancet was rated by 72 HCWs as a low risk device in the transmission of blood-borne pathogens following an injury.

Management of sharps injuries

One hundred and nine (55%) HCWs would have adhered to the hospital policy and correctly managed a percutaneous inoculation injury. Of these, seven would have used soap to wash the affected site, and seven would have covered the injury. However, 35 (18%) would have only washed the affected area and 32 (16%) would have only bled the site.

In relation to individual professions, 80 (59%) nurses, one healthcare assistant and 18 (51%) doctors would have complied with hospital policy. Ninety-one (46%) HCWs would, however, have remained at risk of exposure and potential transmission of blood-borne pathogens because the policy was not followed. Six HCWs identified that skin disinfectant, including Betadine, alcohol and chlorhexidine, should be used to wash the affected site following injury, demonstrating inaccurate information.

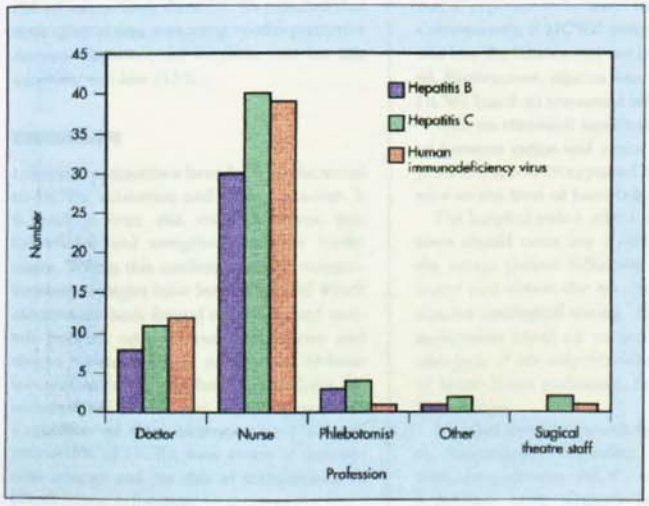

Figure 3. The number of healthcare workers in each profession who were aware of the occupational risk of transmission of hepatitis B, hepatitis C and human immunodeficiency virus following a percutaneous inoculation injury.

Serological testing of blood following a percutaneous inoculation injury

One hundred and eighty two (91%) HCWs agreed that the source patient should have blood taken for serological testing following occupational exposure (95% CI, 88–96%).

All senior nurses ($n = 28$) demonstrated accurate knowledge, as well as 88 out of 94 (94%) junior nurses. Twelve (92%) phlebotomy staff and 14 out of 19 (74%) senior doctors knew that source patients' blood should be tested, compared to 43% of junior doctors; however, no statistical significance was reached.

Only 80 (40%) HCWs designated the medical team to undertake taking blood from the source patient. However, 22 (11%) perceived the responsibility to lie with either the medical team or the ward manager. Furthermore, 12 (6%) HCWs would have taken the source patient blood for testing themselves.

Reporting sharps injuries

Twenty (10%) HCWs recalled the hospital policy procedure for reporting a percutaneous inoculation injury. These included 19 nurses and one 'other' HCW. One hundred and twenty four HCWs (62%), however, would have sought advice from a clinical area allocated to manage inoculation injuries. Twenty-seven (14%) would have only reported the incident by completing a risk management incident form, inferring that no serological blood tests would have been completed. Four doctors did not know how to report an inoculation injury.

HCWs were asked if they reported inoculation injuries (*Table 2*). Reasons for not reporting inoculation incidents included workload pressure, patient's serological status was known, taking patient's blood for serological testing and that the injured person's vaccinations were up to date at the time of the injury.

Reasons for reduced reporting were that patients were perceived to be of low risk. Overall, 26 HCWs (13%) did not report their

inoculation injuries. Of these, 13 were doctors, 11 were nurses and two were phlebotomists. The reason given for reporting all inoculation injuries was the relatively high risk of transmission of blood-borne pathogens to the HCW.

Glove use associated with sharp devices

Twenty-one doctors (60%) wore gloves when inserting a peripheral venous catheter. However, 14 (40%) did not wear gloves, compared to four (3%) nurses. Similarly, 10 (7%) nurses did not wear gloves when drawing blood, compared to 15 (43%) doctors. Overall, gloves were worn when using each sharp device in the clinical setting by more than 60% of HCWs. Gloves were not worn most frequently for administering intramuscular injections (63/161, 39%).

Knowledge of needle-protective devices

HCWs' knowledge regarding needle-protective devices was limited, with only 18 (9%) HCWs documenting that safer peripheral cannulae and needles were methods of increasing safety in the clinical setting.

One hundred and four (52%) HCWs did not know of any needle-protective device available to reduce the risk of percutaneous inoculation injury. Indeed, one HCW identified that wearing gloves would increase the risk of injury. Only three HCWs reported that their clinical area was using needle-protective devices. However, the response rate for this question was low (43%).

Table 2. Results of whether healthcare workers would report an inoculation injury

Would you report an inoculation injury?	Number of healthcare workers and percentage (n=200)
Yes	158 (79%)
No	11 (6%)
Sometimes	15 (8%)

DISCUSSION

Universal precautions have been fundamental to HCWs' education and clinical practice. It is evident from this study, however, that knowledge and compliance remain inadequate. Within this teaching hospital, comprehensive strategies have been employed which incorporate both formal education and written policies on universal precautions and sharps management, in addition to 24-hour inoculation injury telephone advice from the occupational health and safety department. Regardless of these strategies, only a small proportion of HCWs were aware of inoculation injuries and the risk of transmission of blood-borne pathogens.

Within the hospital, nurses had mandatory annual educational updates from both infection control and occupational health and safety teams, whereas doctors received educational training during hospital induction and minimal input thereafter. However, the results demonstrated that doctors were significantly more knowledgeable of inoculation injuries than nurses. Surgical theatre staff also received annual mandatory educational input; however, the majority of this group did not identify that injuries from a scalpel or blade were inoculation injuries, devices frequently used within their clinical setting. This limited level of awareness may be causative in the non-reporting of such injuries.

Recent awareness campaigns by the RCN, DoH and within this hospital appear to have made limited impact on HCWs' knowledge of the risk of transmission of blood-borne pathogens. HCWs frequently perceived the risk of exposure to be lower than the true risk. Consequently, if HCWs' perception of hazard was low, the injuries may not have been reported. Furthermore, injuries were self-assessed by HCWs based on inaccurate information.

With no statistical significance demonstrated between junior and senior staff members, years of experience appeared to have no influence on the level of knowledge or behaviour.

The hospital policy stated that the medical team should carry out a risk assessment on the source patient following an inoculation injury and obtain the necessary blood samples for serological testing. This procedure is undertaken based on an inadequate knowledge base of not only the risk of transmission of blood-borne pathogens, but also inoculation injuries.

A higher level of knowledge was, however, demonstrated regarding risk associated with sharp devices. HCWs were aware that a hollow bore device, having directly accessed an artery or vein, was of greater risk to them than other solid needles access-

> ...healthcare workers were not aware of the availability of needle-protective devices. Numerous products are currently available, with features that aim to reduce the risk of inoculation injury to both the user and other healthcare workers. However, those who are most at risk are unaware of such products.

ing superficial tissue. This, however, appeared to have little impact on behaviours following injury.

The hospital policy regarding the management of inoculation injuries was followed by half of HCWs. By not adhering to the policy, HCWs put themselves and their colleagues at risk of potential exposure to blood-borne pathogens. Indeed, some procedures, e.g. using skin disinfectants following injury, were not evidence-based. Nurses were most knowledgeable regarding this policy, in comparison to only half of doctors. These findings may have been the result of educational programmes or because medical staff were able to gain consent and obtain blood for serological testing, a procedure which was largely inaccessible to nurses. However, 6% of HCWs thought that they could obtain source patient blood themselves. Of these, five were doctors, six were nurses and one a phlebotomist.

Knowledge of the reporting procedure following inoculation injuries was minimal. Indeed, no doctor correctly identified hospital policy. HCWs would instead contact a clinical area competent in the management of inoculation injuries. However, a proportion would have only reported the incident using a risk management incident form. This may have resulted in no follow-up treatment. Discrepancy in the management of such injuries may be owing to the lack of a standardized protocol used within all NHS hospitals. HCWs who frequently change hospitals, e.g. medical staff or agency nurses, may therefore be confused with individual hospital policy and follow self-developed methods of dealing with incidents.

The non-reporting of inoculation injuries was identified in this study. The number of HCWs that did not or only sometimes report inoculation injuries was lower than the estimated 60–80% identified in the current literature (Williams et al, 1993; Hettiaratchy et al, 1998; Patterson et al, 1998). Indeed, this number is lower than previously identified within the trust (65%) (Dobie et al, 2002). It may, therefore, be that the sharps awareness campaign and educational input regarding sharps management and risk of exposure to blood-borne pathogens increased the number of reported inoculation injuries. Those that did report inoculation injuries did so because of the potential risk inflicted on their health and safety. Reporting behaviour may therefore be dependent on the degree of risk perceived by the HCW following injury.

Although gloves were worn in the clinical area when handling sharp devices, this was not routine practice. Doctors wore gloves significantly less frequently than nurses when inserting peripheral venous catheters and drawing blood. These findings concurred with the literature which indicated that universal precautions were not adhered to in the clinical setting (Godin et al, 2000; Scouler et al, 2000). By not wearing gloves, HCWs increase their risk of exposure to blood-borne pathogens and this may increase the risk of cross-infection of microorgansims. Indeed, not wearing gloves does not follow evidence-based practice guidelines.

Finally, HCWs were not aware of the availability of needle-protective devices. Numerous products are currently available, with features that aim to reduce the risk of inoculation injury to both the user and other HCWs. However, those who are most at risk are unaware of such products.

CONCLUSION

Despite a comprehensive educational programme for nursing staff and educational input for medical staff, knowledge level of inoculation injuries remains inadequate. It is essential to review and reassess the efficacy of educational and training methods for HCWs to ensure appropriate use of resources. Indeed, the reason as to why HCWs do not retain information regarding inoculation injuries should be reviewed. Continual training should be provided for both nursing and medical staff to encourage retention of information using flexible methods to meet the requirements of a currently pressurized workforce.

