

Safer Sharps Devices

An Evaluation of Utility in NHS Scotland

A Report for the Occupational Health and Safety Strategy Implementation Group, NHS Scotland



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The authors have used their best efforts to ensure the accuracy and reliability of information contained herein. However, no warranties or guarantees are made that the information contained herein is accurate, complete and current at any given time.

The information contained herein is based on evaluations of the devices by clinical staff in addition to bench-top testing of the devices. The information contained herein is therefore based partly on opinion and partly on a subjective interpretation of data. Accordingly, all information contained herein is general information and is not warranted by the authors, Salus Occupational Health and Safety, NHS Lanarkshire or any other health organisation.

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Executive Summary

This study set out to examine the available sharps devices with an engineered safety feature available to the UK market (as at 2002/3). A total of 50 devices were identified in the following categories :

- a) Venous blood collection devices(13)
- b) Needle and syringe devices for injection (9)
- c) Intravenous cannulation devices (8)
- d) Capillary blood sampling devices (8)
- e) Arterial blood gas collection devices(3)
- f) Scalpels (2)
- g) Blunt suture needles (2)
- h) Theatre devices for disposing of sharps (5)

The epidemiology of sharps injuries in the UK and US is reviewed : UK data suggests a much lower reported injury rate than in the US (12.7 needlesticks/100 beds/year compared to 18-26/100 beds/year in US). Needle and syringe devices have traditionally accounted for the highest number of incidents, though the lowest rate of injury by usage. IV cannulae have the highest injury rate by usage. Blood borne virus transmission to healthcare workers appears to be rare in the UK.

Devices were benchtop tested by the investigators and if found acceptable, evaluated by users across a variety of clinical settings and sites. Training by device manufacturers was provided and users were asked to complete and return evaluation forms. Adequate numbers of evaluations were performed for most categories of device, but the needle and syringe device category had poor returns, possibly reflecting a decline in clinical usage for such devices.

The products were generally rated for ease of use, alteration to technique, time to operate, interference with sampling/use, time till staff were comfortable with device use, users evaluation of patient care issues (e.g. pain), device safety, training needs. Users indicated an overall rating and whether they preferred the trial device or their usual device. An overall rating of devices is given in each category.

Hard evidence for injury prevention is lacking for most of the marketed products. All suppliers were approached for evidence their product prevented injuries, but very few provided this. There are some US studies which suggest similar devices are effective in reducing sharps injuries, though relatively few and in some device categories, there is very little or no such published evidence.

The financial implications of purchasing safety devices are considerable : for a sample Trust (Lanarkshire Acute Hospitals – 1541 in patient beds) an estimate of £198 000 per annum is made as the recurrent cost for conversion in all device categories at current prices. A large proportion of this cost (approximately 53%) would be accounted for by cannulation devices. The cost could be reduced by a selective purchasing policy : this could mean opting to replace

all blood collection and lancet devices (which are relatively low cost) whilst stocking a proportion of needle and syringe safety devices only for percutaneous use. Small supplies of IV cannulation safety devices could be held in stock in all clinical areas for use in higher risk clinical situations.

A comparison of costs of injuries is presented, based on data from Lanarkshire, and for comparison, a London NHS Trust. At present the argument for complete conversion to safety device use is probably not supportable if considered only in financial terms. Selective introduction of devices would reduce the cost differential.

A survey of Scottish NHS Trusts and suppliers indicated that safety devices are not widely used. The only categories of device in widespread use are lancets and IV connectors. Safety cannulae and syringes have not gained acceptance to any degree. There is some trend to blood collection devices being used more extensively.

Besides the evaluations of individual products, the following general recommendations are made :

1. On the basis of efficacy and cost, NHS Trusts should consider further widespread introduction of safety devices for the categories of lancets, blood collection devices, needleless IV connection systems and sharps disposal pads.
2. In contrast, for the same reasons, limited stocking of syringe devices should be considered, for the sole purpose of percutaneous use. Replacement of all standard syringes and needles is not necessary since some of these will not be used for a percutaneous procedure.
3. In the category of peripheral intravenous cannulation devices, due to the high cost, we cannot make a positive recommendation that all NHS Trusts convert completely to safety cannulae. However, safety devices should be considered for use in clinical settings with a higher proportion of patients with risk factors for BBV carriage (e.g. Infectious disease units) and for use where patients are known to be carriers of BBV. This would mean most clinical areas having small stocks of these devices available for selective use, but the standard IV cannula would remain the main stock item. It is recommended that Trusts consider this approach.
4. The use of blunt suture needles in operative surgery should be reviewed by surgical directorates with a view to maximising their use for appropriate indications.
5. Scalpels with safety features have limited application, partly due to the availability of blade sizes, but should be considered for use where clinically appropriate

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1: Introduction

Sharps injuries have been identified as one of the most common types of injury incurred by NHS staff with more than 2200 such injuries reported annually in the NHS in Scotland (1).

In 1999 the Occupational Health and Safety Strategy Implementation Group (OHSSIG) launched the “Towards a Safer Healthier Workplace” strategy. Implicit in this was the commitment to ensure a safer working environment for all NHSScotland employees through adoption of best practice, training and improved audit processes. Following on from this in 2000 The Needlestick Injury Short Life working group was established. Their remit was to ‘investigate the prevalence, cause and prevention of such injuries and to make recommendations to minimise risk to staff’. The publication, in 2001, of the Short Life Working Group Report - ‘Needlestick Injuries: Sharpen Your Awareness,’¹ made key recommendations relevant to evaluation of safer devices and disposal methods:-

Recommendation 23 proposed that “Medical Devices Agency, Health Services Advisory Committee, Health and Safety Executive, Chief Scientist Office, Health Trade Unions and professions and UK health departments should be invited to prepare a co-ordinated plan to test and evaluate safer devices and safer disposal methods”.

Recommendation 24 stated that “The Health Technology Board for Scotland with the Medical Devices Agency (MDA) should be asked as a matter of urgency to evaluate the clinical and cost effectiveness of safer devices”.

Recommendation 25 stated that NHSScotland employers introducing safer devices should first test and evaluate devices. And that to avoid duplication employers should cooperate and collaborate with each other.

It has been proposed that one way of reducing needlestick/sharps injuries could be through use of safer devices. These products, which incorporate engineering controls, may, if used correctly, reduce or eliminate the chance of an exposure incident. Generally safer devices employ a blunting, shielding or retracting mechanism to render the sharps safe.

A report from the General Accounting Office on needlestick prevention in the USA² suggested that the use of safer devices could prevent 29% of needlestick injuries. Furthermore, eliminating unnecessary use of needles could prevent 25% of injuries, and using safer working practices could prevent a further 21% of needlestick injuries.

Figure 1.

Should a similar pattern be reflected in the UK this could have a significant impact in reducing the estimated 100 000 sharps injuries incurred by our healthcare staff each year.

Legislative Background

USA

On January 18 2001 US Congress published the Needlestick Safety and Prevention Act (H.R. 5178) directing OSHA to revise the Blood Borne Pathogens Standard. This legislation required that all healthcare facilities select and implement sharps injury prevention devices with incorporated engineering controls wherever possible. (This new Act expanded the definition of "engineering controls" to include devices with engineered sharps injury protection.) This legislation became effective in April 2001 and incorporated the following additional measures:

- Provision of a written exposure control plan that is updated annually to reflect appraisal and use of safety devices.
- Maintenance of a sharps injury log with detailed information on the type and brand of device, the department or work areas where the incident occurred, and an explanation of how the incident occurred.
- Involvement of frontline workers in the selection, evaluation and implementation of safety devices.

UK

There is no specific legislation mandating the use of 'safer devices' in the UK. However employers have duties under the Health And Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999(MHSWR) and Control of Substances Hazardous to Health Regulations (1999/2002)(COSHH) to ensure a safe(r) working environment and safe working practices through risk assessment and training.

Under the **Health And Safety at Work Act 1974** (HSWA) employers have an duty to ensure, so far as is reasonably practicable, the health, safety and welfare at work of not only their employees but anyone else who may be affected by their business activities.

The HSWA Act 1974 is an enabling Act, from which subordinate legislation has been developed such as the Management of Health and Safety at Work Regulations 1999 (MHSWR) and Control of Substances Hazardous to Health Regulations (2002)(COSHH).

Under the **Management of Health and Safety at Work Regulations 1999** (MHSWR) employers must carry out a risk assessment and have in place preventative and protective measures. Furthermore they must also provide their employees with adequate health and safety training.

Under both the Health And Safety at Work Act, and Management of Health and Safety at Work Regulations, employers have a duty to ensure employees are appropriately trained and are competent in the procedures necessary for working safely. Equally employees have a responsibility to comply with the systems and procedures put in place by their employers to ensure their health, safety, and welfare.

The key duty under COSHH 2002, in relation to biological hazards, is to prevent exposure. These regulations are intended to protect employees (and others) from recognised hazards, and to protect those at risk of exposure through work activities. These would include microbiological hazards such as may be incurred by needlestick injuries. Complying with COSHH requires assessment of the risk of infection for employees (and others) affected by work practices. Where this risk is known suitable precautionary measures must be taken to

protect health. Work must not be carried out which could expose employees to hazardous substances without first considering the risks and the necessary precautions. If there is no risk to health or the risk is trivial, no more action is needed. If there are health risks, then employers must take steps 'calculated' to reduce or control the risk. These steps would include:

- Designing safer working procedures, or introducing engineering controls to prevent or minimise infection,
- Instituting means for the safer collection, storage and disposal of contaminated materials.
- Specifying procedures for taking, handling and processing samples that may contain biological agents.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

(RIDDOR) require employers and others to report accidents and some diseases that arise out of, or in connection with work. These reports enable the enforcing authorities (generally the Health and Safety Executive) to identify where and how risks arise and to investigate serious accidents. Reportable diseases include any other infection reliably attributable to work with biological agents; exposure to blood or body fluids or any potentially infective material. Sharps injuries where the source patient or contact is known to be positive for a blood borne virus e.g. HIV, hepatitis B, hepatitis C, are reportable under RIDDOR. Additional reportable occurrences would include sharps injuries resulting in absence from work for more than three working days.

Safer Device Use in NHS Scotland

With increasing numbers of safer devices now available to the UK healthcare market NHS employers may need guidance for the selection and implementation of these products. Although all are promoted as enhancing staff safety they should be evaluated to ensure that:

- the safety feature works effectively and reliably,
- the device is acceptable to the healthcare worker,
- the device does not adversely effect patient care.

A number of informal evaluations of these products have taken place in Scottish NHS Trusts, but few, if any, reports have been published and the number of safer devices accepted and currently in routine use in the NHSiS is not known.

One reason for the slow uptake and use of these devices could be related to their cost. The financial investment to design, patent, manufacture, and bring to the marketplace safer devices must be recouped; it is no surprise to find that they are, predominantly, more expensive their conventional counterparts.

A further obstacle to widespread use could be the lack of efficacy figures.

There is an assumption that the use of these devices will result in a reduction in needlestick injury. However for many of the devices on the market there is little or no convincing evidence to show a reduction in exposure incidents.

Study Aims

In accordance with the recommendations of the Short Life Working Group the primary aim of this study was to conduct a multi-site user led evaluation on the utility of currently available UK safer devices. Secondly, to perform a financial analysis of the likely costs incurred through their introduction, and to highlight any possible savings through exposure incidents prevented. A further aim was to survey the extent of safer device uptake and use in the NHSiS.

Measures of Efficacy

This study did not set out to determine the effectiveness of safer devices in reducing needlestick injuries. It would not be possible to establish a clear outcome in terms of injury prevention given that multiple devices were evaluated over a short period of time, however supplementary data on sharps injuries was recorded.

2. The Epidemiology of Sharps Injuries and Blood Borne Virus Transmission

Blood Borne Virus Transmission

The most serious consequence of an occupational percutaneous exposure to blood or body fluids is the possibility of transmission of a blood borne pathogen, in particular hepatitis B virus (HBV), hepatitis C virus (HCV) and Human Immuno-deficiency Virus (HIV). Other pathogens have been shown to be transmitted in this manner (Table 1).

In a healthcare setting most blood borne viral transmissions occur as a result of percutaneous sharps exposure to patients blood or body fluids, but cases of conjunctival hepatitis c and HIV viral transmission through exposure to infected blood or body fluids have been documented ³.

Risk of viral transmission

Estimates of risk of viral transmission vary ^{4,5}. Estimates of the risk of viral transmission from infected source patient to a healthcare worker (HCW) are as shown in Table 2.

Table 2. Range of estimates for Risk of viral transmission

BBV	Risk of transmission
Hepatitis B	6%-30%*
Hepatitis C	0.4%-1.8%
HIV	0.25%-0.4%

*Where source patient is HBe antigen positive.

In Italy a multi-centre prospective study on the risk of transference of blood borne virus to healthcare worker following occupational exposure was undertaken between 1994 and June 1998 ⁶. Of the 19,860 occupational exposures recorded 75% were attributable to percutaneous injury.

- No seroconversions to hepatitis B were recorded in 1,155 exposures to HBsAg positive sources. (158 exposures involved susceptible healthcare workers, 117 of whom received active and passive immunoprophylaxis after exposure).
- Healthcare workers exposed to hepatitis C through blood filled hollow bore needles had a seroconversion rate of 0.85%.
- Those exposed to HIV by blood filled hollow bore needle resulted in a seroconversion rate of 0.21%. One healthcare worker seroconverted after conjunctival exposure to infected blood.

Cardo et al ⁷ identified factors associated with increased risk of HIV infection as shown below:

Table 3. Percutaneous injury characteristics associated with HIV transmission

Injury Characteristic	Odds Ratio	95% CI
Depth of injury	15	6.0-41
Procedure with needle placed in source vein or artery	4.3	1.7-12
'Sharp' visibly contaminated with source patient's blood	6.2	2.2-21
Exposure to a source patient who died of AIDS within 2 months afterward	5.6	2.0-16

Other likely risk factors include:

- Viral load of some patients.
- Glove use (50% decrease in volume of blood transmitted) ⁸
- Bore of needle (Hollow bore needle v solid Bore. Large bore of needle weakly associated with increased risk) ⁷
- Drying conditions (tenfold drop in infectivity every 9 hours) ⁹

The presence or absence of key risk factors may influence the risk of transmission in individual exposures.

UK Surveillance Data

1984 saw the first reported occupational transmission of HIV from patient to healthcare worker ¹⁰. In response to this a passive surveillance system was introduced to monitor occupational exposure rates to HIV and other bloodborne viruses in the UK.

The Communicable Disease Surveillance Centre (CDSC) launched an enhanced level of occupational bloodborne virus exposure surveillance in 1997. Data relating to occupational exposures to blood borne viruses was collected from over 200 occupational health and Genito- Urinary Medicine clinics in England, Wales and Northern Ireland.

Over a 5-year period 1550 reports on occupational exposures to one or more blood borne virus were received by the CDSC. Approximately one third of healthcare workers, regardless of source status, were prescribed Post Exposure Prophylaxis (PEP) ¹¹.

Hepatitis C represented 49% of all reports, HIV accounted for 30% and 8% received PEP with unknown source. Follow-up was undertaken at six months for exposure to HIV and hepatitis C with reports sent to CDSC. The reported data for the 5-year surveillance period identified seroconversions in 4 healthcare professionals. One healthcare worker seroconverted to HIV, despite triple PEP. There were three documented seroconversions to hepatitis C. From this data can deduce a crude seroconversion rate for hepatitis C of 0.39% and 0.21% for HIV.

The Scottish Centre for Infection and Environmental Health (SCIEH) has a similar surveillance arrangement to monitor occupational exposure of health care workers to HIV and other blood borne viruses. To date there have been no occupational seroconversions recorded by the surveillance system ¹².

SCIEH surveillance data to June 2002 indicated that 1 in 390 of Scotland's populace was antibody positive for hepatitis C ¹³, and that the cumulative total of HIV positive cases was, up to June 2003, 3722 ¹⁴. With current population at 5,062,011 (census data 2001) this equates to a prevalence of 1:1428 (0.07%). Figures for the UK as a whole revealed 57763 cases of HIV infection and 19656 AIDS cases (June 2003).

Extrapolating from known data in Scotland, the risk of transmission can be calculated where the lifestyle risk factor only is known, but the BBV status of the source is not.

Table 4. Estimated risk of BBV transmission following percutaneous injury where risk factor only is known. (Scottish data)

BBV/ Risk Factor	Prevalence	Generic Transmission Rate	Risk of Transmission
HIV			
Injecting Drug Use	1%	0.3%	0.003% (1:33000)
Male:Male Sex	3.5% *	0.3%	0.011% (1:9000)
No known risk factors #	0.03%	0.3%	0.00009% (1 in 1 111 111)
Hepatitis C			
Injecting Drug Use	32%*	1.8%	0.57% (1 in 175)
Scottish Population (14390*)	0.26%	1.8%	0.0047% (1:21 276)

*Derived from SCIEH data and census data for Scotland.

data from anonymised antenatal testing.