Other methods of communication should be considered and assessed for their efficacy, e.g. information boards within the clinical area should be available, the literature should be updated and rotated to reduce familiarization. The educational facility may be required to move into the clinical area, rather than removing clinical staff into classrooms. Clinical staff working together in the clinical setting may encourage information retention as well as practical application of the information.

Currently, HCWs' knowledge of inoculation injuries and associated risks is limited despite educational programmes. It is essential to understand the causative factors and methods of increasing HCW knowledge of the risk to their health and safety. BJN

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KEY POINTS

- The risk of exposure to blood-borne pathogens from an inoculation injury has been well documented since 1984, following the first reported occupational exposure to the human immunodeficiency virus.
- Universal precautions and sharps management educational programmes were introduced to reduce healthcare workers' risk of occupational exposure to blood-borne pathogens.
- Healthcare workers are not compliant with universal precautions and sharps management procedures in the clinical setting.
- The level of knowledge of the risks associated with inoculation injuries and the management and reporting of procedures following an injury are inadequate.
- Healthcare workers are placing themselves and their colleagues at risk of occupational exposure to blood-borne pathogens because of their lack of awareness.
- Reasons for non-compliance with universal precautions and the efficacy of educational programmes must be reviewed.

3.

A comparative user evaluation of three needle-protective devices

Debra Adams, TSJ Elliott

Abstract

Needlestick injuries (NSI) can result in healthcare workers being exposed to bloodborne viruses. Between 1997 and 2002, three healthcare workers in the UK have seroconverted to hepatitis C and one to human immunodeficiency virus (Public Health Laboratory Service (PHLS), 2003). Experience both in the UK and the USA suggests that even robust educational strategies may be insufficient to reduce the number of occupationally acquired NSI (Jagger et al, 1988). Needle-protective devices have now become more widely available and several studies have demonstrated an associated reduced risk of NSI. It is, however, essential that the devices are appropriately evaluated before introduction to ensure that they meet user requirements, do not interfere with function and reduce NSI risk. This article describes an evaluation programme carried out at the University Hospital Birmingham, UK. The programme focused on three key areas: safety, usability and compatibility. Results demonstrated that nurses rapidly adapt their practices to use the new safety devices and the study highlighted key education requirements that would be required before implementation. In addition, without this evaluation, it would not have been identified that attachment of the safety needles to the syringes requires a push-and-twist method or the use of LuerLok™ syringes to prevent detachment on activation of the safety procedure.

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Healthcare workers are at risk from transmission of bloodborne pathogens resulting from exposure to blood through needlestick injuries (NSI) (Centre for Disease Control (CDC), 1997). Studies have shown that the hollow bore needle has been responsible for up to 68% of all NSI (May and Churchill, 2001; Tan et al, 2001), has the greatest capacity for inoculating blood (Jeans, 1999) and is associated with the transmission of bloodborne pathogens (Cardo et al, 1997; International Healthcare Worker Safety Centre (IHCWSC), 1999).

Munro (2001) estimated that at least 100 000 NSI occur to healthcare workers annually in the UK. No single solution exists for avoiding NSI and a variety of different preventive strategies need to be adopted (Jagger et al, 1988). Approaches include finding alternative methods for performing procedures that are not reliant on needles and designing needles that have incorporated safety features.

There are three published reports from the USA that have evaluated the effectiveness of hypodermic needle-protective devices on the reduction of occupationally acquired NSI. Younger et al (1992) evaluated the impact of a safety syringe on NSI among healthcare workers at three American medical centres. The study demonstrated a significant reduction in NSI. However, it was noted that healthcare workers also had the opportunity of using the conventional product; this, therefore, might have led to distortion of the results.

In comparison, a study evaluating the efficacy of a safety syringe in an emergency department in California demonstrated that no corresponding reduction in NSI was attributable to the introduction of the device (Mulherin et al, 1996). In addition, healthcare workers found the product unsatisfactory and over 40% of the syringes observed had not had the safety feature activated (Mulherin et al, 1996).

Finally, Reddy and Emery (2001) assessed the effect of introducing a safety syringe and a needleless intravenous (IV) system throughout a hospital in Texas, USA. A significant reduction in the incidence of NSI was reported when comparing data 3 years before and 3 years after implementation. Again, however, confounding variables such as traditional needles and systems were still available and a comprehensive education programme was introduced part way through the study which may also have influenced the outcome. At present there have been no clinical trials in the UK to demonstrate the effect that hypodermic needle-safety devices can have on the reduction of NSI.

The first stage of introducing any needle-protective device into the clinical arena should be a user-acceptability study. Such evaluations take a relatively short time to complete and they provide valuable information regarding user preferences and product characteristics (Pugliese et al, 2001). Such a study was

designed and carried out at the University Hospital Birmingham NHS Trust (UHB) on three hypodermic needle-safety devices: Eclipse™, SafetyGlide™ and SafetyGlide™ insulin (Becton Dickinson, Oxford, UK)

METHODOLOGY

Fifty nurses from a range of specialties within the UHB were randomly selected to evaluate three needle-safety devices (*Figure 1*): Eclipse™, SafetyGlide™ and SafetyGlide™ insulin using a standardized user evaluation questionnaire, which was adapted from Emergency Care Research Institute (ECRI, 2002) (*Table 1*).

The questionnaire was divided into two sections. First, 10 statements were scored using a Likert scale, which evaluated key features of needle-safety devices, including safety, usability and compatibility. The statements were then rated against the following scale: strongly agree = 1, agree = 2, ambivalent = 3, disagree = 4, strongly disagree = 5. In the second section, specific questions about the devices were answered. These included whether the device became detached from the syringe, whether splashing occurred on activation of the device, and whether there were any clinical applications when the devices would be deemed unsuitable.

To determine the routine practice for administering an intramuscular (IM) or subcutaneous (SC) injection, a standard green needle with a slip-lock syringe (standard syringe type used within the UHB) was initially used. Five different combinations of the three needle-protective devices with two types of syringe were selected following computer randomization and these were then assessed. The combinations were SafetyGlide™ insulin (single unit), SafetyGlide™ with slip-lock syringe, SafetyGlide™ with LuerLok™ syringe, Eclipse™ with slip-lock syringe and Eclipse™ with LuerLok™ syringe. The nurses demonstrated their technique for giving an IM/SC route of injection by drawing up 2 ml sterile water and then injecting a simulated dummy model (Adam,Rouilly, Kent).

The nurse was then asked to activate the safety feature on the trial devices and complete the evaluation form. In order to assess how intuitive the products were to use, no training was given before the evaluation. In addition, the research observer also evaluated the activation process. This included how the devices were attached to the slip-lock syringes, the method for device activation and whether the devices splashed or became disconnected from the syringe on activation.

ETHICAL APPROVAL

Ethical committee approval was granted by the research ethics committee before commencement of this study.

RESULTS

Fifty nurses completed a standardized evaluation questionnaire. The three evaluation criteria — safety, usability and compatibility — were then used to evaluate both the user and the observational data (see *Table 1*).

Safety

The design of safety devices should allow a one-handed technique as this reduces the risk of injury to the other hand and minimizes the chances that the device will not be activated (ECRI, 2001). The results from the user evaluation questionnaire demonstrated that the nurses considered that the three devices met the safety standard for this criterion (mean score range = 1.78–1.88). The initial method of device activation was compared to subsequent uses, except for SafetyGlide™ insulin which was only used once. It was evident that after only two uses, nurses were becoming proficient in the activation techniques

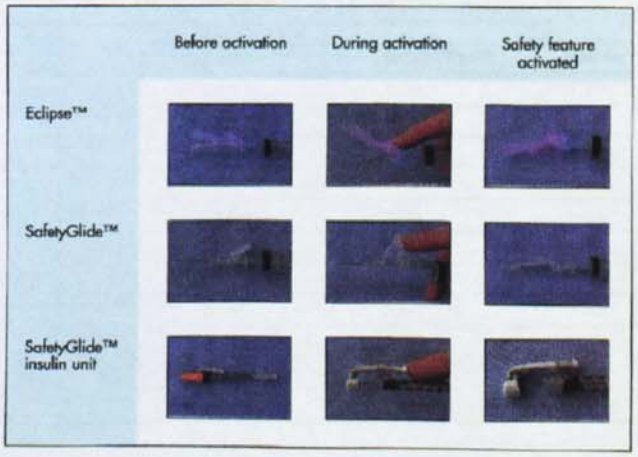

Figure 1. Three needle-protective devices from Becton Dickinson (Eclipse™, SafetyGlide™, SafetyGlide™ insulin unit). Figures demonstrate devices before, during and after activation of the safety features.

and there was a trend towards single-handed activation (*Table 2*).

It is important that the user of any safety device should be unequivocally aware when it has been activated; similarly, the device should not be easily deactivated. All the nurses considered that the devices allowed activation to be clearly designated (mean score range = 1.30–1.58). The scores also demonstrated that when reasonable force was applied, none of the safety devices could be deactivated (mean score range = 1.60–1.74).

Safety devices should not create additional infection control issues. Two further aspects of the safety devices were evaluated in this study: detachment of the needle from the slip-lock syringe (not applicable to SafetyGlide™ insulin) and splashing on activation. Slip-lock syringes are the standard syringe used within the UHB. It was therefore important to determine whether these needles detached when the safety feature was activated. A failure rate of 4% (two out of 50) was associated with SafetyGlide™ and 2% (one out of 50) with Eclipse™. All three needles had been attached by right-handed nurses using a 'push-on' rather than a 'push-and-twist' method and, in each case, the device was the last one to be evaluated in the scenarios.

When standard practice for attaching slip-lock syringe and conventional needle was analysed, 58% (26 out of 50) of nurses attached needles to the syringe using the 'push-on' method. Forty per cent (20 out of 50) of the nurses considered that a LuerLok™ syringe would be safer than a slip-lock syringe as it was less likely to disconnect even with standard needles.

The three needle-protective devices were also evaluated to assess whether splashing occurred on activation. Splashing was defined as the production of a spray of liquid from the needle when the safety feature was activated. Splashing on activation of the safety feature was noted in 3% (three out of 100) of the SafetyGlide™ needles evaluated. The splash occurred directly in front of the needle. This may have been associated with a lack of familiarity with the product as no education or training had been given before its use. No splashing was noted with either SafetyGlide™ insulin or Eclipse™ devices.

Usability

The design of protective devices should enable easy assembly and use. In addition, the technique for use should be similar to that of standard products. The nurses reported that the

Table 1. Evaluation of the three safety needles by 50 nurses at the University Hospital Birmingham NHS Trust during 2002

	Mean score from 50 respondents whose evaluations ranged between 1 and 5 (optimum score = 1)		
Statement: The needle safety feature...	SafetyGlide™ insulin	SafetyGlide™	Eclipse™
– is easy to activate	1.64	1.58	1.7
– is intuitive to use	1.78	1.78	1.74
– could be activated using one hand	1.78	1.8	1.88
– did not hinder routine use	1.7	1.75	2.1
– does not restrict visualization of the tip of the needle	1.66	1.56	1.82
– does not require more time to use than conventional products	1.74	1.7	1.86
– is easy to determine when it has been activated	1.58	1.34	1.44
– does not require detailed training to use	1.74	1.6	1.68
– would be effective in reducing NSI	1.36	1.48	1.48
– could not be easily deactivated	1.48	1.5	1.56
Overall total (optimum score = 10)	16.46	16.09	17.26

NSI = needlestick injuries

three devices were easy to activate (mean score range = 1.58–1.70), intuitive to use (mean score range = 1.74–1.78), did not hinder routine use (mean score range = 1.70–2.1), did not require more time to use than conventional products (mean score range = 1.74–1.8) and did not require detailed training to use (mean score range = 1.60–1.74).

Compatibility

Needle-protective devices should, as with conventional systems, be able to be used in all circumstances and be compatible with devices from other suppliers. The nurses agreed that the safety feature did not hinder the product's use (mean score range = 1.70–2.1) and when the nurses were asked whether they could envisage any situations where the devices would be unsuitable, only 6% (three out of 50) were concerned whether the devices could be used for phlebotomy. Further studies are required to assess compatibility with venepuncture.

Overall comments by the nurses included how easy the devices were to use and how staff safety should be seen as a priority. They also considered that using needle-protective devices was a method to decrease the risk of occupationally acquired NSI.

Table 2. An evaluation of how the safety feature was activated by the 50 clinical nurses

Method of activation	SafetyGlide™ insulin	SafetyGlide™ needle		Eclipse™ needle	
	1st activation	1st activation	2nd activation	1st activation	2nd activation
Two-handed	10% (5)	14% (7)	8% (4)	28% (14)	14% (7)
Forefinger	14% (7)	16% (8)	6% (3)	24% (12)	32% (16)
Thumb	76% (38)	70% (35)	86% (43)	48% (24)	54% (27)

Percentage of nurses performing the activation method, actual number of nurses shown in brackets

DISCUSSION

The 50 clinical nurses who took part in this comparative study confirmed that the three devices evaluated met all the safety criteria specified in the questionnaire. The nurses rapidly adapted their practices to the safe use of the products. However, two key training issues need to be addressed before implementing these devices in a clinical setting. The study revealed that disconnection of the safety needle on activation from a slip-lock syringe can occur in a minority of cases. In order to overcome this problem there are two options available: training of all staff, specifying that needles must be attached using the push-and-twist method, or recommending the use of LuerLok™ syringes. Second, splashing occurred when activating one of the safety devices in a small number of cases. Training must, therefore, also include the method used to activate the device smoothly in order to reduce this phenomenon.

The implementation of safety devices is not inexpensive. Mendelson et al (1998) noted that the introduction of needleless intermittent IV access devices would add an additional $230/1000 bed days. However, this has to be weighed against the costs of staff being injured and potentially infected following an occupational exposure. Costs associated with providing a safer working environment for staff are not a new occurrence. The previous implementation of universal precautions in the USA was estimated to have cost an additional $336 million in the fiscal year 1989; 64% of this cost was as a result of the introduction of rubber gloves and 25% because of the introduction of isolation gowns (Doebbeling and Wenzel, 1990).

CONCLUSION

It is evident that occupationally acquired NSI represent a significant risk of bloodborne virus transmission and therefore methods for reducing this risk must be identified. Evaluation of needle safe devices within the UK is a relatively new scenario. Fundamental to this process of implementing new safety devices is the evaluation by frontline healthcare workers. Without their input it has been proven that the change process can fail (Occupational Safety and Health Administration (OSHA), 1997; Fahey and Henderson, 1999).

This evaluation clearly demonstrated that the safety devices reviewed were intuitive to use and accepted by the nurses. However, without this evaluation it would not have been identified that attachment of the safety needle to the syringe requires a push-and-twist method or the use of LuerLok™ syringes. This may have affected the

> The purchase costs of safety devices are higher than standard products. However, all costs have to be weighed against the costs of staff being injured and potentially infected following an occupational exposure. It is inconceivable that healthcare workers should not wear protective clothing when dealing with blood and body fluids.

performance and acceptability of the devices when introduced into the clinical setting.

The purchase costs of safety devices are higher than standard products. However, all costs have to be weighed against the costs of staff being injured and potentially infected following an occupational exposure. It is inconceivable that healthcare workers should not wear protective clothing when dealing with blood and body fluids. The use of needle-protective devices to reduce the risk of NSI must surely follow soon after appropriate evaluation.

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KEY POINTS

- Surveillance of occupational transmission of bloodborne viruses in the UK demonstrated that there have been three seroconversions to hepatitis C and one to human immunodeficiency virus between 1997 and 2002.
- Studies have shown that the hollow bore needle has been responsible for up to 68% of all needlestick injuries (NSI).
- It is estimated that at least 100 000 NSI occur to healthcare workers annually in the UK.
- The implementation of safety devices is not inexpensive. However, this has to be weighed against the costs of staff being injured and potentially infected following an occupational exposure.
- Fundamental to implementing any new safety device is an evaluation by frontline healthcare workers. This evaluation identified that attachment of the safety needle to the syringe requires a push-and-twist method or the use of a LuerLok™ syringe in order to prevent detachment of the needle on activation of the safety feature.
- The clinical use of needle-safety devices in the UK must be evaluated to assess their effectiveness in reducing occupationally acquired NSI. Following this detailed evaluation, a clinical trial to assess their effectivenes in reducing NSI is being undertaken.

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Evaluation of a 2% chlorhexidine gluconate in 70% isopropyl alcohol skin disinfectant

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KEYWORDS
ChloraPrep®; Chlorhexidine; Disinfectant; Povidone iodine; Isopropanol; Skin antisepsis

Summary The efficacy of a new skin disinfectant, 2% (w/v) chlorhexidine gluconate (CHG) in 70% (v/v) isopropyl alcohol (IPA) (ChloraPrep®), was compared with five commonly used skin disinfectants against *Staphylococcus epidermidis* RP62A in the presence or absence of protein, utilizing quantitative time-kill suspension and carrier tests. All six disinfectants [70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG, 0.5% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) aqueous povidone iodine (PI)] achieved a $\log_{10}$ reduction factor of 5, in colony-forming units/mL, in a suspension test (exposure time 30 s) in the presence and absence of 10% human serum. Subsequent challenges of *S. epidermidis* RP62A in a biofilm (with and without human serum) demonstrated reduced bactericidal activity. Overall, the most effective skin disinfectants tested against *S. epidermidis* RP62A were 2% (w/v) CHG in 70% IPA and 10% (w/v) PI. These results suggest that enhanced skin antisepsis may be achieved with 2% (w/v) CHG in 70% (v/v) IPA compared with the three commonly used CHG preparations [0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA].

Introduction

Coagulase-negative staphylococci are frequently associated with catheter-related bloodstream infections.[1,2] A characteristic feature of these micro-organisms is their ability to adhere and form biofilms on prosthetic devices, resulting in resistance to antimicrobial agents. In order to reduce the risk of microbial colonization and subsequent sepsis of peripheral vascular catheters, it is recommended that the skin insertion site should be disinfected for 30 s with an antimicrobial solution.[3] A chlorhexidine preparation is preferred;

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however, povidone iodine (PI) or 70% isopropyl alcohol (IPA) may be used.[4-6] These agents use different modes of action to achieve antisepsis, which may be reduced in the presence of organic matter.[7,8] Two percent chlorhexidine gluconate (CHG) preparations have not been universally available in the UK. Recently, a 2% (w/v) CHG in 70% (v/v) IPA solution (ChloraPrep®: Medi-Flex® Incorporated; Kansas, USA) for skin decontamination has been developed and is currently under review for approval by the Medicines and Healthcare Products Regulatory Agency (UK) for marketing authorization. Clinical studies have demonstrated that this skin disinfectant provided a significantly better and more persistent antimicrobial activity than 70% (v/v) IPA or 2% (w/v) aqueous CHG at 24 h in patients receiving pre-operative skin antisepsis on abdominal and inguinal sites ($N=106$).[9] This enhanced residual antimicrobial activity may also potentially reduce the risk of subsequent phlebitis for patients requiring a peripheral vascular catheter.

The criterion for determining the antimicrobial activity of a disinfectant is usually the rate of reduction of the number of viable micro-organisms when exposed to the antiseptic agent. The most widely recognized definition with regards to bactericidal activity is a $\log_{10}$ reduction factor of 5.[10] Assessing the efficacy of a disinfectant may be undertaken by various quantitative in vitro methods including suspension tests and carrier tests.[11]

The aim of the present study was to determine the antimicrobial efficacy of 2% CHG in 70% (v/v) IPA, which has recently become available in the UK, and to compare it with 70% (v/v) IPA, 10% (w/v) aqueous PI, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA utilizing quantitative in vitro time-kill tests against *S. epidermidis* RP62A at 30 s. Suspension tests were used to determine the effectiveness of the disinfectant in reducing the potential risk from impaction on insertion of vascular catheters. Although biofilm formation develops following medical device insertion, some disinfectants have residual activity. Therefore, in addition to the suspension tests, carrier tests were undertaken to evaluate the potential inhibition of biofilms on disinfectant activity.