Overall the absolute risk of BBV transmission from a patient with no known factors is extremely low. In contrast, the risk of HIV and HCV transmission is significant from sources with risk factors.

Data from the Health Protection Agency revealed that there have been five documented occupational HIV seroconversions and 12 possible/probable occupational HIV seroconversions in the United Kingdom ¹⁵.

Post Exposure Prophylaxis (PEP)

The timely use of appropriate immunization or PEP can influence the likelihood of seroconversion following injury.

Hepatitis B

Hepatitis B poses a risk to healthcare workers who are not immune to hepatitis B. A vaccine is available but 4-8% may mount an insufficient antibody response. Susceptible staff exposed to HBV may be given post exposure prophylaxis with hepatitis B Immunoglobulin and initiation of hepatitis B vaccine. This is more than 90% effective in preventing infection

Hepatitis C

At present there is no vaccine or post exposure prophylaxis regimen for Hepatitis C.

HIV

There is no vaccine for HIV. Current PEP guidance recommends a triple therapy regimen. Absolute efficacy is unknown, and there is not direct evidence to show that 2 or 3 drug PEP is more effective than 1 drug. Cases of seroconversion despite 3-drug PEP imply efficacy less than 100%. Post Exposure Prophylaxis (PEP) should ideally be administered within one hour of the exposure incident. Analysis of HIV PEP failures does not however, suggest a clear time limit over which PEP should not be administered.

The Incidence of Sharps Injuries

The generally accepted and often quoted figure on needlestick injuries sustained by UK healthcare workers is estimated at around 100,000 needlestick injuries per year ¹⁶. The true incidence of such injuries is difficult to ascertain with some authors estimating underreporting between 29- 61% ¹⁷.

A survey of percutaneous/mucocutaneous exposures identified the following reasons for not reporting sharps injuries. ¹⁸:

- Sterile or clean stick.
- Subjective evaluation of patients for potential risks.
- Too busy.
- Dissatisfaction with follow-up.

At present there is no national co-ordinated surveillance data on needlestick exposure. Generally the information that is recorded and analysed at local level is insufficient to provide powerful argument to instigate change.

The Occupational Health and Safety Strategy Implementation Group (OHSSIG) has recognised the need for a minimum dataset to monitor the occupational health and safety performance of the NHSScotland. Crucial to this will be the collection of needlestick injury data that will be undertaken at local and national level. All NHSScotland organisations are requested to record the number, rate and occupational group of needlestick and sharps injuries. Needlestick injury data for the period April 2000 to 2001 was collected retrospectively and the report for this cohort of data will be published toward the end of 2003.

Voluntary surveillance programs such as Exposure Prevention Information Network software (EPINet)¹⁹ and National Surveillance system for Healthcare Workers (NaSH) can be used in the collection on epidemiological data on sharps injuries.

The 'Be Sharp, Be Safe' campaign, launched by the Royal College of Nursing in 2000, sought to reduce the occurrence of sharps injury through education, research, and surveillance, while concurrently piloting the EPINet programme.

Needlestick exposure data from the first year of the campaign (July 2000 to June 2001) was collected from 14 hospitals in England, Scotland and Wales. The following year, the number of participating hospitals rose to 19. A needlestick Incidence of **12.74/100beds/year** was estimated from 1445 exposure incidents²⁰.

Quality improvement programmes aimed at reducing sharps injury at Glasgow Royal Infirmary indicate needlestick incidence of:

- 8.8 NSI/100 beds/year²¹

Data submitted to Scottish Executive minimum dataset for Lanarkshire Acute Trust²² shows a needlestick incidence of:

- 7.9 NSI/100 beds/year.

Table 5 (overleaf) compares US and UK Epinet data.

Table 5. EPINet data from the RCN ‘Be Sharp Be Safe’ Campaign, and US EPINet data from 1999 and 2001. ^{23,24}

Category	UK EPINet 2002	US EPINet 1999	US EPINet 2001
Number of Incidents (No. of facilities)	1445 (19)	2025 (21)	1929 (58)
Job Description			
Nurse	41.2%	40%	43.6%
Nursing Student	3.4%	1%	0.6%
SHO/HO – MD (intern/resident/fellow)	14.5%	14%	6.6%
Consultant –MD	8.9%	8%	8.1%
Phlebotomist	3.1%	4%	5.9%
Where Injury Occurred			
Patient Room/Ward	40.5%	30%	31.5%
Operating Theatre	20.6%	25%	28.8%
Treatment Room	10.1%	6%	4%
A&E (emergency Room)	6.5%	7%	9.4%
Outpatient clinic	3.1%	6%	4.8%
Labour room	2%	2%	2%
ICU	2.5%	8%	4.8%
Service Utility Areas	4.1%	2%	1.5%
Source Patient Identifiable (Yes)	82.2%	90%	90.7%
Injured worker was original user of sharp	56.4%	62%	57.3%
Sharp identified as contaminated	80.5%	87%	90.3%
Original Purpose of Sharp Item			
Injection (IM/SC)	23.2%	16%	20.9%
Withdraw Venous Blood	11.9%	16%	15.8%
Suturing	10.2%	17%	17.3%
Cannulate IV	7.5%	-	-
Fingerstick/Heelstick	4.3%	2%	2.3%
Withdraw Arterial Blood	2%	3%	2.2%
Device Type Causing Injury			
Disposable syringe	25.7%	26%	36.1%
Suture Needle	8.8%	16%	17%
Winged Steel Needle	6%	9%	6.7%
Needle/holder blood collection	6.9%	4%	4%
IV catheter (stylet)	6.3%	5%	3.6%
Lancet	2.9%	2%	2.2%
Scalpel disposable	4.1%	5%	2.7%

US EPINet data for 1999 and 2001 show the following Percutaneous Injury (PI) rates:

1999	40 Injuries/100 beds	Teaching Hospital
	34 Injuries/100 beds	Non-Teaching Hospital
2001	26 Injuries/100 beds	Teaching Hospital
	18 Injuries/100 beds	Non-Teaching Hospital

The decrease in PI rates is possibly attributable to:

- The increase in use of safer devices (especially since OSHA revised the directive for BBP standard in November 1999).
- Increased training in the proper use of safer devices.
- Substantial reduction in needles used to access intravenous lines.

The authors caution that better education and awareness about risk associated with sharps may reduce the incidence of underreporting and may as a consequence increase the number of incidents reported.

Device specific injury rates

EPINet data deals with absolute numbers, for example syringes are reported as the device responsible for the greatest number of injury. But, EPINet data does not reveal the amount of devices used per facility; hence device specific injury rates cannot be calculated.

In a longitudinal study by Ippolito et al ²⁵ investigators sought to identify medical devices causing needlestick injuries (NSI) among Italian healthcare workers, and the device specific injury rates per 100,000 devices used /year.

Their data showed that syringes/hypodermic syringes accounted for the highest number of injuries (59.3%) followed by winged steel needles (33.1%). IV stylets accounted for 5.4% of injuries. However analysis of injury rates revealed that syringes accounted for the lowest rate of NSI with an incidence rate of 3.8/100,000 devices used, and IV catheter stylets accounted for the highest needlestick injury rate with 15.7/100,000 devices used.

These injury rates reflect similar findings by Jagger et al ²⁶. In a review of 326 percutaneous injuries, syringes were identified as the product causing the highest number of needlestick injuries (35%); IV stylets responsible for 2%. However when corrected for the number of needlestick per device type purchased disposable syringes had the lowest rate of needlestick with 6.9 per 100,000 syringes purchased whereas IV catheter stylets accounted for 18.4 per 100,000 items purchased.

Similarly the EPINet data reports that the absolute number of sharps injuries is reportedly higher in nursing staff although proportionally the rate may be higher in physicians.

Figures from the DOH ²⁷ shows that nursing staff (including qualified nursing, midwifery and health visiting staff) account for approximately 56% of the professionally qualified and clinical staff, whereas medical and dental staff account for approximately 13%. Proportionally, the number of injuries sustained by medical staff is higher than that of nursing staff given their representation in the workforce ²⁸.

Further data summarised from prospective studies of sharps injuries reported a rate of 1.8 sharps injuries per year for physicians and 0.98 for nurses working on the same medical wards ²⁹.

Recent Scottish Data

Recently published data on needlestick injuries within NHSiS ⁶⁰ reported that, in contrast to other studies, the procedure associated with the highest number of needlesticks was venepuncture (19%) rather than injection (14%). This study also estimated that 14% of incidents would “definitely” have been prevented by the use of safety devices and a further 41% would “probably” have been prevented.

In summary,

- **The incidence of reported sharps injuries in the UK is considerably less than in the US, but this data may be confounded by underreporting.**
- **Needle and syringe devices traditionally account for the highest number of incidents but have the lowest rate of injury by usage (however see latest Scottish report indicating venepuncture may have overtaken percutaneous injection as the leading procedure associated with injury).**
- **IV cannulae have the highest injury rate by usage.**
- **BBV transmission to healthcare workers is rare in the UK.**
- **Due to mass immunisation against hepatitis B amongst healthcare workers the greatest absolute risk of infection from injuries is from hepatitis C, particularly from an injecting drug users source.**

Section 3. Methods : Identification of Safety Devices and Evaluation

Safer needle devices are products with incorporated engineering controls intended to reduce the risk of needlestick exposure. Only devices with a CE mark, which have been passed safe and fit for purpose when used in accordance with their instructions for use, can be used in the UK.

There are two categories of safer device:

1. Needleless system, such as intravenous connectors.
2. Sharps with engineered sharps injury protection.

The products evaluated within this study are those that incorporate engineered sharps protection.

Safer devices may reduce or eliminate the chance of an exposure incident, devices requiring no additional action to trigger the safety mechanism (i.e. Passive Devices) are preferable, as the safety mechanism is triggered automatically through ‘normal ‘ use of the device. Active devices require manual deployment of the safety mechanism and there is a risk that the user could omit this action.

The US Federal Drug Administration has listed desirable design features for needle using devices.

Identification of UK available ‘Safer Devices’ and Selection of devices to evaluate

A database of devices with safety-engineered controls was constructed from Internet and literature searches. Devices considered for inclusion in the trial had to CE marked and available for sale to the UK healthcare market. Sources included the **ECRI Sharps Safety and Needlestick Prevention report**³⁰ and the National Alliance for the Primary Prevention of Sharps Injuries website (www.nappsi.org).

UK sources included:

- The Safer Needles Network champion issues relating to Needlestick Injuries, and the introduction of safer devices in the UK. Their website provides a list of UK available safer devices. <http://www.needlestickforum.net>
- NHS Purchasing and Supply Agency website devotes a section to Needlestick Injury research and provides a comprehensive list of safety devices. <http://www.pasa.doh.gov.uk>

Additionally, all companies that market and manufacture conventional devices in the UK were contacted to find out if they manufactured a safety device.

Bench-top Testing

Samples of all UK available safer devices were examined for their suitability for inclusion in the evaluation exercise. Devices were examined for reliability of safety feature to ensure the safety mechanism worked reliably and the needle could not be exposed once the safety mechanism activated.

Evaluation Form Design

The most important factors in selecting 'safer devices' are healthcare worker safety and patient care. However there are other criteria to consider when ensuring selection of the most appropriate device, these include, Ease of Use, Training, Compatibility, and Availability.

The Training for Development of Innovative Control Technologies Project (TDICT)³¹ are a collaboration of healthcare workers, product designers and industrial hygienists working together to prevent exposure to blood and body fluids through better design and evaluation of medical devices and equipment. This group have a standard safety feature evaluation forms for over 20 different types of safety devices. These forms include devices used for venous blood collection, intravenous cannulation, percutaneous injection and arterial blood sampling.

We opted not to use the TDICT evaluation forms but have devised our own for each category of device to capture the issues relating to the utility, safety and functionality of each generic product as outlined below.

Additionally each form type included questions specific to each category of product.

Features relating to Compatibility and Availability were determined from product literature and information from device representatives.

Comparative Evaluation Form

At the conclusion of the product evaluations staff were asked to compare the devices they had used. Each category of device had a unique comparative form and participants were asked to indicate which devices performed best relating to category specific issues. Staff were also asked to rate all devices used in order of preference.

Selection and Recruitment Process

From the outset it was proposed that each participating Trust would be allocated a generic group of devices to evaluate as outlined in table 6.

Table 6. Allocation of Device Types to Participating Trusts

Trust	Device Category
Fife Acute Hospitals Trust/Fife Primary Care Trust	Needle and Syringe
Lanarkshire Acute Hospitals Trust	Intravenous cannulae
Lothian University Hospitals Trust	Combination of Products
North Glasgow Hospitals University NHS Trust	Blood Collection devices
South Glasgow Hospitals University NHS Trust	Needle and Syringe
Tayside University Hospitals Trust and Primary Care	Blood Collection devices

In recognition that the functionality of safer devices may not be suitable across all clinical areas and that the needs of the user may differ, it was proposed that a variety of clinical areas and staff grades be represented.

Meetings were held with Health and Safety staff, Infection Control Nurses, Medical Directors, and Clinical Nurse Managers to identify suitable clinical areas and staff to approach. At this time the safer devices were demonstrated in order to establish if they met the clinician's needs. Staff were not allowed to choose individual devices to evaluate, they could of course opt not to use devices they felt unsuitable for their practice.

To ensure robust product evaluations an arbitrary target was set to achieve 500 usages per device. To achieve this 50 staff were recruited per device on the proviso that each performed a minimum of 10 activations of the safety device.

Recruitment Criteria

Staff considered for recruitment had to fit the following criteria:

- They should expect to achieve a minimum of 10 activations of the safety device during the evaluation period.
- They should perform this procedure as part of their routine duties

It was thought that an evaluation period of 2 weeks would be sufficient to allow the participants a comprehensive usage of the safer device. This period would allow for variations in workload due to shift patterns and time off. There was an assumption that recruited staff would perform all procedures related to the use of the safer device and that non-participating staff would not perform such procedures.

Training

Device suppliers were approached to ensure all participants received training in the safe and correct use of the safety device. The training representatives were provided with a list of recruited staff to ensure all received training. Where available supporting product literature was made available to staff for reference. In units where training was problematic due to staff shifts and work commitments proxy staff demonstrated the devices to their colleagues.

Where companies could not provide training, and where clinical staff agreed, the research assistant undertook demonstration on the correct use of the safety feature.

Stock

Areas anticipating high usage of the safety product were given approximately 50 devices per recruited staff member. Those predicting a lower rate of use were given on average 25 devices but had the option of requesting more if needed.

Participants were provided with appropriate needle and cannulae gauges corresponding to those routinely used. At the end of each product evaluation period the remaining trial stock was removed from use and new stock delivered.

One great restriction, due to the small number of staff recruited per area, was that we were unable to clear each participating unit of their conventional stock. Consequently we could not ensure that staff used trial devices exclusively.

Safety

Staff were advised that they should not continue with the 'safety device' if they felt it put them at risk of sharps injury, or if they felt it was detrimental to patient care. Participants were advised to record the reasons for discontinuation in the comments section of the evaluation form.

Field Evaluation

Devices were evaluated sequentially with staff completing one evaluation form for each brand evaluated (generally no more than 4 devices in a generic category). Participants were encouraged to use as many of the trial devices as was reasonably practicable, where usage was slow the study period was extended until the minimum of 10 activations was reached. Following evaluation of the final product staff were asked to compare each device used, grade them and indicate which they would prefer to use. Samples of the trial devices (and or literature) were provided along with the comparison forms as a reminder of all devices evaluated.

Section 4. Results of Evaluations

4.1 Capillary Blood Sampling

Conventional Capillary Blood Sampling

In adults routine capillary blood sampling is obtained by pinprick of thumb or fingers using a lancet or lancing device. These lancets use a solid needle tip to create a subcutaneous wound for blood sampling. The lancet unit consists of a small plastic casing with a protruding solid needle tip that is uncovered just prior to use. Following use the sharp point is left exposed and should be immediately disposed of in a 'sharps container' in accordance with local protocol.

Some conventional lancets can be used manually as a single unit, or inserted into an automatic lancing device. These lancing devices allow a standardized pressure of 'jab' thus reducing user variation (and consequently reducing pain /trauma).

These devices, with changeable lancet needles, can be used on many patients but may pose a risk of cross infection if the platform is not cleaned properly between uses. Three outbreaks of hepatitis B have been associated with the use of multi-use spring loaded lancing device. Failure in changing platform and lancet needles between patients was cited as the cause of infection³².

Injury Incidence Data:

UK data on sharps injuries recorded by EPINet data collection software, (Jan 2002-Dec 2002) revealed that 4.3% of the reported 1445 sharps injuries occurred through using devices intended for fingerstick/heelstick sampling (Year 1 data showed 4% incidence).³³

Safer systems for Fingerstick/Heelstick Sampling:

Eight safer lancets were identified through Internet and literature searches.

Table 7. Outlines the lancet device, method of sampling and unit costs.