Methods

Six skin disinfectants were evaluated: 70% (v/v) IPA (BDH; Poole, UK) was prepared by diluting 100% (v/v) IPA in sterile distilled water; 0.5% (w/v) and 2% (w/v) aqueous CHG (Sigma; St Louis, USA) were prepared by diluting 20% (w/v) CHG in sterile distilled water; 0.5% (w/v) CHG in 70% (v/v) IPA (Adams Healthcare; Leeds, UK); 2% (w/v) CHG in 70% (v/v) IPA (Medi-Flex® International; Kansas, USA) and 10% (w/v) aqueous PI (Seton Healthcare; Oldham, UK).

Evaluation of the efficacy of the antimicrobial agents was undertaken at 30 s; the recommended time for disinfecting the intended skin site of a peripheral vascular catheter prior to insertion.[3]

A neutralizing agent was prepared containing 2% (v/v) Tween 80 (BDH; Poole, UK), 1.17% (w/v) lecithin (Fisher Scientific; Loughborough, UK), 0.1% (v/v) Triton X-100 (Sigma; St Louis, USA) and 0.5% (w/v) sodium thiosulphate (BDH; Poole, UK) in sterile distilled water. This was sterilized at 121 °C for 15 min and then stored at 4 °C until required. Prior to commencing the antimicrobial time-kill studies, verification of the effectiveness and non-toxicity of the chosen neutralizing agent against the range of antimicrobial agents and the efficacy of the antimicrobial agents against the challenge micro-organisms were determined.

S. epidermidis RP62A stored on microbank beads (Pro-Lab Diagnostics; Ontario, Canada) was revived by placing one bead in 3 mL brain heart infusion (BHI) broth (Oxoid; Basingstoke, UK) and incubating at 37 °C in air for 24 h. *S. epidermidis* RP62A is a reference biofilm-positive strain and 'slime' producer, which was confirmed under current test conditions by Freeman *et al.*'s technique.[12]

In the suspension test, 10 µL broth containing 3×10^6 colony-forming units (cfu) *S. epidermidis* RP62A was added to 990 µL disinfectant and mixed. After 30 s contact time at room temperature, 100 µL suspension was removed and added to 900 µL neutralizing agent, mixed and left to dwell for 5 min. Serial dilutions were inoculated on to BHI agar plates which were incubated at 37 °C in air for up to 48 h. Further suspension tests were undertaken by adding 10% (v/v) human serum (Sigma; St Louis, USA) to the suspension prior to adding the disinfectant. The evaluations were carried out in triplicate.

To evaluate the efficacy of the disinfectants against a biofilm, a carrier test was undertaken with a 96-well polystyrene flat-bottomed microtitre tray (Immulon® 2HB Thermo Labsystems; Franklyn, MA, USA). A suspension of *S. epidermidis* RP62A was diluted in BHI to approximately 1×10^4. Two-hundred-microlitre aliquots of the suspension were inoculated into 16 wells of a sterile microtitre

tray. This was then covered with a microplate sealer (Greiner-Bio-One; Gloucester, UK) and incubated at 37 °C in air for 24 h. Confirmation of biofilm production was undertaken by O'Toole and Kolter's[13] technique. To determine the efficacy of the disinfectants against a biofilm in the presence of protein, the carrier test was repeated; a suspension of *S. epidermidis* RP62A was diluted in BHI to approximately 1×10^4 cfu/mL and 10% human (v/v) serum was added.

The cells in suspension in each well were removed by inversion of the plate; the wells were then washed with 250 µL phosphate-buffered saline (PBS). Two-hundred microlitres of the selected disinfectant was added to each well and allowed to dwell for 30 s. The disinfectant was aspirated and 250 µL neutralizing agent was added to each well and left for 5 min. The neutralizing agent was removed by inversion of the tray, and the microtitre wells were washed with PBS. Removal of the biofilm from the microtitre well was undertaken by adding a 200-µL aliquot of BHI to each inoculated well. With a sterile pipette tip, the walls of the microtitre wells and base were scraped 10 times and the BHI was removed from each well and collected. This procedure was repeated a further three times and the inoculum was mixed thoroughly. Previous studies had demonstrated that four consecutive scrapes were required to remove >99% of the micro-organisms in a biofilm attached to a microtitre well; successive scrapes failed to statistically reduce this number further. The numbers of viable *S. epidermidis* RP62A in suspension were enumerated by serial dilutions, and 100 µL of each dilution was inoculated on to BHI agar plates. The plates were then incubated at 37 °C in air for up to 48 h. Tests and controls were carried out 16 times.

Statistical analysis

Data were compared using the Mann-Whitney *U*-test. *P* values of equal to or less than 0.05 were regarded as significant.

Results

In all tests, the controls containing no disinfectant resulted in a complete recovery of the initial inocula.

Table I outlines the results of the suspension and carrier tests in both the presence and absence of protein. Efficacy of the disinfectant activity is represented as the $\log_{10}$ reduction factor of the initial cfu/mL. None of the skin disinfectants tested achieved a $\log_{10}$ reduction factor >5 in all four tests. Four disinfectants [70% (v/v) IPA, 0.5% (w/v) CHG in 70% (v/v) IPA, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) aqueous PI] achieved a $\log_{10}$ reduction factor >5 at 30 s in the suspension tests, both in the presence and absence of human serum, and in the carrier test when challenged with *S. epidermidis* RP62A in a biofilm.

When evaluating the effectiveness of the six disinfectants against *S. epidermidis* RP62A in a biofilm enriched with 10% (v/v) human serum, 70% (v/v) IPA, 0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA achieved a $\log_{10}$ reduction factor between 2 and 4 at 30 s. In comparison, 2% (w/v) CHG in 70% (v/v) IPA and 10% (w/v) aqueous PI achieved a $\log_{10}$ reduction factor of between 4 and 5. There was no statistical difference between the two disinfectants on analysis ($P=0.28$).

Table I Comparing the efficacy of 2% (w/v) chlorhexidine gluconate (CHG) in 70% (v/v) isopropyl alcohol (IPA) against five standard skin disinfectants on *Staphylococcus epidermidis* RP62A after 30 s of contact time utilizing suspension and carrier tests

Antiseptic	$\log_{10}$ reduction factor in cfu/mL of *S. epidermidis* RP62A			
	Suspension test	Suspension test with 10% human serum	Carrier test: biofilm	Carrier test: biofilm enriched with 10% human serum
2% (w/v) CHG in 70% (v/v) IPA	6.5	6.3	5.3	4.7
70% (v/v) IPA	6.5	6.3	5.4	2.8
0.5% (w/v) aqueous CHG	6.5	6.3	4.1	2.3
2% (w/v) aqueous CHG	6.5	6.3	4.8	2.8
0.5% (w/v) CHG in 70% (v/v) IPA	6.5	6.3	5.8	3.6
10% (w/v) aqueous povidone iodine	6.5	6.3	5.9	4.4

cfu, colony-forming units. Bold type indicates a failure to achieve a $\log_{10}$ reduction factor of 5.

Discussion

This study compared the antimicrobial effectiveness of 2% (w/v) CHG in 70% (v/v) IPA with five standard skin disinfectants. The findings demonstrated that the range of disinfectants tested were capable of achieving a $\log_{10}$ reduction factor of 5, in cfu/mL, when in suspension both in the presence and absence of protein. However, when challenged with *S. epidermidis* RP62A in a biofilm (with or without protein), the antimicrobial effectiveness was reduced, thus reflecting previous reports that disinfectants may be inhibited in the presence of organic matter.[7,8]

The application of effective skin antisepsis is essential in the strategy to reduce catheter-related sepsis. The Centers for Disease Control and Prevention[4] recommend the use of a 2% chlorhexidine-based preparation for skin decontamination prior to line insertion, but do not specify the use of either an aqueous solution or one in 70% IPA. Pratt *et al.*[5] and the National Institute for Clinical Excellence guidelines[6] recommend an alcoholic chlorhexidine solution but do not specify a concentration. This study supports the recommendation of a chlorhexidine in alcohol product. Indeed, the in vitro results suggest that 2% (w/v) CHG in 70% (v/v) IPA offers an improved antimicrobial effect compared with all three standard preparations of CHG currently available in the UK [0.5% (w/v) aqueous CHG, 2% (w/v) aqueous CHG and 0.5% (w/v) CHG in 70% (v/v) IPA] when challenged with *S. epidermidis* RP62A in a biofilm in the presence of 10% human serum ($P=0.0001$).

Further in vitro studies are required to assess the potential clinical effectiveness of 2% (w/v) CHG in 70% (v/v) IPA against a wider range of pathogens. In addition, assessment of the residual antiseptic activity on the skin compared with other commercially available chlorhexidine preparations needs to be studied. This study, however, suggests that 2% (w/v) CHG in 70% (v/v) IPA may offer advantages over the other chlorhexidine products available. In vivo studies are required to assess the effectiveness of this product in the clinical situation.

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Infection risk associated with a closed luer access device

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KEYWORDS
Needleless connector;
Microbial contamination;
Q-Syte™

Summary The potential for microbial contamination associated with a recently developed needleless closed luer access device (CLAD) (Q-Syte™; Becton Dickinson, Sandy, UT, USA) was evaluated in vitro. Compression seals of 50 multiply activated Q-Syte devices were inoculated with *Staphylococcus epidermidis* NCTC 9865 in 25% (v/v) human blood and then disinfected with 70% (v/v) isopropyl alcohol followed by flushing with 0.9% (w/v) sterile saline. Forty-eight of 50 (96%) saline flushes passed through devices that had been activated up to a maximum of 70 times remained sterile. A further 25 Q-Syte CLADs that had undergone multiple activations were challenged with prefilled 0.9% (w/v) sterile saline syringes, the external luer tips of which had been inoculated with *S. epidermidis* NCTC 9865 prior to accessing the devices. None of the devices that had been accessed up to 70 times allowed passage of micro-organisms, despite challenge micro-organisms being detected on both the syringe tip after activation and the compression seals before decontamination. These findings suggest that the Q-Syte CLAD may be activated up to 70 times with no increased risk of microbial contamination within the fluid pathway. The device may also offer protection from the external surface of syringe tips contaminated with micro-organisms.