Manufacturer	Device	Lance Type	Unit Cost
Becton Dickinson	Genie	Needle	9.7p
Greiner Bio-one	Medlance Lancet	Needle	13p
Tyco	Monolettor	Needle	23p
Owen Mumford	Unistick 2	Needle	7.8p
Becton Dickinson	Quikheel	Blade	-
International Technidyne Corp.	Tenderfoot	Blade	-
International Technidyne Corp.	Tenderlett	Blade	-
HaeMedic	Haemolance	Needle	-

All of the devices were examined to ascertain their suitability for inclusion in the trial.

The HaeMedic lancet could be re-used by depressing the activation button, therefore it was not included in the evaluation exercise. An improved version of this lancet, the Haemolance Plus, has now been released to the market incorporating a mechanism preventing lancet reuse.

Although all of the bladed lancets were found to be acceptable for inclusion in the trial none of the clinical areas approached within our Partner Trust indicated routine use of a lancet blade for fingerstick/heelstick blood samples. Therefore only needle tipped lancets were considered for evaluation. The devices included for evaluation were: Genie (Becton Dickinson), Medlance (Greiner Bio-One), Monolettor (Tyco Healthcare), and Unistick 2 (Owen Mumford).

Images of the 4 lancets used in the evaluation exercise shown before and after activation.

All lancets, except the Monolettor, are available in a range of penetration depths and are identified by a colour coding system. At the time of the evaluation exercise the Monolettor lancet was only available in a penetration depth of 2.4mm.

The safer lancets all utilise a similar design theme.

- A removable cap, to prevent pre-use injury, covers the lancet tip.
- The lancet needle or blade and safety mechanism are enclosed in a plastic casing.
- An external activation button releases the lancet for sampling.
- The lancet tip is automatically and permanently retracted immediately after use.

These devices all share similar mechanism of operation requiring removal of protective cover and depression of activation button to trigger lancet penetration. The protective mechanism ensures a single shot and automatic retraction of lancet-tip into casing. This mechanism prevents reuse and the lancet is disposed of as a single unit.

One device (Unistick range) requires an additional step of setting the firing mechanism. This is achieved by pushing the cap up into the casing to set the spring.

The advantages of using a safer lancet include:

- Lancet sharp covered before and after activation.
- Automatic needle or blade retraction into casing.
- Mechanism that prevents reuse.

Efficacy:

Literature searches were undertaken to ascertain the effectiveness of these devices in reducing sharps exposure. Additionally, lancet suppliers were approached and requested to provide evidence or publications indicating device efficacy.

Owen Mumford provided a publication (letter)³⁴ indicating a 16% reduction of needlestick injury with the use of Unistick 2 lancet. In 1992 Queen Mary's University Hospital, London established a sharps audit programme, the results showed that for the period of part of 1992 and the whole of 1993 lancets accounted for 16% of reported sharps injuries. Following introduction of the Unistick 2 lancet in 1995 this figure dropped to 2% and in 1996 there were no reported lancet injuries.

Recruitment Phase

In 2001 the North Glasgow University Hospitals NHS Trust Health and Safety department, concerned about risks inherent in using conventional lancet devices, mounted an evaluation of safer alternatives. Following a formal evaluation and economic investigation the Trust introduced the Unistick 2 lancet. It is highly probable that clinical areas and staff that would have been approached to participate in this evaluation study would have already contributed to the Health and Safety department study. Therefore alternative areas within our Partner Trusts were considered for recruitment.

During the recruitment phase areas were targeted where staff routinely perform a high number of capillary blood samples.

Participants were recruited from 9 departments within the following 5 areas:

- Diabetic outpatient departments. (Monklands Hospital, Edinburgh Royal Infirmary)
- Diabetic wards. (Wishaw General Hospital, Monklands Hospital)
- Anticoagulation clinics (Monklands Hospital, Hairmyres Hospital)
- General Medical ward. (Monklands Hospital)
- Emergency Receiving Unit. (Monklands Hospital)
- Renal Unit (Monklands Hospital)

Senior staff were shown samples of the trial devices to determine if products matched their clinical requirements. Each of the 9 areas recruited agreed to use all 4 lancets.

Evaluation

Although the devices are described in the product literature as easy to use, company representatives were approached to provide training on the safe and correct use of their lancet prior to staff using the product. The devices were evaluated sequentially with an evaluation period of around 2 weeks per device. The anti-coagulation clinic at Hairmyres Hospital reported taking on average 45 samples per clinic; their evaluation period ran to 3 days per device type. Participants were requested to complete one Device Utility Evaluation form per product type used, plus a comparison form at the conclusion of the evaluation exercise.

RESULTS

A total of 80 staff were recruited to evaluate this group of lancet devices (see Figure 2).

Figure 2. Distribution of nursing staff recruited.

Unfortunately compliance was low in some areas : one unit, where 30 staff were recruited did not return a single evaluation form. Staff were requested to attain high usage of these products during the evaluation period. Figure 3 shows the extent of individual device use since training. Figure 4 indicates user assessment of the level of training required to ensure safe and effective use of the lancet.

Lancet Devices : Evaluation results analysis

Ease of Use :Participants were asked to grade each device with regards to overall ease of use.

Table 8. Ease of Use:lancet devices

Device (Number of users)	Genie (35)	Medlance (28)	Monolettor (28)	Unistick 2 (34)
Staff comfortable using device with <5 uses	72.2%	52.2%	56.5%	79.4%
Needle cap removal graded as easy	100%	81.5%	84%	97%
Trigger activation rated easy	57.1%	51.9%	56%	72.2%
Lancet use requires additional dexterity	18.2%	40.7%	37.5%	27.3%

Although the lancets all utilise a similar design theme in terms of having an internal mechanism to permanently retract needle after penetration all employ different ways to ‘trigger’ activation. It is therefore reasonable to expect that the user may find some easier to operate than others. 72.2% of Unistick 2 users rated the operation of the trigger mechanism as easy, followed by 57.1% Genie, 56% Monolettor, and 51.9% of Medlance users rating the trigger button as easy to activate.

Staff were asked to indicate their approximate number of uses with the lancet before feeling comfortable with it. When using the Unistick 2 lancet 79.4% of participants indicated feeling comfortable using the lancet in 5 or less usages. Similarly, 72.2% of Genie lancet users reported feeling comfortable with the device in 5 or less uses. Those using the Monolettor and Medlance lancets, 56.5% and 52.2% respectively, reported being comfortable using the device with 5 or less uses. The Monolettor lancet had the highest levels of users reporting that they never felt comfortable using the device.

Only 18.2% of Genie and 27.3% of Unistick 2 users indicated that using this devices required additional dexterity, this increased to 37.5% for Monolettor users and 40.7% with staff using the Medlance lancet.

Patient Care

Table 9. Patient care issues: lancet devices

Device(users)	Genie (35)	Medlance (28)	Monolettor (28)	Unistick 2 (34)
Amount of Blood obtained				
Too Much	8.6%	25.9%	28%	8.8%
Adequate	88.6%	70.4%	72%	85.3%
Too Little	2.9%	3.7%	0	5.9%
Staff Perception of Pain				
More Pain	20%	29.6%	28%	27.3%
No Difference	71.4%	70.4%	60%	51.5%
Less Pain	8.6%	0	12%	21.2%

The amount of blood obtained for sampling and levels of pain experienced were identified as the most important issues relating to patient care.

Staff were asked if, in their opinion, patients were subjected to more pain through the use of a safer lancet. Although a subjective measurement, this was included as the study design did not allow for the collection of patient data. The majority of users felt that the use of a safety lancet was equivalent to their conventional lancet in terms of pain caused; 71.4% of Genie and 70.4% of Medlance users felt these devices were similar to conventional lancets in terms of pain experienced by patients. 60% of Monolettor and 51.5% of Unistick 2 users indicated likewise.

Some staff reported that the use of these devices caused less pain to the patient with 8.6% of Genie and 12% of Monolettor users indicating the use of these lancets caused less pain to the patient. Over 21% of Unistick 2 users indicated that the use of this lancet caused less pain when subjectively comparing it with their conventional lancet.

The amount of blood obtained for testing should be sufficient for clinical requirements; subjecting patients to additional punctures to obtain adequate blood would be unsatisfactory especially if the conventional lancet systems provided adequate blood amounts.

88.6% of staff evaluating the Genie lancet indicated sample amount as adequate, with Unistick 2 (85.3%), Monolettor (72%), and Medlance (70.4%) reporting blood yield as adequate (Table 9). Of Monolettor users 28% indicated that the amount of blood sampled was too much. However, it is worth noting that only 1 depth of needle was available for use in the evaluation (2.4mm depth).

Staff Safety

Table 10. Staff safety issues: lancet devices

Device(users)	Genie (35)	Medlance (28)	Monolettor (28)	Unistick 2 (34)
Obvious Activation of safety feature	97.1%	88.5%	91.3%	87.5%
Felt at risk of needle exposure after activation	0	3.8%	12.5%	12.1%
Preferring to use trial lancet	48.6%	37%	17.4%	54.5%
Confident device could reduce needlestick injury rate	91.4%	92.6%	88%	97.1%

The presence of a needle tip cover and automatic retracting mechanism should in theory eliminate the risk of needlestick exposure. It is reassuring to note that none of the users recruited to this group reported sustaining a needlestick injury from any of the safer lancets used.

User confidence with these devices is high with over 90% of users of Unistick, Medlance and Genie, and 88% of Monolettor lancets indicating confidence that these lancets would help reduce the risk of needlestick injury.

When given the choice between using a safer lancet or the conventional lancet only 17.4% of Monolettor users chose to use the safety lancet. However over 50 % of the Unistick users indicated a preference for the safety lancet over their routinely used device.

Training

Table 11. Training issues: lancet devices

Device(users)	Genie (35)	Medlance (28)	Monolettor (28)	Unistick 2 (34)
Device Self Evident to Use	54.3%	65.4%	52%	30.3
Minimal training required	28.6%	23.1%	44%	63.3%
Training essential	17.1%	11.5%	4%	6.1%

All devices are promoted by suppliers as easy to use, and all have a similar mechanism of activation. The Medlance lancet appears the most intuitive to use with 65.4% of users indicating that training was not required as the device was self evident to operate. This compares with 52% of Monolettor, 54.3% of Genie and 30.3% of Unistick 2 users.

63.3% of recruits using the Unistick 2 lancet indicated that minimal training in the form of posters or product literature was required, this is higher compared with the other lancet devices and could be attributed to being the only device requiring setting of the safety mechanism.

17.1% of users of the Genie lancet and 11.5% of Medlance users indicated that hands on training would be essential prior to using this device, whereas only 6.1% of Unistick, and 4.0% of Monolettor users indicated this more intensive training would be necessary.

Comparative data.

At the conclusion of the study period participants were asked to complete a comparative evaluation form indicating their preferred device from a list of criteria.

Over 94% of respondents reported receiving training on all of the devices evaluated. 91.7% reported that the evaluation period was long enough to warrant a thorough evaluation of product.

Figure 5. Overall grading of each lancet product with 1=Poor ranging to 10=Excellent

Table 12. Results of Lancet Device Comparison Forms (24 forms returned)

Device(users)	Genie	Medlance	Monolettor	Unistick 2
Easiest to handle	31.8%	4.5%	0	63.3%
Easiest trigger mechanism	39.1%	4.3%	4.3%	52.2%
Most reliable feature	31.8%	13.6%	0	54.5%
Blood sample	27.3%	0	9.1%	63.6%
Effective NSI Prevention	27.3%	9.1%	0	63.6%
Least Pain	36.4%	4.5%	4.5%	54.5%
User Preference	31.8%	9.1%	0	59.1%

Users were asked to grade the lancets in order of preference using a scoring system where 1 equated to their most preferred device through to 4 indicating least favoured lancet.

The Unistick 2 was identified as most preferred device in 63.6% of responses, with 31.8% rating the Genie as their most preferred device. 1 user rated Medlance as their most preferred device. None of the users of the Monolettor graded this as their most preferred device. The Monolettor was consistently recorded as least favored device with 57.1% of staff grading it as a 4. Using this rating system users indicated the sequence of preferred devices as Unistick 2, Genie, Medlance then Monolettor.

Discussion

User Comments

Many of the participants expressed strong views on these products; staff were encouraged to document their views in the comments section of the evaluation forms. These comments have been included as they may give further insight into strengths and limitations of the product that the evaluation forms may not pick up.

The users views have been divided into positive and negative comments.

Summary points of safer lancet devices

Genie

- Good range of penetration depths available.
- Product literature available.
- Very high standard of product training and support available from Becton Dickinson.
- Good blood yield.
- Comments from user indicated that the 'blue' lancet was less painful.
- Some users commented that the device was awkward to use.

Medlance

- Good range of penetration depths available.
- Product literature available.
- Product training and excellent level of assistance from company representative.
- Some users felt the device was awkward to use.
- One depth of lancet (2.0mm) yielded too much blood.

Monolettor

- Limited product literature available but compensated by excellent training and assistance from company representative
- Presently lancet available with only 1 penetration depth (2.4mm).
- Slightly awkward to use, with three points of contact required for thumb and fingers.

Unistick 2

- Good range of penetration depths available
- Product literature and evidence of device effectiveness available from Owen Mumford.
- Very high standard of training and assistance from company representative.
- The needle requires a pre-set action prior to activation.
- Could in theory be re-activated. This would require inserting a cap cover into the opening of the needle shaft and pushing back on the spring- in practice it seems highly unlikely this would happen

Conclusions

We would grade all of the evaluated lancets as acceptable alternatives to be used in the reduction of needlestick injuries. Clearly from the evaluation results and user comments some devices were rated better than others in terms of functionality.

All of the devices, which are single use disposable lancets, performed well with no reports of needlestick injuries. **User confidence was high with over 88% of users confident that these products would help reduce needlestick injury.** Paradoxically user acceptance appeared low with the majority of participants preferring to use their routine device instead of the safer alternative.

The evaluations indicated that the Unistick 2 lancet was the consistently preferred device, even with the additional step of having to set the activation mechanism. The Genie lancet was a close second.

A review of the product literature for these lancets reveals the devices as easy to use with minimal training, the results from the majority of users would concur with this. However, some users have indicated that hands on training would be essential before they would undertake to use these devices. This additional training may help overcome the initial reservations with device acceptance.

Users commented most on pain experienced by patient, awkwardness to handle and amount of blood obtained for sampling. Initial awkwardness in handling may be overcome in some instances with prolonged use of devices. For some devices there may be a long learning curve. With 50% or less of users indicating a preference to use safety lancets it may take time for staff to accept these devices.

Rating	1	2	3	4
Device	Unistick 2	Genie	Medlance	Monolettor
Cost	7.8p	9.7p	13p	23p

Note: There are 2 Medlance lancets on the market.

- **Medlance (Greiner Bio-One).**
- **Medlance II (MediServe).**

4.2 Venous Blood Collection

Conventional Systems

Venous blood sampling is routinely carried out using a closed system such as the Vacutainer (vacuum tube) and Monovette systems. These approaches employ the common principle of aspiration of blood through a multi sample needle.

The vacuum tube system uses a double pointed multi sample needle which is screwed into a plastic tube holder. One end of the needle is inserted into the vein, the other, which is rubber sheathed and protected by the tube holder, is used to pierce the vacuum tube bottle, thus drawing blood into the sampling tube. Using this type of needle many samples can be taken from the same puncture site.

The Sarstedt S-Monovette system uses a single point needle which is used for venepuncture. Blood sample bottles are attached at the docked end of the needle with blood aspirated into sample bottles by retracting the plunger. The needle remains in the vein while further sample bottles can be attached for sampling.

With fragile, small or difficult veins winged butterfly needles are used to draw blood. The vacuum force is less (an effect due to the length of tubing) and it is less like to collapse small veins. A multi sample adaptor allows this system to be used with a vacuum tube holder. Alternatively some clinicians use conventional needle and syringe to tease blood samples from small or difficult veins.

In replacing traditional needle and syringe draws the closed system technique prevents blood sample transfer hazards. Although staff are still at risk from the exposed needle when it is withdrawn from the vein.

Efficacy of injury prevention

Safety device suppliers were approached for evidence of their device reducing needlestick injury and the literature was reviewed. There is relatively little in the current literature reporting the efficacy of venous blood collection devices. The Safety-Lok winged steel needle (Becton Dickinson) was evaluated in a New York healthcare facility³⁵ and showed a reduction in needlestick injuries associated with butterfly needles of 52.2% (95% CI 31%-73%). Injuries were reported with the use of this device, with approximately one third associated with users not deploying the safety mechanism and almost 40% occurring before activation of the safety mechanism was feasible.

Another study of Safety-Lok showed a injury reduction of 23% ($p=0.07$).⁴⁶ In the same study, a self-blunting vacuum tube needle (Punctur-Guard, Bioplexus Inc.) and shielded device (Needle-Pro, Portex) showed injury rate reductions of 76% and 66% respectively ($p=0.003$).⁴⁶

UK EPINet data³³ for 2002 shows 11.9% of needlestick injuries are attributed to devices for withdrawing venous blood and 6.9% of injuries are caused by needle/vacuum tube holder devices. In Lanarkshire Acute Hospitals NHS Trust (LAHT), needle/vacuum tube holders are responsible for 6.25% of reported needlestick injuries. According to LAHT procurement data, approximately 240 000 needle/vacuum tube holders are purchased annually, with an injury rate of 2.5 injuries per 100 000 devices used.

Safer Mechanisms employed for the collection of Venous Blood

Literature and Internet searches revealed 14 safer alternatives, available to the UK healthcare market, for the collection of venous blood samples.

Table 13. List of safer devices found following literature and Internet searches. The safety feature and unit cost per device is included.

Device (Manufacturer)	Safety system	Unit Cost
Eclipse (Becton Dickinson)	Vacuum tube	£0.20p
Needle-Pro (SIMS Portex)	Vacuum tube	£0.12p
Quikshield (Greiner Bio-One)	Vacuum tube	£0.31p*
Vanishpoint (International Technidyne Corp)	Vacuum tube	£0.36p
Vacuguard (SafeGard Medical)	Vacuum tube	£0.06p
NeedleGuard International (NeedleGuard International)	Vacuum tube	-
Angel Wing (Tyco Healthcare)	Vacuum tube butterfly	£0.92p
Surflow (Terumo)	Vacuum tube butterfly	£0.42p
Safety Lok (Becton Dickinson)	Vacuum tube butterfly	£0.40p
Vacurette (Greiner Bio-One)	Vacuum tube butterfly	£0.13p
Vaku-8 (Alaris Medical)	Vacuum tube butterfly	-
Safeguard Medical	Vacuum tube butterfly	-
Monovette system (Sarstedt)	Monovette system	£0. 21p
DonorCare Needle Guard (Baxter Healthcare)	Venesection system	

*Although 31p unit cost quoted as list price, device available for approx 18p per unit.

The Unit Costs for Vaku-8, NeedleGuard International and Safeguard Medical devices are not included in this table. These devices were not included in the evaluation exercise, as outlined in pre-evaluation testing section.

Safer mechanisms compatible with the Vacuum tube system

Shielded Needle- (Eclipse Needle-Becton Dickinson)

The blood collection needle incorporates an attached plastic hinged shield, the unit is screwed into the Vacutainer holder and the shield is placed over the needle after venepuncture.

The needle is permanently locked into the shield and this with the holder is discarded as a single unit as per Trust protocol.

Shielded Holder- (Needle-Pro-SIMS Portex, VacuGuard-SafeGard Medical, Quikshield-Greiner Bio-One)

The Vacutainer holder unit incorporates a hinged needle shield which the user moves into place to permanently cover the contaminated needle immediately after venesection. The entire assembly is discarded into a sharps container.

Retractable Needle- (Vanishpoint International Technidyne Corp.)

The vacuum tube holder contains a spring mechanism that triggers needle retraction upon closure of the tube holder cap. A single activation step retracts the needle from the patient's vein into the tube holder.

Vanishpoint International Technidyne Corp

Vacuum Tube Butterfly system

Needle Retraction – Angel Wing (Tyco Healthcare), Safety-Lok (Becton Dickinson), Vacuette (Greiner Bio-One).

The winged needle is permanently covered by a plastic or metal casing. This is achieved by either advancing the secure plastic casing over the butterfly needle, or pulling the tubing backward to draw the needle into a protective casing. The assembly is discarded as a single unit. With some devices the needle can retract directly from the vein into the safety casing.

Needle Sheath - Surflow (Terumo)

A hinged plastic sheath attached to the butterfly needle 'folds' over to permanently conceal the contaminated needle. The unit is discarded as a single unit.

Safer mechanisms compatible with the Sarstedt Monovette system.

Needle retraction (Safety Monovette)

A tube holder attaches to the docked end of the blood collection needle in the same manner as the sampling bottle. At the other end of the tube a 'plunger' is pulled back thus drawing the needle from the vein securely into the tube. This mechanism locks preventing needle exposure and is discarded as a single unit.

Safer mechanisms compatible with using a Needle and Syringe

Hinged cap – The cap comes attached to a standard IM needle which in turn can be attached to any conventional syringe. Following venepuncture the cap is placed on a firm surface and the needle clicks into the hinged cap. (Portex hypodermic Needle-Pro blood draw syringe).

The cap and needle assembly is discarded as per unit protocol.

*Other safer needle and syringes are outlined in Syringe chapter

Evaluation Exercise

Pre Evaluation

During the pre-evaluation phase study investigators examined all devices to determine their suitability for inclusion in the evaluation exercise.

Three devices were not included in the study due to safety concerns. Investigators received needlestick injuries when deploying the safety mechanism on the following devices:

- Vaku-8
- Needleguard International.

During testing of the Safeguard Medical butterfly needle the safety mechanism was easily bypassed and the needle did not fully retract into protective casing. With such apparent risk of injury these devices could not be included for evaluation in a clinical setting.

Recruitment Phase

It was proposed that North Glasgow University Hospitals NHS Trust, and Tayside Primary and Acute Trusts undertake the evaluation of the safer blood collection devices.

As the Sarstedt Monovette system is not used anywhere within these Trusts alternative areas within the Partner Trusts were approached for recruitment. The Southern General Hospital (South Glasgow University Hospitals NHS Trust) and the Royal Infirmary of Edinburgh both employ the Monovette system.

Additionally, the phlebotomy staff at Monklands Hospital were recruited to evaluate winged butterfly needles. Following discussion with unit managers most areas opted to evaluate 4 'safety devices'. However, areas expressing a preference to use 5 devices were allowed to do so. The evaluation period lasted 2 weeks per device, staff completed one evaluation form per device type used. A device comparison form was completed at the conclusion of the device group.

Demographics

167 staff were recruited from North Glasgow Hospitals University NHS Trust, South Glasgow Hospitals University NHS Trust, Lanarkshire Acute Hospitals Trust, Tayside University Hospital Trust, Lothian University Hospitals Trust and the State Hospital at Carstairs.

Figure 6 shows the breakdown of the clinical staff recruited to evaluate devices compatible with the Vacutainer blood collection system. Table 14 outlines the number of staff recruited from each area.

**Figure 6. Vacuum tube device
User distribution.**

**Table 14. Recruited staff for vacuum tube
systems**

Phlebotomists made up the largest group of users accounting for 92 (55%) of all staff recruited. Areas with high blood sample requirements had a dedicated phlebotomy service e.g. general medical and surgical wards, cardiology. With most of the routine blood sampling performed by phlebotomy staff this left limited scope for recruiting nursing and medical staff to use these devices, and is reflected in the range of clinical staff and types of clinical areas recruited.

In areas without phlebotomy cover, pre-operative assessment clinics, haematology and oncology units we found that nurse practitioners and clinical nurse specialists routinely perform venepuncture. In nurse led specialty areas i.e. community midwifery and ante natal out patient, midwifery staff performed almost all routine phlebotomy. 11 staff were recruited to evaluate the Sarstedt Safety Monovette device (6 phlebotomy staff. 5 Nursing staff from a High Dependency Unit).

Figure 7. Number of uses of safety Vacuum tube holder and needle use

Figure 8. Number of uses of Winged Butterfly Needle Devices

RESULTS

i) Vacuum tube holder and needle devices : evaluation results

Ease of Use

Table 15. Vacuum tube holder devices : ease of use

Device (Users)	Eclipse (90)	Needle-Pro (90)	VacuGard (88)	Vanishpoint (28)	Quikshield (34)
Able to activate safety feature using 1 hand technique	95.6%	95.6%	66.3%	61.5%	82.4%
Device use results in alteration of venepuncture technique	7.9%	13.6%	27.1%	30.8%	76.5%
Safer device longer to use compared with 'usual' device	20%	25.8%	71.8%	72%	71.9%
Staff comfortable using device with <5 uses	65.9%	75.3%	30.5%	28%	25.8%
Preference to use safer device over 'usual' device	77.8%	75%	9.5%	19.2%	3.0%
Safety mechanism interferes with blood sampling	6.7%	15.7%	11.4%	23.1%	76.5%

Vanishpoint (28) –The device supplier was unable to provide training or demonstration of the safety feature, consequently few participants were willing to use this device without training.

Quikshield (34). This device was released to market once main group of device evaluations complete.

Activation of safer device using a one handed technique

A review of product literature and training instructions revealed that all devices could be activated using a one handed technique. The Eclipse and Vacugard employ a similar mechanism of activation using the thumb to place the shield over the needle. 95.6% of Eclipse and 66.3% of Vacugard users were able to engage the safety mechanism in recommended method.

Although not structurally similar, the Needle-Pro and Quikshield employ a similar mechanism of activation. The shield is placed on a flat surface to allow the needle to click into the shield. 95.6% of Needle Pro, and 82.4% of Quikshield users managed to deploy the safety mechanism using a single-handed activation.

The Vanishpoint product relies on an internal spring, activated by closure of a cap at the end of the barrel, to retract the needle into the vacuum tube holder. 61.5% of users managed a single handed activation.

Alteration to technique

76.5% of Quikshield users indicated that using this device resulted in a change of their blood collection technique. This was considerably higher than any other device in this group. Only 7.9% of Eclipse users and 13.6% of Needle-Pro reporting a change in technique required.

More time to operate

72% of the Vanishpoint users indicated that this device took longer to operate than the device they normally used, followed by 71.8% and 71.9% of Vacuguard and Quikshield users.

20% of Eclipse and 25.8% of Needle-Pro users reported that these devices took longer to use when compared with their routinely used device.

Safety Mechanism Interference with sampling

With some devices (Eclipse, Quikshield), the needle shield is in a fixed position (and the needle oriented in a bevel up position). The Needle-Pro and Vacuguard have a shield that can rotate freely.

Only 6.7% of Eclipse users indicated the shield got in the way of sampling, compared with 76.5% of Quikshield users. With the rotating shields, 15.7% of Needle-Pro users and 11.4% of Vacuguard users indicated the shield interfered with blood sampling.

Vanishpoint with its unique mechanism had 23.1% of users reporting the safety mechanism interfered with blood sampling.

Staff comfortable with the device with 5 or less uses.

75.3% of Needle Pro and 65.9% of Eclipse users indicated that they were comfortable using this product with 5 or less uses. Only 30.5% of Vacuguard users were comfortable using this product after 5 or less uses.

Preference to use trial device

Staff were asked their preference on whether they would like to use trial device or usual device following evaluation of each product. 77.8% of staff that used Eclipse and 75% of Needle Pro users indicated a preference to use the safer device over the system in routine use. This was proportionally higher when compared with VacuGuard and Quikshield. 90.5% of Vacuguard users given the choice would rather use their routine (non safety) device. Only 3% of Quikshield users would choose to use this safer system.

Patient Care

Table 16. Vacuum tube holder and needle devices and pain

Device(users)	Eclipse (90)	Needle-Pro (90)	VacuGard (88)	Vanishpoint (28)	Quikshield (34)
Device associated with increased patient pain (staff perception)	1.1%	0	1.2%	48%	15.6%

Only the Vanishpoint device can be activated with the needle still in the patient’s vein, although it was not recorded how many users opted to do so. 48% of staff using the

Vanishpoint system indicated that they thought this device caused additional pain or trauma to patient when compared with standard phlebotomy device. This was considerably higher than other devices in this group.

Safety

Table 17. Safety issues :Vacuum tube holder and needle devices

Device(users)	Eclipse (90)	Needle-Pro (90)	VacuGard (88)	Vanishpoint (28)	Quikshield (34)
Safety mechanism activation causing blood splash	8.9%	5.6%	40.9%	14%	5.9%
Safety Feature Not Activated:	8%	8.1%	42.9%	23.1%	21.2%
Due to Product Failure	1	1	15	3	1
User Chose not to deploy mechanism	4	4	16	2	4
Other	2	2	5	1	2
Users confident device could reduce needlestick injury rate	83.7%	87.5%	33.7%	65.4%	68.8%
Number who sustained needlestick injury using safer device	1	0	1	0	0

Blood splash

A large proportion (40.9%) of Vacuguard users reported blood splash/splatter on activation of the safety mechanism.

Non-activation of safety feature, product failures/other

There were episodes where the safety mechanism was not used for each safety product in this group. Both the Eclipse and Needle-Pro had 1 report attributed to product failure and 4 instances where the safety mechanism was not used because the user chose not to deploy it.

There were 3 reported product failures with Vanishpoint and 15 incidences of product failures with the Vacuguard. Additionally with the VacuGuard sixteen users reported periods where they chose not to deploy the needle shield.

Confidence in device ability to protect against sharps exposure

User confidence in the ability of the devices to protect against needlestick injury varied. 83.7% of Eclipse and 87.5% of Needle Pro users confident that device would help reduce risk of Needlestick injury. Whereas only 33.7% of Vacuguard users were confident that this device would help protect against needlestick injury.

Reported Needlestick injury

There were 2 reported needlestick injures from devices within this group. In an incident using an Eclipse Needle it was claimed that difficulty in removing the needle cover resulted in a scratch to palm of hand. This occurred prior to venepuncture. In an incident involving a VacuGuard Sheath the injury occurred post venepuncture and prior to deploying the sheath.

Training

Table 18. Vacuum tube holder and needle training issues

Device(users)	Eclipse (90)	Needle-Pro (90)	VacuGard (88)	Vanishpoint (28)	Quikshield (34)
Device Self Evident to Operate	43.8%	58.9%	52.4%	26.9%	67.7%
Minimal Training Required	42.7%	33.3%	32.9%	30.8%	19.4%
Hands on Training Essential	13.5%	7.8%	14.6%	42.3%	12.9%

Figure 9. Users perception of the training require to operate each safety feature in a correct and safe manner.

ii) Sarstedt Safety Monovette Device

Results and Analysis

Only 11 staff were recruited to evaluate this product. There was difficulty recruiting users as there were areas that had previously tried the device who refused to use it again.

Nine of the eleven users indicated that given the choice they would prefer to use their routine device for the collection of venous blood. Although the device did not take longer to use (10 users indicate equivalent time use) when compared with the conventional method of sampling, 45.5% of users found there was an alteration to their phlebotomy technique when using this product.

Ease of use

45.5% of users reported feeling comfortable using this product with 5 or less uses, however 36.4% of users reported never feeling comfortable using the Safety Monovette. Users were asked to rate the device with regards to ease of handling : the rating system ranged from 1 indicating Awkward, up to 10 equivalent to Easy. 72% of users indicated a score of 5 or less.

Safety

1 user reported experiencing blood splash/ splatter using this safety product. 36.4% of users felt confident that this device would help reduce the risk of needlestick injury, 45.5% of users were uncertain this device would reduce needlestick injury risk . Two users left this answer blank but commented that the device might reduce injury if staff use it. The other user was unsure if the device would reduce injury risk.

1 participant verbally reported a needlestick injury from using this device but did not return a study needlestick incident form.

Patient Care

When asked the length of time it took to use the safety monovette 90.9% indicated this system took longer to use than the conventional system. The described mechanism of use for the safety mechanism is withdrawal of the needle from the patients vein into a safety tube retracting a plunger mechanism . 81% of users indicated that they could not activate this device using a one handed technique.

Training

Only three users found the device intuitive to use with 36.4% indicating minimum training would be necessary and 30% indication training would be essential prior to device use. Pre-evaluation review of this device by the study investigators found that on several occasions the needle did not lock on retraction. The study investigators rated this device as awkward to use: withdrawing the plunger to retract the safety mechanism is awkward especially while trying to keep pressure on the puncture site.

iii) Winged Butterfly Needle Devices : evaluation results

Ease of Use

Table 24. Winged butterfly needle device ease of use

Device(users)	Vacurette (49)	Angel Wing (48)	Safety Lok (38)	Surflow (48)
Able to activate safety feature using 1 handed technique	16.7%	45.8%	35.1%	51.1%
Device use results in alteration to venepuncture technique	24.4%	40.4%	22.2%	32.6%
Safer device longer to use compared with 'usual' device	51.1%	56.3%	55.6%	71.1%
Safety mechanism interferes with blood sampling	8.7%	35.4%	24.3%	10.6%
Staff comfortable using device with <5 uses	42.2%	37.8%	27.8%	17%
Preference to use safer device over 'usual' device	43.5%	31.9%	26.5%	12.8%

Activation of safer device using a one handed technique.

Only 16% of Vacuette users reported being able to activate this device using the one handed technique. This was considerably lower than the products in the rest of the group.

Alteration to technique

40.4% of Angel Wing users reported that using this device resulted in an alteration of their blood collection technique. Those using the Safety Lok reported the lowest incidence of technique change (22.2%).

More time to operate

More than half of users of all evaluated butterfly devices reported that using the safer device took longer than the conventional system. For example, 71.1% of Surflow users reported that device took longer than the non-safety equivalent. Vacuette users had the lowest proportion reporting the device took longer to use, at 51.1%.