Introduction

Patients who require an intravascular catheter (IVC) as part of their clinical management are at risk of developing a device-related infection. The main

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routes by which micro-organisms gain access to an IVC are extraluminal, intraluminal, haematogenous seeding, contaminated infusates or impaction on insertion.[1] The most common source is intraluminal migration, caused by the manipulation of a contaminated hub.[2,3]

Studies have demonstrated that microbial contamination rates of IVC hubs are as high as 31% and that there is a clear correlation between the contamination rate and the frequency of manipulation.[4] Needleless connectors have more recently been introduced into the clinical setting to reduce the risk of occupationally acquired needlestick injuries.[5] However, evaluation of the microbial contamination associated with these needleless connectors has produced conflicting results. Cookson *et al.*[6] found a significant increase in bloodstream infection rates associated with the introduction of a needleless connector, which was attributed to unfamiliarity with the device and practices differing from the manufacturer's recommendations. Conversely, several studies have demonstrated no statistically significant difference in the rate of fluid pathway contamination when comparing standard access hubs with needleless access devices.[7-11] However, Brown *et al.*[12] and Casey *et al.*[13] reported that when needleless systems were decontaminated effectively, the risk of microbial contamination of the IVC via the internal lumen was reduced.

The aim of this study was to determine the in vitro risk of microbial contamination associated with a new needleless closed luer access device (CLAD) (Q-Syte™; Becton Dickinson, UK) following multiple activations (Figure 1). Two methods were chosen, firstly to ensure that effective decontamination of the septum was achievable using standard methods, up to and including 70 activations, and secondly to determine that the internal structure and the associated efficacy of the CLAD septum were maintained following multiple uses, therefore preventing microbial ingress from contaminated external luer syringe tips.

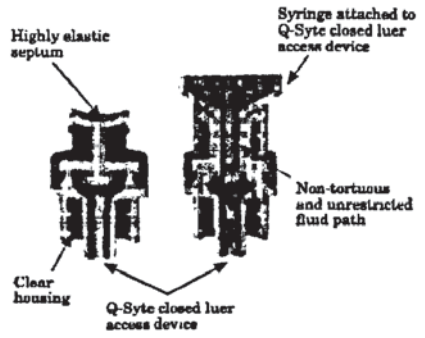

Figure 1 Q-Syte™ closed luer access device. Graphic supplied courtesy of Becton Dickinson, UK.

Materials and methods

To evaluate the efficacy of the Q-Syte CLAD in preventing internal pathway contamination of IVCs, two in vitro studies were designed. Two potential routes of microbial entry into such a closed system were investigated, namely contaminated compression seal surfaces and syringe tips.

Evaluation of the potential risk from a contaminated compression seal was undertaken utilizing 60 sterile Q-Syte CLADs; 50 were used as test devices, five were used as positive controls and five were used as negative controls. Ten test Q-Syte CLADs were not activated. Ten each of the remaining 40 devices were activated by repeatedly pressing a new, single-use, sterile luer lock syringe into the CLAD septum (mimicking clinical practice) nine, 29, 49 and 69 times, respectively. The compression seals of 55 Q-Syte CLADs were then inoculated with a 10 μL suspension, containing 1.5×10^7 colony-forming units (cfu) *S. epidermidis* NCTC 9865 in brain heart infusion (BHI) (Oxoid, Basingstoke, UK), supplemented with 25% (v/v) human blood which was then allowed to dry at 37 °C in air for 30 min. Five Q-Syte CLADs were not inoculated and acted as controls. The 50 test Q-Syte CLADs and five negative controls were then disinfected by firmly applying individual swabs containing 70% (v/v) isopropyl alcohol (IPA) (Sterets; Seton Healthcare, Oldham, UK) to the compression seal and rotating five times through 360°. The 70% (v/v) IPA was subsequently allowed to dry for 2 min. The five positive controls were not disinfected. To ensure that any microbial contamination detected was attributable to the device and not from potentially contaminated, manually drawn up flushes,[14] a sterile, prefilled syringe containing 10 mL of 0.9% (w/v) saline (Saline XS; Becton Dickinson, Le Pont-de Claix, France) was pushed in to each Q-Syte CLAD and then flushed.

Evaluation of the potential risk of internal pathway contamination from a contaminated syringe luer tip was undertaken utilizing an additional 28 sterile Q-Syte CLADs. Twenty-five were used as test devices challenged with a contaminated syringe, and three acted as negative controls and were activated with uninoculated syringes. The devices underwent multiple activations as described in the previous

evaluation of contaminated compression seals. The final activation of each device was carried out using a prefilled, sterile syringe containing 10 mL of 0.9% (w/v) saline (Saline XS; Becton Dickinson, Le Pont-de Claix, France). Before use, the external surface of each luer tip was inoculated with a 5 µL suspension containing 3×10^2 cfu *S. epidermidis* NCTC 9865 in BHI, and allowed to dry at 37 °C in air for 30 min. The syringe was then attached to the Q-Syte CLAD and subsequently flushed with 10 mL of 0.9% (w/v) saline.

Assessment of the level of microbial contamination of the flush solution, the compression seal and the syringe tip was subsequently undertaken. The initial 5 mL 0.9% (w/v) saline flush was collected in a sterile Petri dish, and the remaining 5 mL was collected in a further sterile Petri dish. Fifteen millilitres of molten nutrient agar (Oxoid) cooled to 56 °C was added to each dish, mixed thoroughly and allowed to set at room temperature. In addition, the compression seal of each Q-Syte CLAD and each syringe luer tip was imprinted on to the surface of a nutrient agar plate (bioMérieux, Basingstoke, UK). The plates were then incubated at 37 °C in air for up to 48 h, after which the number of cfu of *S. epidermidis* NCTC 9865 was determined for the Q-Syte CLAD compression seal, the syringe luer tip and per 10 mL flush solution. Enumeration of the cfu on the plates was grouped as follows: 0, 1-9, 10-100 and >100 per plate.

Results

Forty-eight of 50 (96%) saline solutions obtained following infusion through Q-Syte CLADs remained sterile (Table I). Two of 50 devices (4%) that were activated 10 times had associated flush solutions contaminated with *S. epidermidis* NCTC 9865. No micro-organisms were detected on any of the syringe tips or the compression seals following activation and decontamination with a 70% (v/v) IPA swab (Table I).

All the saline flush solutions recovered following passage through 25 multiply activated Q-Syte CLADs challenged with a syringe, the external luer tip of which was contaminated with *S. epidermidis* NCTC 9865, remained sterile (Table II). Challenge micro-organisms were detected on both the syringe tips after activation (23 of 25; 92%) and on the external septum of the connector before decontamination (11 of 25; 44%). No micro-organisms were detected on the Q-Syte CLAD septum following decontamination with a 70% (v/v) IPA swab.

Discussion

Needleless connectors are widely used within the healthcare setting. However, there are currently no recommendations on the number of times that needleless devices may be accessed. Therefore,

Table I Microbial contamination of 0.9% (w/v) saline following flushing through a multiply activated Q-Syte™ needleless closed luer access device (Becton Dickinson, USA)

Test devices		Number of bacteria in 10 ml flush fluid		Syringe luer tip contamination following activation of the Q-Syte device		Q-Syte compression seal contamination following activation of the device	
Times activated	Number tested	No. of flushes contaminated	Range of cfu	No. of tips contaminated	Range of cfu	No. of connectors contaminated	Range of cfu
1	10	0	0	0	0	0	0
10	10	2	>100; 11-100	0	0	0	0
30	10	0	0	0	0	0	0
50	10	0	0	0	0	0	0
70	10	0	0	0	0	0	0
Control devices							
Positive control: 10	5	5	>100	5	10-100	5	10-100
Negative control: 10	5	0	0	0	0	0	0

The device had been contaminated with *Staphylococcus epidermidis* NCTC 9865 containing 1.5×10^7 colony-forming units (cfu) in BHI (Oxoid) supplemented with 25% (v/v) human blood (University Hospital Birmingham) and then disinfected with 70% (v/v) isopropyl alcohol. The fluid flushed after disinfection, syringe luer tip and Q-Syte compression seal were sampled for the presence of micro-organisms. Bold type indicates contamination.

Table II The microbial contamination of 0.9% (w/v) saline following flushing through a multiply activated Q-Syte™ needleless connector (Becton Dickinson, USA) with a syringe luer tip externally inoculated with a suspension containing 30 colony-forming units (cfu) of *Staphylococcus epidermidis* NCTC 9865 in BHI (Oxoid)

Test devices		Number of bacteria in 10 ml flush fluid		Syringe luer tip contamination following activation of the Q-Syte device		Q-Syte compression seal contamination following activation of the device and subsequent disinfection			
Times activated	Number tested	No. of flushes contaminated	Range of cfu	No. of tips contaminated	Range of cfu	No. of connectors contaminated before disinfection	Range of cfu	Number of post decontamination percentage	
1	5	0	0	5	1-10	0	0	0	
10	5	0	0	5	1-10	2	1-10	0	
30	5	0	0	4	1-10	2	1-10	0	
50	5	0	0	4	1-10	3	1-10	0	
70	5	0	0	5	1-10	4	1-10	0	
Negative controls									
10	3	0	0	0	0	0	0	0	

The fluid flushed after disinfection, syringe luer tip and Q-Syte compression seals were sampled for the presence of micro-organisms. Bold type indicates contamination.

the potential risk of microbial contamination and possible subsequent infection remains unclear.[6,11 13]

The current study demonstrated that when the compression seal of the Q-Syte CLAD was inoculated with a high inoculum of *S. epidermidis* (1.5×10^7), compared with that reported in the clinical arena,[12] and subsequently disinfected with a 70% (v/v) IPA swab, only 4% of devices allowed passage of micro-organisms compared with standard entry ports which have had a reported microbial contamination rate of 22%.[15] This indicated that effective decontamination of the compression seal was not effected following multiple activations which may have caused damage to the septum, resulting in greater microbial attachment. In addition, when the Q-Syte CLAD was accessed with a luer syringe tip that had been microbially contaminated on the external surface, no contamination of the flush solution following infusion was identified. Challenge micro-organisms were detected on the syringe tip after activation and on the external septum of the compression seal. It therefore seems likely that despite being activated up to 70 times, the septum of the device prevented any micro-organisms present on the external luer surface of the syringe from entering the fluid pathway. In the clinical environment, where a lower risk of microbial contamination is expected compared with these in vitro studies, the Q-Syte CLAD may be of value in reducing the risk of introducing micro-organisms into the fluid pathway during administration of intravenous fluids.