Device Interference with sampling

Only 8.7% Vacuette users felt the safety device interfered with sampling followed by Surflow (10.6%). This was significantly lower than for the Angel Wing (35.4%) and Safety Lok (24.3%).

Reporting comfort with device after 5 or less uses

Only 17% of Surflow users were reportedly comfortable with the device with 5 or less uses, followed by Safety Lok at 27.8% and Angel Wing at 37.8%. At 42.2% the Vacuette had highest proportion of users comfortable with 5 or less uses.

Preference to use trial device

Users remained unconvinced by these devices. Less than 45% would choose to use the safer device over their routinely used device. Only 12.8% of Surflow users would prefer to use this device to their routinely used product.

Patient Care

Table 25. Winged butterfly device use and pain

Device (Users)	Vacuette (49)	Angel Wing (48)	Safety Lok (38)	Surflow (48)
Device associated with increased patient pain (staff perception)	10.4%	25%	8.1%	11.4%

The safety mechanisms for the Vacuette, Angel Wing and Safety Lok can be activated while the needle is still in the patient's vein, but it is not known how many users chose to do so.

Staff were asked their perception of pain experienced by patient on activation of the safer devices. A quarter of all Angel Wing users perceived that this device caused additional pain/trauma to the patient. This was higher than any other device in this group.

Safety

Table 26. Winged butterfly device use and safety

Device(users)	Vacurette (49)	Angel Wing (48)	Safety Lok (38)	Surflow (48)
Safety mechanism activation causing blood splash	18.8%	16.7%	41.7%	31.9%
Safety Feature Not Activated:	17 (34.6%)	15 (31.2%)	14 (36.8%)	19 (39.6%)
Due to Product Failure	2	8	6	9
User chose not to deploy mechanism	10	4	8	7
Other	5	3	-	3
Confident device could reduce needlestick injury rate	75.6%	52.1%	52.9%	29.8%

Blood splash

41.7% of Safety-Lok and 31.9% of Surflow users reported experiencing blood splash using these devices. The Angel Wing had the lowest report of blood splash.

Non-activation of Safety Mechanism

All of the devices in this group are categorised as Active devices and such require an additional input from the user to deploy the safety mechanism. All had reports of the safety mechanism not being used. The Vacurette had the lowest incidence of product failures with 12% of non-activations being attributed to this. The Angel Wing had the highest reports with just over half of its non-activations being attributed to product failure. Worryingly, 59% of Vacurette and 57.1% of Safety Lok non-activations were due to the user opting not to use the safety mechanism.

Confidence in device ability to protect against sharps exposure

Of Vacurette users 75.6% were confident that this device would help reduce needlestick injury; this was significantly higher than the other devices in this group. User confidence in the Surflow being able to reduce needlestick injury was significantly lower than that for other devices.

Reported Needlestick Injury

There were no reports of needlestick injury using any of the butterfly products in this group.

Training

Table 27. Winged butterfly device use and training issues

	Vacurette (49)	Angel Wing (48)	Safety Lok (38)	Surflow (48)
Device Self Evident to Operate	25.5%	22.9%	11.1%	34%
Minimal Training Required	55.3%	60.4%	58.3%	44.7%
Hands on Training Essential	19.1%	16.7%	30.6%	21.3%

Figure 10. Users perception of the training require to operate each safety feature in a correct and safe manner (winged butterfly devices).

iv) Device Comparison Results (84)

3 groups of products were evaluated. Some users opted to use only Butterfly devices, some Vacutainer holder with needle, others chose to use mixed devices as this reflected their normal practice. 89.2% of users indicated the length of the study period was long enough to evaluate devices properly

The results show the comparison results for the Vacutainer and Butterfly group.

Vacuum tube holder/needle comparison group (47)

(It should be noted that 33 phlebotomists in one of the hospital settings had previous familiarity with the Eclipse system).

Easiest to Handle

59.6% of forms returned for this group indicated that the Eclipse was easiest to handle followed by the Needle-Pro with 40.4%. None of the other devices in the group were rated as being easiest to handle.

Easiest Mechanism to Deploy

The Eclipse was identified as having the easiest mechanism to deploy in 59.6% of returned forms. 40.4% indicated that the safety mechanism on the Needle Pro was easiest to deploy.

Most Reliable Safety Feature

Eclipse 59.6% Needle-Pro 40.4%

Best for obtaining Blood Sample

59.6% Eclipse

40.4% Needle-Pro

Device Potential to Reduce Needlestick Injury

27.7% of Needle-Pro and 57.4% of Eclipse. 14.9% of Vacutainer returns –device may be effective in reducing NSI. No other devices made it into this category.

Device Preference (one option)

Asked which of devices trialled the user would prefer to use 40.4% indicated Needle-Pro, 59.6% indicated the Eclipse. No other device in this category was identified as being preferred to use.

Device Rating (graded)

Staff were asked to grade the device with 1 equating to their most preferred device through to 5, least preferred device.

- **Most Preferred Device**

59.6% identified the Eclipse as the most preferred device, 40.4% identified the Needle-Pro as their most preferred device.

- **Least Preferred Device**

53.2% of forms indicated that the VacuGuard was the least preferred device, 12.8% Vanishpoint, 4.8% Quikshield.

Winged Butterfly Needle Comparison Group (18)

Easiest to Handle

Angel Wing 33.3%, Safety Lok 27.8%, Vacuette 22.2%, Surflow 11.1%

Easiest Mechanism to Deploy

Safety Lok 38.9%, Angel Wing 33.3%, Vacuette 16.7%, Surflow 11.1%

Most Reliable Safety Feature

Both the Angel Wing and Safety Lok achieved 33.3%, followed by Vacuette (22.2%) and Surflow(11.1%).

Best for Obtaining Blood Sample

Angel Wing 38.9%, Safety Lok, 33.3%, Vacuette 16.7%, Surflow 11.1%

NSI Prevention

Safety Lok 38.9%, Angel Wing 33.3%, Vacuette 16.7%, Surflow 11.1%

Device Preference (one option)

Angel Wing 33.3%, Safety-Lok 33.3%, Vacuette 16.7%, Surflow 11.1%

Device Rating (Graded)

- **Ranked as most preferred device:** Safety-Lok 38.9%, Angel Wing 33.3%, Vacuette 16.7%, Surflow 11.1%.
- **Ranked as least preferred device:** 33.3% Angel Wing, Surflow 27.8%, Vacuette 22.2%, 16.7% Safety-Lok.

User comments : Vacuum tube holder and needle devices

User comments : winged butterfly devices

User comments : Sarstedt Safety Monovette

CONCLUSIONS

Vacutainer holder and needle device summaries

CONCLUSIONS

Vacuum tube holder and needle device summaries

Eclipse (Becton Dickinson) : Preferred

Overall this device was favourably evaluated with regards to ease of use. Almost all users could activate the device with a one handed technique and more than 65% of users were comfortable with the device with 5 or less usages. There were reports of activation of the safety mechanism causing blood splash albeit fairly low at 8.9% of users.

The one reported needlestick injury with this device was a low risk incident which occurred before venepuncture whilst attempting to unsheath the needle. Several users commented on difficulty in removing the needle cover prior to venesection. Caution is needed in removing the needle sheath.

Over 40% of users felt that this device was self evident to use, and 42.7% felt that minimal training would be necessary for safe use of this device.

Caution: There were reports of staff not deploying the safety mechanism. There may be a need to emphasise safety feature use.

Needle-Pro (SIMS Portex) : Preferred

This device received a favourable evaluation with regards to easy to use, almost all could activate the safety mechanism using a one hand technique . The safety mechanism worked effectively with only 1 product failure recorded, and 4 staff opting at some point not to use the safety feature.

There were no reported needlestick injuries from using this device and only 5.6% of users indicated presence of blood splash on activation of the safety mechanism. Overall, this device proved easy to use with 60% of users indicating the device was self evident to operate.

The Needle-Pro safety mechanism requires activation on a flat surface, which negated the need to move finger or thumb towards needle. However some users felt the safety shield could get in the way of sampling.

Caution : Due to reports of staff not deploying the safety mechanism, there appears to be a need to emphasise correct use through training.

Quikshield (Greiner Bio-One) : Acceptable

There was excellent support from the supplier.

The results from the utility evaluation were poor for this device. Over three quarters of staff returning evaluation forms indicated that the safety feature interfered with sampling and given the choice between using this device or their conventional system, only 3% expressed a preference for Quikshield. User comments highlighted that the safety feature got in the way and was awkward to use.

There was only 1 report of product failure plus 4 users opting not to deploy mechanism. The safety feature requires activation on a flat surface, which negates the need to move finger or thumb towards the needle.

VacuGard (SafeGard Medical) : Not recommended

There was a good level of support from the supplier. The evaluation with regards to utility and safety was poor. 42.9% of users indicated periods where the safety mechanism was not used.

There was a high incidence of safety feature failure and users not deploying the safety mechanism, mainly due to concern that the force required to clip the needle into its sheath

was excessive causing the needle to bend. Users comments that using the device could increase rather than decrease the risk of needlestick injury and a high number of users commented this device was unsafe.

Vanishpoint : Not recommended

The mechanism employs a principle of withdrawing the needle from the vein into a barrel. The supplier was unable to provide training or adequate supplies of the device. There was possible additional discomfort when the device was activated in-situ. If the mechanism is activate when the needle is exposed this can lead to blood splash. Just under half of the participants believed this device may cause more pain or trauma to the patient. Blood splash was noted on activation. It is also noted that this device was unsuitable for small sample bottles (e.g. EDTA)

Monovette : Not recommended

We cannot recommend this device due to the concerns of users, the awkwardness demonstrated on benchtop evaluation and the reluctance of previous users to participate in further evaluations.

Table 28. Summary Recommendations : Vacuum tube holder and needle devices

Eclipse	Needle-Pro	QuikShield	Vacugard	Vanishpoint	Monovette
Preferred	Preferred	Acceptable	Not recommended	Not recommended	Not recommended
£0.20p	£0.12p	£0.18p	£0.06p	£0.36p	£0.21

*Needleguard International device was excluded at pre-evaluation stage and is therefore not recommended

Butterfly Needle Device Summaries

Angel Wing : Acceptable

There was excellent support from the supplier. The device evaluated reasonably with regards to utility, though there appeared to be a divided opinion amongst users, some rating the device highly and others rating it their least preferred device. There were less favourable results with regards to safety, 8 users reported episodes of product failure, 4 staff opted not to use the safety mechanism. There were reports of the mechanism breaking, exposing a contaminated needle. Other reports included activation of the safety feature during needle insertion

Safety-Lok: Preferred

There was excellent support from the supplier. The device evaluated reasonably with regard to utility. In terms of safety, there were 6 product failures and 8 instances where staff opted not to use safety mechanism. There was a high reported incidence of blood splash.

Surflow : Not recommended

There was a very good level of support from the supplier. The device evaluated reasonably with regards to ease of use. However flimsy construction of needle shield, which can fail to cover the needle, a high number of product failures and users choosing not to deploy safety mechanism counted against this device. Users generally did not rate the device highly. There was also a high incidence of blood splash

Vacurette : Preferred

There was an excellent level of support from the supplier. There was a reasonable evaluation of utility. There were few product failures, but a high number of users opted not to deploy safety feature (difficulty in activation). There was a low incidence of blood splash.

Preferred Devices Summary

Differences: Safety-Lok users reported more blood splash than Vacurette.

Staff using Vacuette reached comfort with the device quicker than Safety-Lok. Both have fairly similar training assessments. However, comments from users indicated that with Vacuette, the safety mechanism would be easier to activate if the ‘wings’ were bigger, Greiner have subsequently release a newer version of this product with easier to pinch wings.

Table 29. Summary recommendations : winged butterfly devices

Angel Wing	Safety-Lok	Surflow	Vacuette
Acceptable	Preferred	Not Recommended	Preferred
£0.92	£0.40	£0.42	£0.13

*The Vaku-8 and Safeguard Medical devices were excluded at pre-evaluation stage and are therefore not recommended.

Venesection

DonorCare Needle Guard (Baxter Healthcare)

One group of staff nurses already recruited to evaluate safety cannulae, identified that the needles and tubing used for venesectioning patients with haemochromatosis posed an increased risk of needlestick injury. Often during disposal of the venesection set the lengthy tubing curled back, commonly described a ‘cobra effect’, thus exposing staff to the risk of needlestick injury.

A safety product search revealed the DonorCare Needle Guard (Baxter Healthcare) could be used to shield venesection needles.

Five of the staff in this unit agreed to evaluate this device.

User Evaluation

Four of the five recruited staff used this device a minimum of 20 times. One member of staff used it between 31 and 50 times during the evaluation period. Staff generally adapted quickly to the device, with four out of the five users indicating being comfortable with the device after 5 or less uses. Similarly, 4 out of the 5 users rated the device as easy to handle. All of the recruited staff rated the device as easy to activate and the mechanism of operation as obvious. None of the users indicated that the device required an increase in dexterity required to use the product. There were no reports of needlestick injury or blood splash/splatter using this product.

Each of the users in this small group indicated that this product would help to reduce the risk of needlestick injury. Although only a small user group evaluated this product combined with investigator benchtop testing we would rate this product as a suitable safety alternative to use during venesection. **Rated as Preferred**

4.3 Arterial blood gas sampling

Conventional Arterial Blood Gas sampling

Arterial blood sampling kits include a needle, heparinized syringe, rubber block and a luer tip cover. Prior to analysis of the blood sample the needle must be separated from the syringe. This can be achieved by inserting the needle into the rubber block and is done primarily to prevent contact with air and 'spoiling' the blood sample, although it can help reduce the risk of injury during removal of the needle. Alternatively, some clinicians re-cap the needle. Once the needle has been removed from the syringe, and the tip luer capped, the sample can be sent for analysis.

Potential for Sharps Exposure

Injury may occur:

- On removal of the needle from the patient's artery.
- Recapping of needle sheath
- During separation of the needle from syringe barrel.
- Inserting needle tip into cube.
- Disposal related (unsafe and inappropriate disposal).

EPINet

Royal College of Nursing EPINet data (2002)³³ shows that 2% of sharps injuries are attributed to items where the original purpose was the withdrawal of arterial blood.

Safer Alternatives

3 safer devices for arterial blood sampling were identified as available to the UK healthcare market.

1. Eclipse Needle for arterial blood collection (Becton Dickinson)
2. ProVent/ Pulsator with Needle-Pro device (SIMS Portex)
3. Sure-Lok Sheath Arterial Blood Gas syringe (Vital Signs)

These products incorporate the following safety mechanisms:

- **Integral Needle sheath**-The needle incorporates a plastic hinged sheath that locks over needle and allows safe detachment from syringe.
 - The Pro-Vent, and Pulsator (Sims Portex) both incorporate a pre-attached needle with the Needle-Pro device. The Needle-Pro requires to be placed on a flat surface to allow the needle to be locked into the sheath.
 - The Eclipse needle for arterial blood collection (Becton Dickinson) is activated by placing one finger on the shield, and moving the sheath towards the needle.

Needle-Pro

Eclipse

- **Free standing sheath**-The hypodermic needle is inserted into a free-standing needle sheath.
 - Sure-Lok Sheath (Vital Signs) ABG syringe.
Following arterial puncture the needle is inserted, using a one-handed technique, into a free-standing sheath. A clip on the needle component engages with the shield thus allowing separation of needle and syringe.

Included in the Sure-Lok kit is a syringe, hypodermic needle with plastic clip, a base plate, needle shield and syringe cap.

Evaluation Exercise

The Needle-Pro and the Eclipse mechanisms had already been evaluated in the syringe and phlebotomy groups and were therefore not evaluated in this section.

The Sure-Lok mechanism had not been evaluated in any other group of devices, as a result this was the only ABG syringe evaluated.

Efficacy data

Device companies were approached for evidence of device effectiveness in reducing needlestick injury. No such information was received. Literature searches did not uncover any efficacy data for ABG syringes.

Recruitment

Areas with predicted high arterial blood gas sampling requirements were targeted for staff recruitment. These areas included ITU, respiratory units, cardiothoracic units and acute receiving wards. We were limited by the number of staff that could be recruited in each area, arterial blood gas sampling is relatively less frequent and staff indicated that the distribution of sampling meant that it would be unlikely the same member of staff would take samples. A lengthy evaluation period would likely ensue due to discontinuity of sampling.

In areas with expected high sampling frequency for example cardiothoracic and ITU, many patients requiring frequent sampling had arterial lines in-situ, negating the need for arterial puncture. As a result, 18 Staff were recruited to evaluate this device, and were recruited from the following clinical areas:

General Medical ward
Respiratory outpatients department
Accident and emergency
Acute medical receiving

Four staff were specialist nurses trained to take arterial blood gases, the remaining participants were medical staff.

Results

Only 5 evaluation forms from 18 recruits were returned.

All 5 users claimed to be comfortable with the device with 5 or less uses, 2 users employed this product less than 10 times, 3 users managed between 10 and 20 uses of this syringe. All but one user managed to use the safety system using a one handed technique and the syringe offered a clear view of its contents in all 5 cases. Two users reported that this device took longer to use than their conventional device and all reported an alteration of their blood sampling technique using this product. None of the users perceived an increase in patient pain or trauma from using this device and only 1 user reported blood splash/splatter.

There were no reports of product failures, and no reported needlestick injuries. Three of the five users if given the choice would rather use this ABG syringe rather than the conventional method, however only two of the users felt this product would help reduce needlestick injury.

Analysis and Discussion

Too few evaluation forms were returned forms to glean any useful information. However this feedback is included to augment the additional information obtained through bench-top testing, product literature review and review of ECRI evaluation.

In some recruited areas the syringes were returned with notes from user (no returned forms)

- Consultant Physician. “We found these more difficult and potentially more risky than conventional gas syringe”. This device was not readily accepted, staff stopped using.
- Respiratory technician: “from a technical point of view, these syringes were no easier to use than Pulsators and we had a few instances of clots forming as the solid state heparin had not dissolved properly”.
- Respiratory lab nurse: note indicated the “doctors all expressed a preference for the old Pulsator system, so we stopped trying to make them use the new ones”. “From a technical point of view, we had a few instances of clotting occurring so the heparinisation is not as good as the Pulsator”.

Conclusion

With such a low return of evaluation forms these results should be viewed with caution, however combined with a review of the ABG syringe product literature and bench top testing we are able to make the following recommendations:

Sure-Lok Sheath (Vital Signs) : Not Recommended

- The safety feature is an accessory to the device, and as such there is no 'prompt' to use the shield. Staff may omit construction of the shield.
- Additionally, the device needs positioned on a flat sturdy surface.
- Inserting the needle into the shield requires a steady hand, precision, and more than minimal force to ensure the needle clip is attached to the shield.
- The risk of needlestick in our view remains high. Even with training, users will almost certainly steady the shield with their other hand when inserting the needle.

This system may be safer than the conventional arterial blood gas sampling system, however two other safety ABG syringes are currently available that do not require assembly of the safety feature.

Eclipse (Becton Dickinson) : Preferred

- The safety mechanism can be activated using a one handed technique.
- The shield is integral to the hypodermic needle. There is more of a visual prompt to use the mechanism.
- The shield is placed over the needle by digital pressure.

Needle-Pro (SIMS Portex) : Preferred

- The shield is integral to the hypodermic needle. More of a visual prompt to use the mechanism.
- Like the Eclipse the safety mechanism can be activate using a one handed technique.
- The needle is levered into the shield by placing the shield against a flat surface.

4.4 Peripheral Intravenous Catheter

Conventional Peripheral Intravenous Catheter

Peripheral intravenous catheters (or cannulae) are inserted directly into the vein for the administration of fluid, nutrients, blood products and medications.

An introducer needle, which extends just past the tip of the catheter, is used to perform venepuncture thus allowing placement of the catheter. The presence of a blood 'flashback' confirms the correct placement and the introducer needle can then be removed from the catheter.

Figure 11. Structure of Peripheral Intravenous Cannulae

Peripheral Intravenous Cannulae have a luer compatible structure that allows the connection of intravenous tubing or IV injection adaptor. An optional port is used for administration of additional medication or heparin flush to keep line open. Wings, which are used to secure the catheter to skin, are also optional.

Cannulae with side ports are not available for sale to the US market, however, both ported and non-porting cannulae are used within the UK healthcare setting, although in UK the cannulae market is predominantly ported. The presence of a port is a potential entry site for infection.

EPINet Data

UK EPINet data (2002) for the Royal College of Nursing campaign 'Be Sharp Be Safe'³³ identified intravenous cannula as being responsible for 6.3% of needlestick injuries.

Needlestick Risk Potential

Needlestick injuries may arise:

- Pre-Use i.e. removing cannulae cover and prior to venepuncture.
- Following removal of introducer needle and prior to disposal.
- Inappropriate disposal.

Safer Alternatives.

These safer alternatives for intravenous cannulation were identified from Internet and literature reviews.

Table 30. Peripheral Intravenous catheters used in evaluation exercise.

Name	Manufacturer	Port
Safelon	BD	Ported
Insyte Autoguard	BD	Non-Ported
Saf-T-Intima	BD	Y site butterfly
Acuvance	Johnson & Johnson	Ported
Protectiv Plus	Johnson & Johnson	Non-Ported
Vaxess	NMT	Ported and Non ported
Vasofix*	bBraun	Ported
Introcan Safety*	bBraun	Non-Ported

*The Vasofix and Introcan Safety came on to the UK market towards the end of the cannula evaluation exercise, therefore only limited feedback on their utility was obtained.

Each cannula underwent bench top testing prior to clinical evaluation. All were judged suitable for inclusion in the evaluation exercise.

Product Review

All of the above device suppliers were approached for evidence on device efficacy to reduce risk of needlestick injury. Additionally literature review was undertaken to ascertain effectiveness of safety intravenous cannula.

Efficacy data is sparse. There was no reported data on the effectiveness for any of the ported cannulae in reducing needlestick injuries. We propose that one reason for this could be that the US, which is the largest market for safety devices, does not use intravenous cannulae with a side port and the bulk of safety device research is carried out by US facilities.

An abstract of a study (not published in peer-reviewed literature) from the Mount Sinai Medical Centre in New York³⁶ reported on an evaluation of the Insyte Autoguard (Becton Dickinson) to reduce needlestick injury. The authors showed an 89% reduction in intravenous stylet related needlestick injury using the Insyte Autoguard. There was 1 reported needle stick injury, and was attributed to the healthcare worker failing to activate the safety mechanism. This device had an overall activation rate of 85%

Jagger⁴⁸ reported an injury reduction of 83% with a needle encasing device, whilst O'Connor⁴⁹ et al reported a reduction to zero injuries using a "self-capping" cannula (injuries per 100 000 uses = 0, 95% CI 0-46).

Asai et al³⁷ assessed the use and efficacy of a safeguarded intravenous cannula and compared the Insyte Autoguard with the conventional Autoguard. There was no significant difference between groups with regards to ease of insertion, however the safety device yielded significantly less bloodstain than the conventional device. The authors judged handling of withdrawn needle using the Insyte Autoguard safer than the conventional Autoguard. Asai et al³⁸ conducted a randomised trial to study the efficacy and safety of Insyte Autoguard and Protective Acuvance by comparing them with a conventional catheter needle (Autoguard). The authors judged the handling of the Insyte Autoguard as significantly safer than the other two cannulae with less blood contamination recorded.

Safety Mechanisms

The cannulae used in this evaluation exercise are based on the following safety mechanisms:

- Needle Shield
- Needle Retraction
- Blunting Needle

Needle Tip Shield

Removal of the introducer needle automatically triggers the covering of the needle tip with either a metal clip or plastic casing. Activation of the safety mechanism requires no

additional steps beyond those used for a conventional cannula. Examples include Vaxess, Safelon, Vasofix and Introcan Safety, which are all Passive devices.

Needle Retraction

Following confirmed placement of catheter the introducer the entire needle is retracted into a protective casing.

Needle retraction can be achieved by:

- A push button trigger activates a spring mechanism retracting the needle into the protective casing (Insyte Autoguard).
- Sliding an outer plastic sleeve backwards thus withdrawing the needle into the protective casing (Protectiv Plus).
- Pulling back on a plastic grip telescopes the needle into a protective casing (Saf-T-Intima).

With all 3 devices the safety casing covers the entire length of the needle.

All of these devices require additional steps beyond those needed for activation of conventional device; they are therefore classified as Active Devices.

Self Blunting Needle

The introducer needle is automatically blunted before removal of the needle from the catheter. A squared tip slides down from the inside of the needle squaring off the sharp tip and effectively blunting the needle (e.g. Acuvance). No additional action beyond what is normally taken to use a conventional device is necessary to activate the safety mechanism; it is therefore a Passive device.

Evaluation Exercise

Recruitment

Hospitals within Lanarkshire Acute Hospitals NHS Trust (Wishaw General, Monklands and Hairmyres hospitals) were invited to evaluate cannulation devices. Few areas within these hospitals routinely used non-ported cannulae therefore additional Partner hospital trusts were approached.

These included Ninewells Hospital Dundee, Stobhill Hospital Glasgow, Glasgow Royal Infirmary, Western Infirmary Glasgow, Edinburgh Royal Infirmary, and the Dental hospital, Glasgow.

The Vasofix and Introcan Safety cannulae were released once the main evaluations were completed, additional areas within St Johns Hospital Livingston, Glasgow Royal Infirmary, Edinburgh Royal Infirmary were approached to evaluate these cannulae.

Staff were recruited from a variety of clinical areas including: A&E, Anaesthetics, Endoscopy, High Dependency Unit, Clinical Trials Research Unit, Medical Day Unit, Maternity, radiology, oncology, endocrine outpatient department, dental sedation.

Allocation of Devices

Cannulae were categorised by presence or absence of a side port and essentially split into two groups. Initially 6 safer cannulae were available for evaluation. Two cannulae were available only in a ported version, 1 cannulae had a ported and non-ported version, 2 were solely non-ported and 1 was a Y-site cannulae with extension tubing.

Staff were not allowed to choose individual devices to evaluate, only the category of devices i.e. ported or non-ported cannulae.

From evaluation forms returned staff demographics were determined.

Staff Demographics:

Most of the clinical areas with high intravenous cannulation demands have designated trained nursing staff that undertake this procedure. This is reflected in the demographics of the staff recruited (figures 12 and 13).

Very few of the areas approached reported routine use of non-ported cannulae. The oncology and haematology areas recruited do use non-ported cannulae, but again, specialist nursing staff in these areas tended to perform the highest number of cannulations.

None of the medical staff approached use non-ported cannulae, and were not keen to adopt a different system of work. Only a few medical staff agreed to try the Saf -T-Intima device.

Evaluation Period

Initially an evaluation period of 2 weeks per device was set. During this period staff were expected to reach a minimum of 10 cannulations, although higher use was encouraged. Rates of device usage was monitored, where use was found to be low the length of the study period was extended so that the users could reach at least the minimum numbers of activations.

Following completion of individual device evaluations staff completed a Utility Evaluation Form. Comparative Evaluation Forms were completed following evaluation of a group of devices.

RESULTS

The Evaluation forms were constructed to capture topics relevant to the utility of the safer cannulae. Ease of use, Patient care, Staff safety and Training were identified as issues relevant to the overall acceptance of these devices. The results are described by utility category.

Non-Ported Cannulae : Evaluation Results

Ease of Use

Table 31. Non ported cannulae : ease of use

	Insyte Autoguard (29)	Protective Plus (36)	Saf-T-Intima (43)
No. of uses till comfortable with device			
< 5 Uses	48.1%	45.7%	70%
5-10 Uses	18.5%	14.3%	12.5%
11-20 Uses	0	2.9%	2.5%
Never	33.3%	37.1%	15%
Users reporting change in cannulation technique	69%	72.2%	41.9%
Users reporting device taking longer to use	75.9%	69.4%	35.7%
User reporting rapid visualisation of flashback	65.5%	80.6%	79.3%
Safety device use requiring additional dexterity (compared with conventional cannulae)	75%	75.6%	28.6%
Easily secured to patient	60.7%	45.7%	92.9%
Users preferring to use conventional cannulae	78.6%	73.5%	42.5%

All of the products in this group are active devices, and as such will require additional steps to ensure correct activation of the safety feature. As a consequence of this the method of use may differ from that of conventional cannulae.

Participants were asked to indicate the number of devices used before feeling comfortable with the product. Over 45% of users of Protective Plus and Insyte Autoguard reported feeling comfortable using the safety device with 5 or less uses. 70% of Saf-T-Intima users indicated feeling comfortable with 5 or less uses. Approximately one third of the users of the Insyte Autoguard and Protective Plus cannulae indicated that during the evaluation period they never felt comfortable using those devices. Only 15% of Saf-T-Intima users reported never feeling comfortable with the device during the study period.

The additional steps necessary to use the device may result in an increase in operation time. 75.9% of Insyte Autoguard and 69.4% of Protective Plus users indicated that the device took

longer to use than the device they routinely use. Only 35.7% of Saf-T-Intima users reported an increase in length of time to use.

The presence of blood flashback indicates the correct placement of the catheter. Protectiv Plus (80.6%) had the highest report of rapid visualisation of flashback, followed by Saf-T-Intima (79.3%) then Insyte Autoguard (65.5%).

All of the cannulae in this section require user deployment of the safety feature. The mechanism of activation is unique to each device; consequently it is reasonable to assume a change in the functionality of each cannula. 75.6% of users of the Protectiv Plus cannulae and 75% using the Insyte Autoguard indicated that using this product required increased user dexterity when compared with their conventional cannula, with 28.6% of Saf-T-Intima reporting likewise.

The wing structures are used to secure the cannulae and helps prevent the catheter becoming dislodged. The Insyte Autoguard and Protectiv Plus cannulae are available with or without wings; all of the cannulae evaluated incorporated the winged design. The wings of the Protective Plus and Insyte Autoguard are noticeably smaller than those of the conventional cannula. Less than half the users (45.7%) of the Protectiv Plus reported that the cannula was easily secured to patient; 60.7% of staff evaluating the Insyte Autoguard indicated the device was easily secured.

The Saf-T-Intima, which is a butterfly-winged cannula, has wings visibly larger than those of the other two cannulae, 92.9% of users reported this cannula as easy to secure.

Staff were asked if they thought that the safer cannulae would help prevent needlestick injuries. User confidence was generally positive with 75% of Insyte Autoguard, 88.1% of Saf-T-Intima and 88.6% of Protectiv Plus users indicating confidence that these devices would help reduce needlestick injuries.

Even with fairly high user confidence the acceptance of these devices appears low with only 21.4% of Insyte Autoguard and 26.5% of Protectiv Plus users indicating a preference to use this device over their 'usual' product. The Saf-T-Intima fared better with 57.5% of users indicating a preference to use this product over their usual device.

Patient Care

Table 32. Non ported cannulae and patient care issues

	Insyte Autoguard	Protective Plus	Saf-T-Intima
Increased attempts at vein puncture	37.9%	61.1%	9.3%
Users finding trial device causing more pain/trauma	10.7%	13.9%	4.9%

From the patient care perspective the main considerations are that safer devices should be at least equivalent to, or preferably better than conventional devices. The device should not result in an increase in the attempts at venepuncture and the patient should not be subjected to additional pain or trauma through using these devices.

Staff were asked if by using the safer device they found an increase in the number of attempts at venepuncture. Users of Protectiv Plus (61.1%) indicated an increase in the number of venepuncture attempts, followed by 37.9% of Insyte Autoguard and 9.3% of Saf-T-Intima users.

The design of the study did not allow for collection of patient pain data. To estimate if there was any increase in pain associated with using these safer devices staff were asked their opinion on whether the safer cannulae caused additional pain or trauma to the patient.

13.9% of Protective Plus and 10.7% of Insyte Autoguard users indicated that, in their opinion, the safer device did cause additional pain or trauma. Only 4.9% of Saf-T-Intima users judged the device caused additional pain or trauma to the patient.

Safety

Table 33. Non ported cannulae and safety

	Insyte Autoguard	Protective Plus	Saf-T-Intima
Safety Mechanism not deployed	2	1	5
Product Failure	1	0	4
Users believe device will help reduce needlestick injury	75%	88.6%	88.1%

It is theoretically possible to use all 3 non-ported safety cannulae without fully deploying the safety mechanism. There were 5 occasions where the Saf-T-Intima users reported the safety mechanism not being deployed with four episodes attributed to product failure. There was one report where the user indicated they were ‘not using the device properly’.

With the Insyte Autoguard there were 2 occasions where the safety mechanism was not deployed. One was reportedly due to product failure; the other was attributed to the operator choosing not to deploy the safety mechanism. It was not clear from the user comments why they chose not to deploy the safety mechanism.

The Protective Plus had one reported case where the safety mechanism was not used. The user stated it was possible to withdraw the needle without engaging the safety mechanism; it was not clear from their comments if indeed they did and their reason for choosing to do so.

The Saf-T-Intima includes a clamp that can close the extension tubing to reduce blood contamination. Neither the Insyte Autoguard nor the Protective Plus cannulae incorporate a luer cap. Consequently 86.2% of Insyte Autoguard users and 70.6% of Protective Plus users indicated presence of blood flow from cannulae after needle was removed and prior to IV line connection. 65.2% of the Saf-T-Intima users reported no blood seepage following needle removal.

Users were asked if they thought the safer cannulae would reduce the risk of needlestick injury. 75% of Insyte Autoguard, 88.6% of Protective Plus and 88.1% of Saf-T-Intima users believed the safer devices would reduce the risk of sharps injury.

There were no reported needlestick injuries from any of the safer non-ported cannulae used in the evaluation exercise.