This study also demonstrated that the Q-Syte CLAD can be effectively decontaminated with a 70% (v/v) IPA swab, and may be activated up to 70 times with no increased risk of microbial contamination of the flush solution caused by potential damage to the internal septum following multiple activations. The attributes of this needleless connector in preventing IVC internal pathway contamination may be of value in the clinical setting, and further studies are warranted to evaluate its efficacy against a range of micro-organisms and its effectiveness in reducing catheter-related infections.

Acknowledgements

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2. Adams D and Elliott TSJ. A Clinical Evaluation of SafetyGlide™ Needle Protective Devices. Poster Presentation at: *The 6th International Infection Control Nurses Association Conference,* 2004 (September). Belfast, United Kingdom.

3. Adams D, Karpanen T, Worthington T, Lambert P and Elliott T. Assessment of the Potential Infection Risk Associated with the Q-Syte™ Needleless Connector. Poster Presentation at: *15th European Congress of Clinical Microbiology and Infectious Diseases,* 2005 (April). Copenhagen, Denmark.

4. Quayum M, Adams D, Casey A, Worthington T, Lambert PA and Elliott TSJ. Determination of the Activity of Chlorhexidine Gluconate Against a Range of Clinical Isolates of S. Epidermidis. Poster Presentation at: *University Hospital Birmingham NHS Foundation Trust: Research Development Team Conference,* 2005 (September). Birmingham, United Kingdom.

5. Small H, Adams D, Casey, A, Worthington T, Elliott TSJ. Determination of the Effectiveness of 70% Isopropyl Alcohol and 2% Chlorhexidine Gluconate in 70% Isopropyl Alcohol Skin Disinfection in Preventing Microbial Colonisation of Peripheral Vascular Catheters. Poster Presentation at: *The 6th International Conference of IV Therapy Conference,* 2006 (March). Oxford, United Kingdom.

1.

The Prevention of Inoculation Injuries

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Introduction

- Sharps injuries from medical devices remain a significant problem for healthcare workers.[1]
- Estimated annual sharps injuries; 100,000 in the UK[2]; 800,000 in the USA.[3]
- Sharps injuries are frequently not reported.[1,4]
- Nursing and medical staff are most at risk of sharps injuries. Ancillary staff are also at risk due to inappropriate disposal of sharp devices.[5,6]
- Hollow bore needles are associated with the highest number of injuries, although the injury rate of intravenous introducer needles is significant.[7,8]
- Healthcare workers underestimate the risk of occupational transmission of blood borne pathogens and do not adhere to universal precautions.[9,10]

Aims of the study

1. To audit the rate of under-reporting of sharps injuries in University Hospital Birmingham NHS trust.
2. To audit the level of staff knowledge of inoculation injuries and associated risks.
3. To evaluate the usability of a needle protective device.

Methods

1. Between November 2001 and April 2002, 184 clinical and 119 ancillary staff completed a questionnaire to audit the number of sharps injuries sustained, cause of the injury and whether the incident was reported.
2. Two hundred clinical staff completed a standardised questionnaire to evaluate knowledge of inoculation injuries, the risk of transmission of bloodborne pathogens associated with a sharps injury, the risk associated with sharp devices, the reporting process and use of gloves in the clinical setting.
3. Insertion properties of a needle protective peripheral venous catheter were assessed. The safety mechanism, located in the catheter hub, is passively activated on withdrawal of the introducer needle from the catheter. The safety mechanism comprises a tether along the needle and a guard which covers the needle tip on separation from the catheter.

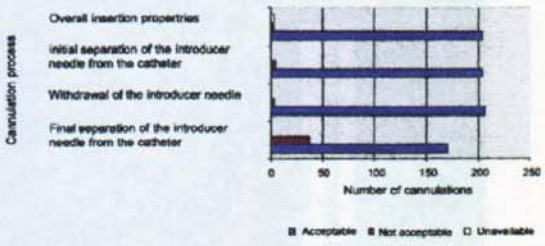
Results

1. Thirty-eight sharps injuries were sustained by 27 clinical staff (table 1).
   Twenty nine percent of incidents were not reported.
   Reasons for not reporting injuries included: the patient was perceived as low risk; the user was up to date with their vaccinations and pressure of workload. Five sharps injuries were sustained by 4 ancillary staff.
   Twenty six near miss incidents were recorded, all of which involved a hollow bore needle. Eight percent of incidents involving ancillary staff were not reported.
2. An inoculation injury was correctly defined by only 4.5% of staff (56% doctors, 33% nurses, 11% operational department operator).
   Only 4.5% of staff knew the risk of transmission of hepatitis B, hepatitis C and HIV (89% nurses, 11% doctors).
   The perceived highest risk associated with a sharp device was a needle and syringe (36%), compared to a peripheral venous catheter (22%) and a vacutainer system (with needle) (10%).
   Only 10% of staff recalled the Trust's policy for reporting a sharps injury.
   Forty percent of doctors did not wear gloves when inserting peripheral venous catheters.
3. The insertion properties of 210 (79%) successful cannulations using the needle protective catheter are shown in figure 1.
   Fifty six (21%) cannulations were unsuccessful.
   Unsuccessful cannulations were frequently due to poor vein quality (57%), the operator (32%) and the product (2%).

Table 1: The number of sharps injuries and percentage of total sharps injuries sustained by individual professions of clinical staff over a 6 month period

Profession	Number of sharps injuries	Percentage of total sharps injuries
Nurse	8	21%
Doctor	25	66%
Phlebotomist	3	8%
ODP/ODA	2	5%

Figure 1: The evaluation of the insertion properties of a needle protective device in the clinical setting



Summary

- A total of 37% of sharps injuries and near miss incidents were not reported. Medical staff most frequently under-reported their injuries.
- Healthcare workers did not appreciate the risk of transmission of bloodborne pathogens from a sharps injury.
- The risk of exposure to hepatitis B, hepatitis C and HIV were underestimated.
- Despite induction programmes and education, established policies to guide the healthcare worker in reporting sharps injuries were not known.
- Gloves are not routinely used when handling sharp devices.
- The insertion properties of the needle protective device were regarded as acceptable by the majority of users. The catheter could be used in the clinical setting, having the advantage of an inoculation injury prevention feature.
- The force required to finally remove the introducer needle from the catheter which activated the safety mechanism did not interfere with the cannulation procedure.
- Failed cannulation attempts were mainly due to the patients' underlying condition or the inexperience of the operator.

Conclusions

- A review of educational methods is essential to improve staff's retention of knowledge of the risk posed by sharps injuries.
- Education and training on the safe disposal of sharp devices and strategic placement of sharps containers is imperative to ensure ancillary staff are not put at risk of injury.
- Knowledge of policies and the importance of reporting sharps injuries and near miss incidents must be reinforced to improve risk management of such incidents.
- Devices which offer protection should be evaluated using an appropriate tool, by medical and nursing staff in different specialities and with varying experience.
- The introduction of needle protective devices should be considered particularly in high risk situations.
- Cost benefit analysis must be undertaken to evaluate the financial implications of needle protective devices.

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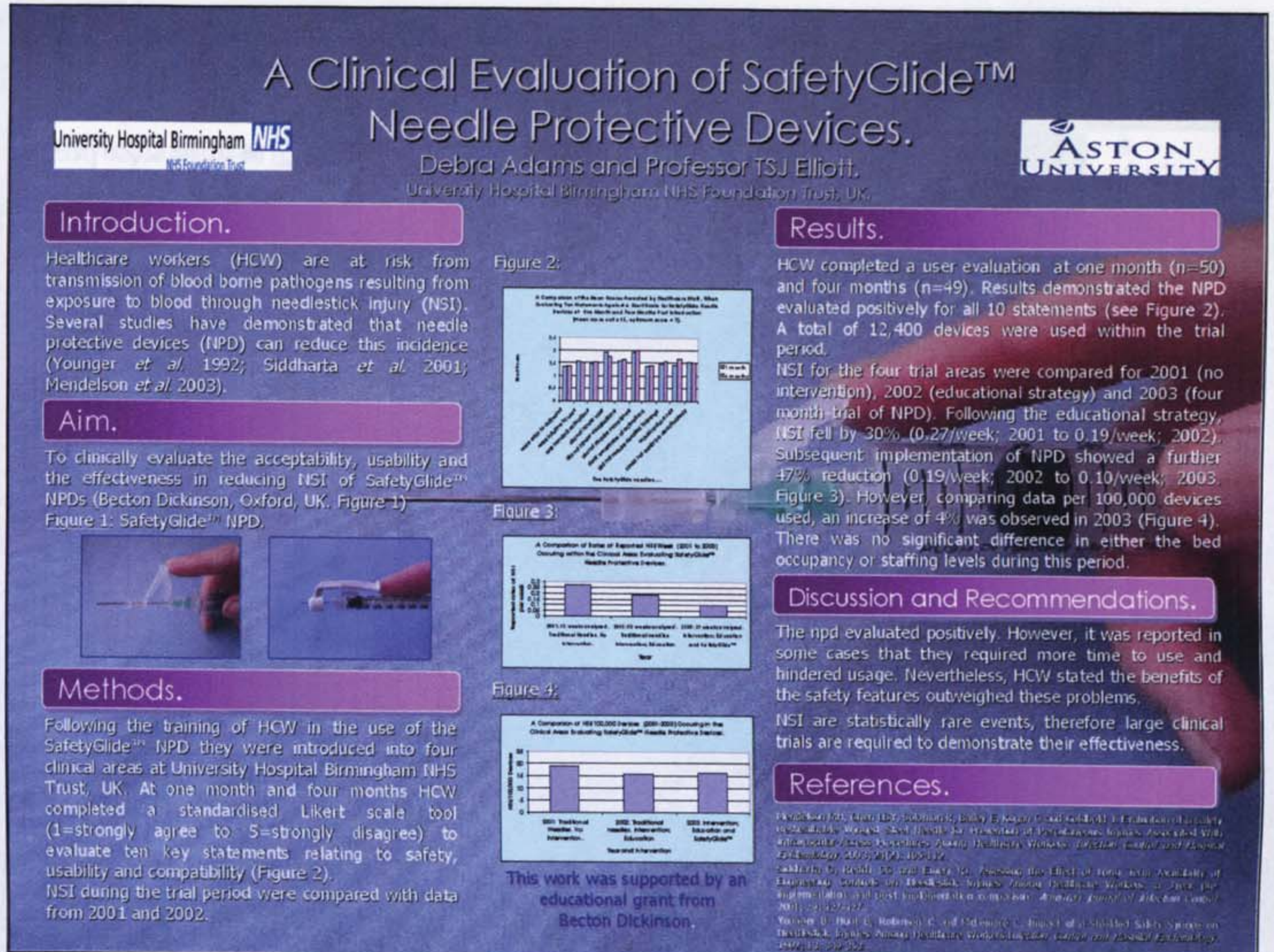