Training

Table 34. Non ported cannulae and training issues

	Insyte Autoguard	Protective Plus	Saf-T-Intima
Grade device as self evident to operate (training not required)	11.1%	16.7%	2.4%
Minimal Training Required	44.4%	33.3%	66.7%
Hands on Training Essential	44.4%	50%	31%

All of the non-ported cannulae are functionally different from conventional products. This is reflected in the users perception of the training needs required for safe and effective operation.

Only 2.4% of Saf-T-Intima, 11.1% of Insyte Autoguard and 16.7% of Protective Plus users considered the device as self-evident to use. Hands on training was considered essential by 50% of Protective Plus and 44.4% of Insyte Autoguard users.

Staff using the Saf-T-Intima indicated that 66.7% would require minimal training, in the form of poster or literature, as the mechanism of use was not self-evident. Hands on training was judged essential by 31% of users.

Ported cannulae : Evaluation Results

Ease of Use

Table 35. Ported cannulae: ease of use

	Vaxess (65)	Acuvance (79)	Safelon (27)
No. of uses till comfortable with device			
< 5 Uses	29.5%	64%	57.7%
5-10 Uses	19.7%	22.7%	19.2%
11-20 Uses	0	2.7%	3.8%
>20 Uses	1.6%	1.3%	0
Never	49.2%	9.3%	19.2%
Users reporting change in cannulation technique	57.1%	35.1%	30.8%
Users reporting device taking longer to use	82.5%	33.3%	52%
User reporting rapid visualisation of flashback with safety device	64.5%	49.4%	76%
Safety device use requiring additional dexterity (compared with conventional cannulae)	91.4%	39.7%	64.1%
Easily secured to patient	80.4%	96.1%	92.6%
Users preferring to use conventional cannulae	96.8%	60.3%	65.2%

All of the cannulae evaluated in this section are passive devices and triggering of the safety mechanism should be automatic. Some cannulae may require a tug to detach the needle casing from the catheter, other devices may be structurally dissimilar to conventional devices and this may be reflected in the device performance.

Approximately one third of the Safelon and Acuvance users reported a change in cannulation technique when using these products. This figure was highest in the Vaxess group with 57.1% of users reporting a change in cannulation technique.

The number of uses to comfort showed that 64% of Acuvance and 57.7% of Safelon users were comfortable with the product with 5 or less uses. 29.5% of Vaxess users were reportedly comfortable with 5 or less uses. 49% of Vaxess users reported never becoming comfortable with the product during the course of the evaluation.

33.3% of Acuvance and 52% of Safelon users reported that the cannulae took longer to use when compared with conventional cannulae. In 82.5% of cases the users reported an increase in length of time to use when using the Vaxess cannulae.

The Safelon had reportedly better visualisation of flashback with 76% of users indicating rapid visualisation of flashback, 64.5% of Vaxess users reporting similar experience. Only 49.4% of Acuvance users reported a rapid visualisation of flashback. This was considerably lower than with the Safelon and Vaxess.

It is reasonable to expect that with passive devices there should not be an increase in manual agility required to use these products. Over 90% of Vaxess users and 64.1% of Safelon users stated that this product required increased dexterity to use when compared with their usual device. Only 39.7% of Acuvance users reported the device as requiring more dexterity to use.

Users reported that all three cannulae, Vaxess (80.4%), Acuvance (96.1%) and (Safelon 92.6%), were easily secured using either an IV dressing or tape.

Patient Care

Table 36. Ported cannulae and patient care issues

	Vaxess	Acuvance	Safelon
Increased attempts at vein puncture	45.2%	19%	12%
Users finding trial device causing more pain/trauma	35.5%	10.5%	7.7%

Participants were asked if by using the safety device users incurred an increase in the attempts at gaining venous access. 81% of Acuvance and 88% of Safelon users reported no increase in the number of attempts to successfully gain venous access.

However 45.2% of Vaxess users reported an increase in the number of attempts to gain venous access.

35.5% of Vaxess users felt that this cannula could possibly result in an increase in pain or trauma experienced by the patient. Only 7.7% of Safelon and 10.5% of Acuvance cannulae users believed patients experience more pain (or trauma) from the use of these devices.

Safety

Table 37. Ported cannulae and safety

	Vaxess	Acuvance	Safelon
Stoppage of blood flow achieved after needle removed	21.1%	32.1%	13.6%
Safety Mechanism not deployed	13	3	2
Product Failure	7	1	2
Believe device will help reduce needlestick injury	84.5%	73.4%	88.5%

All the devices evaluated in this group are passive and should, in theory, activate automatically. However 12 users of the Vaxess cannula reported instances where the safety mechanism was not deployed; 7 were judged by the user to be due to product failure. Three users of the Acuvance cannula reported occasions where the safety mechanism was not activated, one of these incidents was attribute to product failure.

Two users of the Safelon cannulae reported incidences where the safety feature was not deployed, both cases were reportedly due to product failure.

User confidence in the devices ability to reduce risk of needlestick injury was high with 73.4% of Acuvance, 84.5% Vaxess and 88.5% of Safelon users believing the device could reduce the risk of exposure incidents.

Training

Table 38. Ported cannulae and training issues

	Vaxess	Acuvance	Safelon
Grade device as self evident to operate (training not required)	13.3%	37.2%	32%
Minimal Training Required	38.3%	53.8%	56%
Hands on Training Essential	48.3%	9.0%	12%

The activation of passive devices is automatic and should not require additional input from the user thus their method of operation should be self-evident. 37.2% of Acuvance and 32% of Safelon users judged that training was not required as the devices were intuitive to use. In contrast, only 13.3% of Vaxess users considered the device as intuitive to use.

56% of Safelon, 53.8% of Acuvance and 38.3% of Vaxess users would be happy to use the cannulae following minimal training in the form of literature or poster instruction. Whereas 48.3% of Vaxess users indicated a preference for hands on training prior to using the product, only 9% of Acuvance and 12% of Safelon users feel hands on training would be essential prior to using this device.

Comparative Evaluation Forms

34 users completed comparative evaluation forms on different cannulae. None had evaluated all the devices, with most comparing 3 devices and some comparing 4. Users were asked to nominate their most preferred device and rank the devices in order of preference.

Below is a summary of the proportion of users ranking each device as their first preference, when that device was included in a comparative evaluation.

Table 39. Ranking order of most preferred cannulation devices

Device	Number of comparative evaluations	Number (%) where user named the device as their most preferred
Introcan safety (ported)	9	5 (56)
Acuvance (Ported)	24	12 (50)
Safelon (Ported)	17	7 (41)
Saf-T-Intima (non-ported)	12	4 (33)
Protectiv Plus (non-ported)	14	2 (14)
Vaxess (Ported)	14	1(7)
Insyte Autoguard (non-ported)	18	0

Allocating values to the devices when ranked in order of preference is complex, since different combinations of devices were ranked, whilst in some instances 3 or 4 different devices were compared. However, allocating points to devices on a sliding scale and calculating mean values allows some meaningful comparison (When 4 devices compared, on a 4-3-2-1 scale, when 3 devices compared on a 3.5,2.5,1.5 scale).

The table below summarises the findings with the devices ranked in order

Table 40. Ranking of cannulation devices by user preference

Device	Comparative evaluations	Total points	Mean points	Rank
Acuvance	23	74	3.22	1
Introcan Safety	9	27.5	3.06	2
Safelon	17	45	2.65	3
Saf-T-Intima	12	28	2.33	4
Protective Plus	14	29.5	2.11	5
Vaxess	14	29.5	2.11	5
Insyte Autoguard	18	33.5	1.86	7

DISCUSSION

User Comments

We have included some users comments for each product. Although opinions are subjective it is important to gauge users views on these devices as some of these issues may not be captured by the evaluation forms. The comments are grouped into positive and negative comments and all views are represented

User Comments on Non-Ported Cannulae

User comments on Ported Cannulae

Summary points of Safer Cannulae

Non Ported cannulae

Insyte Autoguard

- Product literature, good range of gauges available.
- Excellent level of support and training from the Becton Dickinson representative.
- Compatibility with lipids, chemotherapeutic agents.
- The Insyte Autoguard packaging does not include a luer cap to close off the end of the cannulae, there is a risk of blood spillage and portal of infection.

- The wings were noticeably smaller than other intravenous cannulae. Nursing staff highlighted the difficulty in securing device because of this, risk of dislodging cannulae.
- There were reports of needle casing becoming blood filled.
- There is no control over speed of retraction.
- Users ranked it lowest of all in device comparisons

This device is rated as **Not Recommended**

Protectiv Plus

- Product literature, good range of gauges available.
- Excellent level of support and training from the Johnson and Johnson representative.
- Compatibly with lipids, chemotherapeutic agents.
- This device comes without a luer cap/bung. Consequences for blood spillage and infection control issues.
- Small wings similar size to Insyte Autoguard. Poor securing of cannulae, risk of cannula dislodging, concern with areas these non ported cannulae used, chemotherapy agents, also many of the patient have poor venous access.
- Could in theory be used without activating the safety mechanism.
- Can control speed of needle retraction.

This device is rated as **Acceptable**.

Saf-T-Intima

- Product literature, good range of gauges available.
- Excellent level of support and training from Becton Dickinson representatives.
- Compatibly with lipids, chemotherapeutic agents.
- Good for specialised areas use. Staff using it for subcutaneous infusions liked it.
- Concerns that telescoping mechanism could pull out catheter.
- ‘Big’ wings easily secured. IV tubing can be clamped off to minimise blood contamination.
- Anaesthetic staff did not like it due to lack of port.
- Clip can close off line preventing blood splash
- Overall favourable user evaluation, ranked best in non-porting devices comparisons

This device is rated **Preferred**. It is useful in niche areas/procedures

Ported Cannulae

Vaxess

- Product literature and good range of sizes available.
- Adequate support from NMT in terms of training.
- Good range of cannulae sizes. Comes with a ported and non-porting version.
- Staff consistently criticised it and it ranked poorly in comparative evaluations
- Users found it difficult to disengage the needle and safety mechanism from the catheter. The force of the tug to separate the two could, according to users dislodge the catheter. Also this increased the length of time to insert the cannulae, particularly important where rapid venous access is required.
- The side’ whiskers’, which lie at either side of the needle, can throw a shadow over the vein making inspection difficult.
- Users commented on the appearance of the device, noting that the appearance can startle patients.
- Overall consensus was this device was awkward to use.

This device is rated **Not Recommended**.

Safelon

- Product literature, good range of gauges available.
- Excellent level of support and training from Becton Dickinson representative
- Compatibility with lipids, chemotherapeutic agents.
- Blood spill is a concern
- If needle is not fully retracted when disconnected the needle tip can poke out of safety sheath.
- Simple to use-appears intuitive.

This device is rated **Acceptable**. Caution is required in that the needle must be fully retracted prior to disconnection.

Acuvance

- Product literature, good range of gauges available.
- Excellent level of support and training from Johnson and Johnson representative.
- Compatible with lipids, chemotherapeutic agents.
- Visualisation of flashback is slow, especially in the narrower gauges.
- Simple to use.
- Rated highly in comparative evaluations. Achieved highest ranking overall.

This device is rated **Preferred**.

bBraun Cannulae

The devices below were not evaluated to the same degree as other cannulae due to their becoming available late in the evaluation period. However they are included in the report as the limited user evaluation was very positive and their utility looked promising.

Introcan Safety (Non-Ported)

- Product literature, good range of gauges available.
- Excellent level of support and training from bBraun representative.
- Compatibility with lipids, chemotherapeutic agents.
- Good wing size
- Passive device
- Unfortunately there was less opportunity for user feedback, but the device was ranked highly in comparisons (see above) by users, similarly to the Acuvance
- Investigators benchtop assessment rated highly

Vasofix (Ported)

- Simple to use
- Product literature, good range of gauges available.
- Excellent level of support and training from bBraun rep
- Compatibility with lipids, chemotherapeutic agents.

Both bBraun devices rate well on the basis of benchtop evaluation and some limited user evaluation. In comparison with other devices there was limited user feedback so a formal rating is not allocated, but these devices deserve serious consideration.

4.5 Syringes

Conventional Hypodermic Syringes and Injection Needles

Combined hypodermic needles and syringes have many clinical applications including:

- Injection therapy. (intramuscular, subcutaneous, intra-articular, intralesional or intravenous)
- Blood sampling. Arterial and venous blood collection (the authors acknowledge that a closed system is recommended for venous blood collection).
- Aspiration of fluids; haematoma, ascites, synovial fluid.
- Reconstitution of medication.

Syringes also have many other applications that do not include the use of a hypodermic needle, these include:

- Administration of medication through intravenous catheter port or intravenous connector.
- Irrigation of wounds.
- Inflating catheter balloons, inflating cuffs.
- Withdrawing blood from intravenous and arterial lines.

It is impossible to estimate the proportion of syringes purchased that will be used for procedures where they will not come into direct contact with a patient or require the use of a needle. Given some of the uses above it is reasonable to expect that a proportion of syringes and hypodermic needles will not come into contact with a patient.

EPINet Data

According to the Royal College of Nursing EPINet data³³ for 2002, the device responsible for the highest amount of needle stick injuries is the disposable syringe, more than a quarter of all sharps injuries are caused by disposable syringes.

In Lanarkshire Acute Hospitals Trust needlestick injury data for 2002 revealed that 19 injuries were attributed to hypodermic syringes in the 3 Acute Trust hospitals. Overall, hypodermic syringes accounted for the highest number of sharps injury at 19.8% of all reported percutaneous injuries.

According to Lanarkshire Acute Hospital Trust procurement data an estimated 650 000 2.5ml hypodermic syringes are purchased annually. This gives an incidence rate of 2.9 per 100 000 syringe devices purchased and is similar the data of Ippolito outlined in the Epidemiology section.

Approximately 1 110 000 green hypodermic needles are purchased by this Trust. Assuming that each of these needles is attached to a syringe and used on a patient this gives a reported injury rate of 1.7 per 100 000 needles used.

Risk Potential

Hypodermic needle and syringe associated needlestick injuries may occur during use, on withdrawing the needle from the patient, during disposal, or post disposal through incorrect disposal. Recapping of needles, although not recommended practice, also contributes to needlestick injuries. Additionally, inserting a needle through the port of infusion bag or rubber bung of venous blood collection bottle can lead to injury.

Safer Alternatives

Internet and literature searches revealed 9 safer syringe alternatives.

Table 39. Safety Syringes Available to UK Healthcare Market

	Safety Mechanism	Purchased Unit	Additions*	Price
Magellan (Tyco Healthcare)	Needle Shield	Needle Shield	Syringe	9.3p
Monoject- (Tyco Healthcare/Sherwood Medical)	Needle Shield	Syringe Barrel Shield	Needle	13p
Needle-Pro- (SIMS Portex)	Needle Shield	Needle Shield	Syringe	12p
Safetyglide (Becton Dickinson)	Needle Shield	Needle Shield	Syringe	14p
SecureGard (Safegard Medical)	Needle Retraction	Needle and Syringe	Not required	10p
Smartlock (Alaris Medical)	Needle Retraction	Needle and Syringe	Not required	18p
Stopstick (Griffiths & Neilson)	Needle Retraction	Needle and Syringe	Not required	22p
Vanishpoint (Retractable Technologies)	Needle Retraction	Needle and Syringe	Not required	39p
Zerostick Safety Syringe (New Medical Technology -NMT)	Needle Retraction	Needle and Syringe	Not required	36p

*Some safety devices are supplied as a single unit and require the addition of a conventional hypodermic needle or syringe to make a functional unit.

Product Review

Published evidence on the effectiveness of safety syringes to reducing needlestick injury is sparse. All syringe manufacturers were asked to provide evidence that their product was effective in reducing needlestick injury. Only Tyco Healthcare/Sherwood Medical provided evidence of their products effectiveness.³⁹

Efficacy Data

Younger et al³⁹ evaluated the impact of a 3cc shielded safety syringe (Monoject Safety Syringe, Sherwood Medical) on needlestick injuries among healthcare workers in 3 US medical facilities. Following the training period, employee health departments recorded and monitored all needlestick injuries among healthcare workers for a period of 60 consecutive days. The study showed that use of a shielded safety syringe significantly reduced the occurrence of needlestick injuries involving 3cc syringes. The overall rate of needlestick injuries involving 3cc syringes declined significantly from the baseline (overall injury rate of 14 per 100 000 inventory units (baseline) to 2 per 100 000 for the study phase).

Orenstein et al⁴⁰ sought to determine the effectiveness and direct cost of two protective devices, one of which was a shielded 3ml safety syringe: Safety-Lok (Becton Dickinson). Introduction of the safety devices saw a reduction in needlestick injury from 33 in the 6 months before to 14 in the 6 months after the introduction of the safety devices, There was an overall reduction in needlestick injury rates, (0.785 to 0.303 NSI per 1000 healthcare workers) but no statistical significant reductions could be attributed to the safety devices. They estimated the direct cost of each needlestick injury prevented at \$789.