A Clinical Evaluation of SafetyGlide™ Needle Protective Devices.
University Hospital Birmingham NHS
NHS Foundation Trust
Aston University
Debra Adams and Professor TSJ Elliott.
University Hospital Birmingham NHS Foundation Trust, UK.
Introduction.
Healthcare workers (HCW) are at risk from transmission of blood borne pathogens resulting from exposure to blood through needlestick injury (NSI). Several studies have demonstrated that needle protective devices (NPD) can reduce this incidence (Younger et al. 1992; Siddharta et al. 2001; Mendelson et al. 2003).
Aim.
To clinically evaluate the acceptability, usability and the effectiveness in reducing NSI of SafetyGlide™ NPDs (Becton Dickinson, Oxford, UK. Figure 1)
Figure 1: SafetyGlide™ NPD.
Methods.
Following the training of HCW in the use of the SafetyGlide™ NPD they were introduced into four clinical areas at University Hospital Birmingham NHS Trust, UK. At one month and four months HCW completed a standardised Likert scale tool (1=strongly agree to 5=strongly disagree) to evaluate ten key statements relating to safety, usability and compatibility (Figure 2).
NSI during the trial period were compared with data from 2001 and 2002.
Figure 2:
Figure 3:
Figure 4:
This work was supported by an educational grant from Becton Dickinson.
Results.
HCW completed a user evaluation at one month (n=50) and four months (n=49). Results demonstrated the NPD evaluated positively for all 10 statements (see Figure 2).
A total of 12,400 devices were used within the trial period.
NSI for the four trial areas were compared for 2001 (no intervention), 2002 (educational strategy) and 2003 (four month trial of NPD). Following the educational strategy, NSI fell by 30% (0.27/week; 2001 to 0.19/week; 2002). Subsequent implementation of NPD showed a further 47% reduction (0.19/week; 2002 to 0.10/week; 2003. Figure 3). However, comparing data per 100,000 devices used, an increase of 4% was observed in 2003 (Figure 4). There was no significant difference in either the bed occupancy or staffing levels during this period.
Discussion and Recommendations.
The npd evaluated positively. However, it was reported in some cases that they required more time to use and hindered usage. Nevertheless, HCW stated the benefits of the safety features outweighed these problems.
NSI are statistically rare events, therefore large clinical trials are required to demonstrate their effectiveness.
References.

3.

Assessment of the Potential Infection Risk Associated with the Q-Syte™ Needleless Connector.

University Hospital Birmingham NHS
NHS Foundation Trust

Aston University

Debra Adams, Tarja Karpanen, Tony Worthington, Peter Lambert, Tom Elliott.

Objectives

- To determine the potential infection risk associated with the Q-Syte™ (BD; Utah, USA) needleless connector.
- To determine if multiple activations of the Q-Syte™ needleless connector increases the potential risk of infection.

Method

Fifty Q-Syte™ needleless connectors were inoculated on to the hub surface with a suspension containing 25% (v/v) human blood and 6.5 x105 colony forming units of *S. epidermidis* (Figure 1). Suspensions were allowed to dry. Each device was then decontaminated with 70% isopropyl alcohol as per standard practice. Needleless connectors were next flushed with a pre-filled sterile syringe containing 10ml of 0.9% (v/v) sterile saline. Each flush solution was collected and the number of colony forming units present determined by standard laboratory techniques. A further 50 needleless connectors were activated up to a total of 70 times to simulate clinical practice. After a defined number of activations each needleless connector was inoculated with *S. epidermidis* enriched with 25% (v/v) human blood, decontaminated and flushed with 0.9% (w/v) sterile saline as described above. The number of colony forming units present in each flush solution was determined.

Results

None of the saline solutions flushed through Q-Syte™ needleless connectors which had been activated up to a total of 70 times, contained detectable numbers of microorganisms.

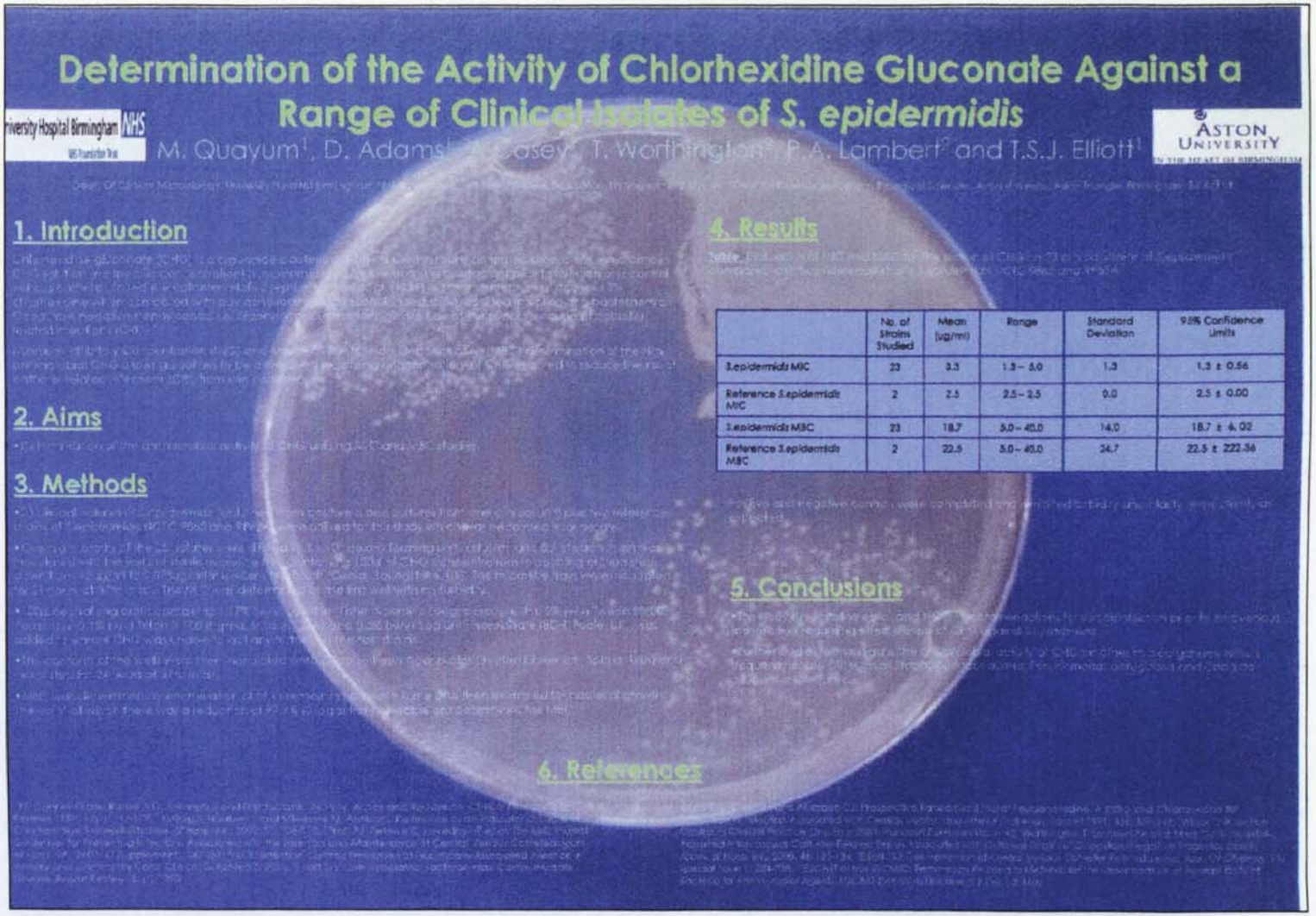
Figure 1: Inoculation of the Q-Syte needleless connector with a suspension of *S. epidermidis* enriched with 25% human blood.

Conclusion

If appropriately disinfected, the Q-Syte™ needleless connector is a needle safe barrier to microbial contamination of flush solutions even following multiple activations. These devices may have the potential for reducing the incidence of catheter contamination, colonisation and sepsis acquired via the intraluminal route.

This work was supported by an educational grant from Becton Dickinson.

4.



	No. of Strains Studied	Mean (ug/ml)	Range	Standard Deviation	95% Confidence Limits
S.epidermidis MIC	23	3.3	1.3 – 5.0	1.3	1.3 ± 0.56
Reference S.epidermidis MIC	2	2.5	2.5 – 2.5	0.0	2.5 ± 0.00
S.epidermidis MBC	23	18.7	5.0 – 40.0	14.0	18.7 ± 6.02
Reference S.epidermidis MBC	2	22.5	5.0 – 40.0	24.7	22.5 ± 222.36

5.

Prospective randomised clinical trial to assess the efficacy of 2% (w/v) chlorhexidine gluconate in 70% (v/v) isopropyl alcohol and 70% (v/v) isopropyl alcohol for the disinfection of skin prior to peripheral venous cannulation

University Hospital Birmingham NHS

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Microbiology Research Group, Department of Clinical Microbiology and Infection Control, University Hospital Birmingham NHS Foundation Trust, The Queen Elizabeth Hospital, Birmingham UK

Introduction

- Intravenous catheters are an integral part of modern medical practice, providing vascular access for the delivery of fluid, drugs and blood products. [1]
- The associated risks in using intravascular devices include microbial colonisation of the device and subsequent bloodstream infection. [2]
- 42% of all hospital acquired bacteraemia are from intravascular device related sources [3]
- An important measure in preventing such infections is the use of an appropriate skin antiseptic for pre and post insertion care. [4]
- The Department of Health and epic guidelines, UK recommend the use of an alcoholic chlorhexidine gluconate solution pre-and post-intravascular catheter insertion [5]
- Similarly, CDC guidelines advocate the use of a 2% (w/v) chlorhexidine based preparation for skin antisepsis pre intravascular catheter insertion and for exit site antisepsis. [6]

Aim of the current study

- To evaluate the microbial colonisation rates of peripheral venous catheters (PVC) tips following skin decontamination with 2% (w/v) chlorhexidine gluconate (CHG) in 70% (v/v) isopropyl alcohol (IPA) (ChloraPrep® Sepp 0.67ml Medi-Flex® incorporated; Kansas, USA.) compared with the conventional 70% (v/v) IPA (Steret® Seton Prabble Ltd, Merseyside UK.)

Methods

Clinical Protocol

- One hundred and seventy patients who required a PVC as part of their clinical management were recruited into the study.
- Each patient was randomly assigned to either 2% (w/v) CHG in 70% IPA or 70% (v/v) IPA for skin disinfection prior to PVC insertion.
- Two percent (w/v) CHG in 70% (v/v) IPA was applied using a back and forth stroke with the applicator over the intended insertion site for 30 seconds Whereas, 70% (v/v) IPA was applied utilizing a circular movement over the intended insertion site for 30 seconds as per hospital protocol.
- The antiseptics were allowed to dry for 30 seconds before a Polyurethane PVC was inserted.
- A semi-permeable dressing was applied (Veca-C TM (BD; Helsingborg Sweden) to secure the PVC and prevent microbial contamination of the insertion site.
- PVC were removed when no longer clinically required and the tips sent for microbiological assessment

Microbiological sampling

- The number of microorganisms, colonising the internal and external surfaces of the PVC tips were determined by a quantitative tip culture method.[7]
- A sterile blade was utilized to remove the PVC tip from the hub of the catheter which was cut to a length of 3 cms.
- The PVC tips were then vortexed in 1 ml of sterile saline for 60 seconds.
- One hundred microlitres of the solution was then inoculated evenly onto the surface of a blood agar plate containing 7% defribinated horse blood (Oxoid Basingstoke, UK).
- The plates were then incubated in air at 37° C for 48 hours. Microorganisms were identified by routine microbiological methods.

Results

- None of the patients in this study showed any clinical signs of infection.
- Table 1 shows the number of PVC tips colonised with microorganisms following the use of 2% (w/v) CHG in 70% (v/v) IPA or 70% (v/v) IPA for skin disinfection prior to PVC insertion.
- Indeed 26 out of 79 (33.1%) PVC tips were colonised with microorganisms in the 70% (v/v) IPA group, whilst only 18 out of 91 (19.8%) PVC tips with microorganisms in the 2% (w/v) CHG in 70% IPA group (P=0.0558).

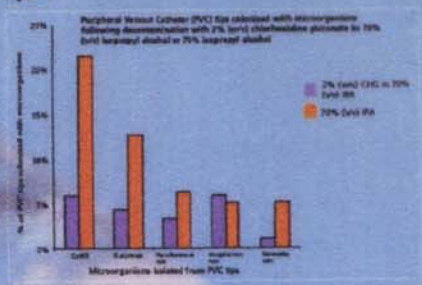
Table 1. A comparison of the number of Peripheral Venous Catheter (PVC) tips recieved against the number of PVC tips colonised with microorganisms

Antiseptic	Number of PVC tips received for microbial analysis	Number of PVC tips colonised with microorganisms
2% (w/v) CHG in 70% (w/v) IPA	91	18 (19.8%)
70% (v/v) IPA	79	26 (33.1%)

P value = 0.0558

- Figure 1 shows that the use of 2% (w/v) CHG in 70% (v/v) IPA led to a reduction in the number of PVC tips colonised with most types of microorganism.
- The number of PVC tips colonised with coagulase-negative staphylococci (CNS) was significantly lower following skin preparation with 2%(w/v) CHG in 70% (v/v) IPA than with 70% (v/v) IPA. Indeed, CNS were isolated from 5 out of 91 (5.5%) PVC tips which was obtained from patients who had received 2% (w/v) CHG in 70% (v/v) IPA. In comparison 17 out of 79 (21.5%) PVC tips in the 70% (v/v) IPA patient group had CNS isolated (P=0.0025).
- Of the PVC which were colonised, there was no significant difference between the mean number of colonies isolated from each PVC tip in the two study groups. Indeed, the average number of colonies yielded from each positive PVC tip was 20.2 in the 2% (w/v) CHG in 70% (v/v) IPA group compared to 5.2 in the 70% (v/v) IPA group (P=0.51).

Figure 1



Conclusion

- 2% (w/v) CHG in 70% (v/v) IPA, resulted in a reduction in the number of PVC tips which were colonised with microorganisms.
- There was a significant reduction in the number of PVC tips colonised with CNS in the 2% (w/v) CHG in 70% IPA group, when compared with the 70% (v/v) IPA group.
- 2% CHG in 70% (v/v) IPA may reduce the risk of catheter-related infection.
- Further studies to confirm the efficacy of 2% (w/v) CHG in 70% (v/v) IPA in the prevention of catheter-related infection are required.

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4. Traore O, Allaert FA, Fournet-Fayard et al Comparison of in-vivo antibacterial activity of two skin disinfection procedures for insertion of peripheral catheters: povidone iodine versus chlorhexidine. Journal of Hospital Infection 2002; 2: 147-150.
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7. Brun-Buisson C, Abrouk F, Legrand P, Huet Y, Larabi S, Rapin M. Diagnosis of central venous catheter related sepsis: Critical level of quantitative tip cultures. Archives of Internal Medicine 1987; 147:873-7.

Acknowledgements

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12.3 Conference Presentations.

1. Safer Needles Network: Needlestick Awareness Week; 2004.
Adams D. SafetyGlide™ Needle Protective Device Trial. *Needlestick Awareness Week.* 2004 (March). Birmingham, United Kingdom.

1.

1.

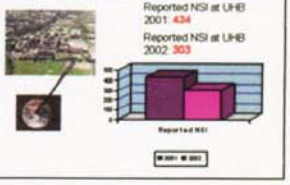
SafetyGlide™
Needle Protective Device Trial

Debra Adams.

2.

3.

NSI; the UHB perspective.



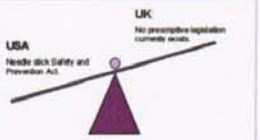
4.

Action Taken from 2001.....

- **Formation of the Inoculation Injury Review Group:** (Infection Control, Occupational Health and Risk Management)
  - Annual audit of reported NSI
  - Educational strategies
  - Fliers with all UHB staff payslips
  - Needle protective devices open day
  - Development of audit tool for safety devices available on Trust intranet site
  - Trial of safety devices (US studies have shown reduction in NSI when used) .

5.

Current NSI preventative legislation: USA v UK.



6.

The Trial; 4 month pilot study of needle protective devices

- **Four clinical areas chosen;** due to their high numbers of reported nsi
- **Education Strategy prior to implementation.**
- **Traditional needle devices removed from all areas** (except 2222 trolleys and for procedures not suitable for devices).
- **Slip lock syringes removed and replaced with Luer lok™ syringes.**

7.

The Needle Protective Devices chosen....

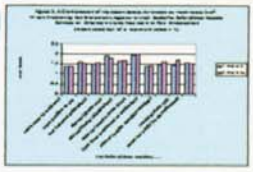
8.

Key Aspects under review....

- **Product Evaluation at 1 and 4 months;**
  - Safety,
  - Usability
  - Compatibility.
- **Effect on reported NSI.**

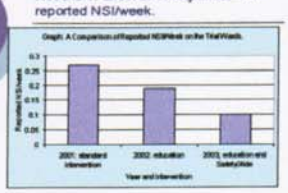
9.

Results; usability at 1 and 4 months
(n=54 at 1 month and 49 at 4 months)



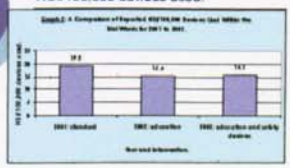
10.

Results 1: effect of SafetyGlide™ on reported NSI/week.



11.

Results 2; effect of SafetyGlide™ on NSI/100,000 devices used.



12.

Investigation following the 2 reported NSI

- **The trial was suspended following the reporting of a high risk nsi whilst using a SafetyGlide™ needle.**
  - The investigation found that the needle protective device was not at fault. However, it did highlight the need for knowledge of Universal precautions whilst carrying out high risk practices.
- **The 2nd nsi was not able to be followed up as the person was not contactable.**

13.

Conclusions and Recommendations 1.....

- **It is essential that healthcare workers are involved in product selection and evaluation of any new devices.**
- **All devices must be assessed regarding their suitability for all procedures.**
- **Needle protective devices should be available for healthcare workers to use if there is a potential risk from a contaminated nsi.**

14.

Conclusions and Recommendations 2.....

- **It must be remembered that new devices are scrutinised more closely than their traditional counterparts and therefore more problems are likely to be highlighted.**
- **NSI are statistically rare events ranging from 1-40 injuries/100,00 devices therefore only large clinical trials using approx 100,000 devices are able to prove significant reduction.**

15.

The Way Forward....

- **An 18 month clinical trial of SafetyGlide™ needle protective devices has commenced in the pilot sites.**