Zakrewsha et al⁴¹ introduced safety syringes in a dental setting resulting in a reduction in avoidable needlestick injuries from 12 per million hours worked in the 3 years before introduction, to 0 per million hours worked in the second year of the introduction.

Safety Syringes-Mechanism of Use

The protective safety mechanisms are based on two different approaches, Needle Shielding and Needle Retraction.

Needle shielding:

- A hinged needle shield is attached to the hypodermic needle. Following use the shield is placed over the needle by:

- Applying digital pressure on the hinge mechanism to manoeuvre the shield cover over the needle tip e.g. Magellan and Safety Glide.
- Placement of the needle shield on a flat surface and levering the needle into the safety shield e.g. Needle-Pro.
- A protective sheath encases the syringe barrel and extends over the hypodermic needle. This shield can temporarily cover the needle during transportation of syringe to patients bedside, and can be permanently locked following injection e.g. Monoject

All of these shielding mechanisms require additional user activation and are categorised as Active Devices.

Needle Retraction

After administration of the syringe contents the hypodermic needle retracts to the inside of the barrel of the syringe. This can be triggered automatically through 'normal' use of the syringe, or through an active input from the user.

- **Active Retraction**-when the syringe plunger is pressed to expel the contents the base of the plunger attaches onto the needle. Pulling back on the plunger will cause the needle to retract into the barrel of the syringe.
The SecureGard, Smartlock and Stopstick syringes all employ this mechanism.
- **Passive Retraction**-Contact on the base on the syringe with the plunger triggers a spring mechanism which automatically retracts the hypodermic needle. No additional steps need to be taken to activate the safety mechanism. E.g. Vanishpoint and Zerostick syringe.

Evaluation Exercise

During the Pre-Evaluation phase all of the syringes were tested to determine their suitability for use in a clinical setting. All of the devices were deemed suitable for use.

With 9 syringes in this group we could not expect staff to evaluate such a high number of devices. The syringes were split into 3 groups of 3 devices. The suppliers of the Stopstick Syringe (Griffiths and Nielsen) were unable to provide the needle gauge and syringe sizes to match the needs of our users, this syringe could not be included in the evaluation exercise.

Recruitment was targeted at areas with predicted high usage of needles and syringes. Participants were expected to reach a minimum of 10 uses of the safety device during the evaluation period. The intention was to have approximately 50 recruits per syringe, splitting the devices into 3 groups would result in 150 users having to be recruited.

Staff Demographics

Overall 168 personnel, all nursing staff, were recruited to evaluate the safety syringes.

The participants were recruited from the following trusts:

- Lanarkshire Acute Hospitals Trust, Lanarkshire Primary Care Trust,
- Fife Acute Hospitals Trust, Fife Primary Care Trust,
- North Glasgow University Hospitals NHS Trust, South Glasgow University Hospitals NHS Trust

The distribution of clinical areas from which nursing were represented is given in Table 40.

Table 40. Clinical areas of nursing staff in syringe evaluation

Health Visitors and District Nurses	53
Midwifery	45
Acute Surgical Receiving	18
Psychiatric Nurses	8
General Practice Treatment room	5
Community Psychiatric Nurses	8
General Medical Surgical IDU Gynaecology	31

Training and Safety

Prior to safety syringe use device company representatives endeavoured to provide training in the safe and effective use of their product. Participants were advised to discontinue syringe use if they considered it put them at risk of needlestick exposure or was in any way detrimental to patient care.

Device Evaluation

Participating staff were asked to evaluate 3 individual syringes in a sequential manner. Users were not allowed to select the syringes for evaluation, but were allowed to reject devices that would not be suitable for their clinical needs.

The projected evaluation period of 2 weeks per device was considerably underestimated. Syringe use was monitored midway through the first evaluation period. The majority of users reported low use, and many stated they had not had the opportunity to use the syringe at all. Thus, the evaluation period was extended to 4 weeks and later to 7 weeks. Even after this length of time some areas reported low and even no opportunity to use the device.

According to the staff this low usage was attributed to:

- Many routine injections now come as a pre-filled system (e.g. Enoxiparin, Hepatitis B immunisation).
- Use of patient controlled analgesia pumps for a patient returning from theatre negates the need for IM analgesia.
- Increasing numbers of nursing staff are trained in the intravenous administration of medications.

RESULTS

Uptake of syringe use was disappointingly low and very few evaluation forms were returned. Caution must be therefore be taken when interpreting user feedback. **Only those devices where 10 or more evaluation forms were returned are shown:**

The evaluation results are reported by utility category, i.e. Ease of Use, Safety (staff and patient) and Training.

Table 41. Ease of use : syringe devices

	Safety Syringes				
	Smartlock (23)	NMT Safety Syringe (26)	SecureGard (23)	Monoject (12)	Safetyglide (22)
Able to activate safety mechanism using 1 handed technique	50%	96.1%	81.8%	25%	95.4%
Syringe offers a clear view of contents	66.7%	100%	100%	100%	95.4%
Syringe takes more time to operate than conventional syringe	90.5%	28%	22.7%	100%	50%
Confident that dosage drawn up was accurately delivered	47.6%	96.1%	95.4%	100%	100%
The design of the safety syringe prompts its use	52.6%	92%	90.9%	50%	68.2%
No. of staff preferring to use trial syringe over conventional syringe	5.3%	83.3%	63.1%	0%	22.7%
Accidental triggering of safety mechanism.	55%	7.7%	36.3%	50%	15%

Figure 14. Charts 1-5 Show the Ease of Use Grading for the Smartlock, Securegard, NMT, Monoject and Safetyglide syringes.

Ease of Handling Rating

The Monoject safety syringe incorporates a barrel shield mechanism which requires manual deployment (using two handed technique) to cover the hypodermic needle; users have given this syringe a mean ease of handling rating 2.67.

The manually retractable Securegard and Smartlock syringes had a mean Ease of Handling rating of 6.38 and 2.95 respectively. The plunger on the Smartlock syringe must engage with a thick clip at the base of syringe, this takes additional force, whereas the plunger on the SecureGard syringe engages with a small clip on the needle and requires considerably less force to ensure attachment.

The safety mechanism on the Safetyglide shield is located on the hypodermic needle and is deployed using digital pressure on the shield hinge, the syringe was graded 5.91 with regards to ease of handling.

The hypodermic needle of the NMT safety syringe is automatically retracted into the syringe barrel following emptying of the syringe chamber; users graded this syringe at 7.10 with regards to ease of handling.

Ability to Activate Mechanism Single Handed

All but one of the NMT safety syringe users (96.1%) were reportedly able to activate the safety mechanism, which relies on automatic needle retraction, using a one handed technique.

The Safetyglide is deployed by digital pressure on the needles shield to cover the hypodermic needle, Over 95% of the Safetyglide users reported being able to activate the hypodermic needle shield using one hand

The Smartlock and Securegard syringes both require manual retraction of the plunger to internalise the hypodermic needle, 50% and 81.3% of users respectively achieved one handed activation of the safety mechanism.

Single-handed activation was found to be considerably lower with the Monoject syringe with only 25% of users reportedly able to activate using a one handed technique. According to the product literature a 2 handed technique is necessary for deploying the safety mechanism.

Clear View of Contents

All but one of the safety devices offers a clear view of the syringe contents. Only 66.7% of the Smartlock users reported that the syringe offered clear view of contents. The presence of an outer sheath covering the length of the outer barrel may reduce the visibility of the syringe contents.

More Time to Operate

The Monoject and Smartlock syringes require additional user input to activate the safety mechanism. All of the Monoject users and 90.5% of Smartlock users reported these devices as taking longer to operate compared with conventional syringe.

The NMT automatically retracts the hypodermic without any additional user input, but 28% claimed this product took longer to use than a conventional syringe.

22.7% of Securegard syringe users claimed this took longer to use than conventional syringe, this device is manually retractable.

Accuracy of Delivery

All of the staff using the Monoject and Safetyglide syringes and more than 95% of NMT Safety Syringe and SecureGard users were confident that the dosage of medication drawn up was accurately delivered.

Only 47.6% of Smartlock users were confident of the accuracy of delivery of syringe contents. One possible explanation for this may be the graduation marks on the outside of the syringe run on the opposite way to the above syringes (additionally the syringe fills from the back of the syringe barrel).

Design Prompts Use

92% of users of the NMT Safety Syringe (with automatic retraction) claimed the syringe design prompted its safety feature use.

The Tyco Monoject uses a barrel shield and only 50% of users felt its design prompted use. Both Smartlock and SecureGard are manually retractable but only 52.6% of Smartlock users agreed its design prompts use compared with 92% of SecureGard users.

Preferring to Use Trial Device

Generally user acceptance for the safety syringes was low. None of the Monoject users would choose to use this device over the conventional syringe and only 5.3% of Smartlock and 22.7% of Safetyglide would prefer to use these devices compared with conventional devices.

Just over 60% of the SecureGard syringe users would prefer to use this safety syringe. However 78.9% of NMT syringe users preferred this when compared with a convention needle and syringe.

Patient Care/Staff Safety

Table 42. Patient pain and staff safety : syringe devices

	Safety Syringes				
	Smartlock (23)	NMT Safety Syringe (26)	SecureGard (23)	Monoject (12)	Safetyglide (22)
Increase in Pain/Trauma	35%	11.5%	13.6%	9%	4.5%
Reports of blood splash/splatter	9.5%	0	4.5%	8.3%	0
Safety Mechanism not deployed	52.4%	11.5%	31.8%	25%	14.3%
Product Failures	7	1	2	1	1
Chose Not To	3	1	-	2	0
Other	1	0	3	0	2
Reported Needlestick injury	3	1	0	0	2

Pain/Trauma

Few staff evaluating the shielded syringes associated the use of these syringes with increased pain or trauma to the patient (Monoject Syringe-9%, Safetyglide-4.5%). With these devices the safety mechanisms are activated after the needle is withdrawn from the patient.

The retractable NMT Safety syringe (Passive) and SecureGard (Active) can be activated while the needle is still in the patient. Users perception of the pain caused was broadly similar with 11.5% of NMT Safety Syringe user and Securegard 13.6% but higher than those devices activated once removed from the patient.

The Smartlock syringe safety feature, although retractable, should be withdrawn from the patient before deploying the safety mechanism. Engaging the safety requires additional force and if done while in-situ may account for increase in users perception of pain experienced by the patient (35%).

Blood Contamination

There were low reports of blood splash or splatter upon using the syringe safety mechanisms. The highest was associated with the Smartlock syringe, with 9.5% of users reporting blood splash. There were no reports of blood splash or splatter from the Safetyglide or NMT Safety Syringe users.

Non-Use of Safety Mechanism

Each of the evaluated syringes had reports where the safety mechanism was not used. More than half of the Smartlock users reported incidents where the safety mechanism was not deployed. Seven users attributed this to product failure; 3 users opted not to use the safety mechanism, however no reasons were given.

Next in terms of product failure was the SecureGard syringe, 2 users reported the mechanism did not engage due to product failure. The NMT Safety Syringe, the Monoject and the Safetyglide had 1 report each of product failure. 2 users of the Monoject and Safetyglide chose not to deploy the safety mechanism (again their reasons for doing so were not disclosed).

Accidental Triggering

The Monoject and Smartlock safety features were reported as being accidentally triggered at some point during the evaluation period by around half of their users. The Tyco shield can be

deployed but not locked while transporting the syringe to the patient's bedside, accidental locking of the mechanism was reported by 50% of users. More than half of the Smartlock users reported accidental triggering of the safety mechanism; this device is unusual in that it fills from the back of the syringe and expulsion of the air bubble may trigger the mechanism.

Accidental activation of safety mechanisms may occur when the base of the plunger connects with the triggering mechanism. 36.3% SecureGard mechanisms were accidentally triggered, whilst only 7.7% of NMT syringe users reported accidental activation of the safety mechanism. 15% of the needle mounted Safetyglide shields were accidentally triggered, here the safety mechanism is fixed onto the hypodermic needle and requires users digital pressure to engage the sheath.

Needlestick Injuries

There were 6 reports of needlestick injuries during the evaluation of the safer syringes. Three staff using the Smartlock syringe reported sustaining a needlestick while using this product, all of the injuries occurred prior to patient use. Similarly with the Safetyglide, two users reported needlestick injury when using this syringe, again these injuries occurred prior to contact with patient. There was one reported needlestick injury associated with the use of the NMT Safety Syringe, the user did not disclose details of the exposure incident. There were no reported needlestick injuries with the Securegard or Monoject syringe.

Training

With the Smartlock and Monoject safety syringes the majority of their users indicated that hands on training would be essential prior to the use of these devices. The Smartlock syringe fills from the back and has graduation marks running in the opposite direction from conventional syringes, this may explain the high proportion of users claiming that hands on training is essential prior to this device use. The Monoject may be easily inadvertently locked when the user intends just to cover the hypodermic needle, practice is needed to become familiar with this mechanism and this is reflected in the training views of the users.

Safetyglide, SecureGard and NMT Safety Syringe had the highest proportion of users stating that minimal training would be necessary for safe and effective use of these syringes. None of the users of the NMT Safety Syringe or SecureGard thought the device was self evident to use and all considered some form of training would be necessary.

Figure 15. Training issues : syringe devices

Review of limited feedback results:

Magellan (Tyco Healthcare)

Four completed evaluation forms were returned.

Three users indicated feeling comfortable using this syringe with 5 or less uses, the other user reported that 5-10 uses were required before reaching comfort. The device appears easy to use with 2 staff grading the device as 9/10 and 1 user grading the syringe as 10/10 with regards to ease of handling (grading scale: 1=Poor to 10=Easy).

All of the users reported a change of injection technique through using this product, but all reported a clear view of contents and all were confident that the syringe contents were accurately delivered. The device appears intuitive to use with all 4 users claiming the design of the safety feature prompted its use. There were no reports of blood splash or additional pain or trauma, or accidental triggering of this syringe.

All 4 users would prefer to use the Magellan rather than a conventional device and all were confident that this safety device would reduce risk of needlestick injury. There were no reports of users sustaining needlestick injury using this product.

Investigators Comments on Magellan Safety Device: (from Bench-top testing)

This safety device appeared intuitive to use, the mechanism has a smooth action and activation of the safety feature is easily achieved using a one handed technique. The safety mechanism does not obscure the syringe contents nor does it interfere with the injection process.

The Magellan is sold as a needle and shield unit, this can therefore be fitted to any Luer lock/luer slip syringe. One advantage of this is that a conventional needle can be used to draw up and the safety needle can be used to inject. The user's hand remains behind the needle, however the user's finger moves the shield towards the needle to activate the mechanism. The safety feature is not automatic and the onus is on the user to ensure activation; with this type of device there is the concern that the user omits or forgets to deploy the mechanism.

Needle-Pro (SIMS Portex)

8 evaluation forms were returned, but 4 users stated they did not have the opportunity to use the safety device. All 4 users indicated feeling comfortable with this device with 5 or less uses, 2 users rated ease of handling as easy, the remaining two users graded this as a 7 and 5 (where 1=poor and 10 =easy).

All reports indicated that users believed the design of the safety feature prompted its use but three users claimed using this device would result in the change of their injection technique. Only 1 user reported accidental triggering of safety mechanism prior to its use. None of the users perceived an increase in patient pain or trauma and there were no reported needlestick injuries or reports of blood splash or splatter using this device. 3 users felt that only minimal training would be required to ensure the correct and safe use of the product. Given the choice 3 of the staff would prefer to use this syringe over their routinely used syringe.

Users comments included:

“Experience no problems with the trial of needles and felt comfortable and safe using it”
“These needles are distracting to start off with but very good as no finger is required to activate the safety feature”.

Investigator Comments of SIMS Portex Needle-Pro: (from Bench-top testing)

The safety feature requires activation on a flat surface, but in deploying needle shield fingers are not moved towards the needle tip. The safety feature is easy to engage and has a smooth activation. The shield allows a good view of syringe contents, and as it is sold as a needle shield unit, can fit onto any syringe size. It would be possible to draw up with a conventional syringe and change to the safety needle to administer an injection. Nurses are taught to swap needles especially if during drawing up the needle has to puncture a rubber topped vial (Source :Bell College of Nursing).

Vanishpoint (Retractable Technologies)

5 evaluation forms were returned.

One of the 5 users reported that the device was awkward to use and graded its handling of the device as 1, three staff graded it highly = 9. All staff reported using this device resulted in a change of their injection technique. 4/5 reported confidence that medication dose was accurately delivered and all had a clear view of syringe contents.

The action of this syringe is passive and all users indicated that the syringe design prompted its use. There were no reports of accidental triggering of safety mechanism, no reports of needlestick injury of blood splash or splatter. 1 user perceived its use as causing more pain to the patient, this may be due to the syringe safety feature being activated while the needle is still insitu.

Four of the 5 users felt use of this device would help reduce the risk of needlestick injury. Given the choice between using this syringe or the conventional syringe 2 users opted for usual device and 2 opted the for trial device, with one missing response.

Investigator Comments on Vanishpoint: (from Bench-top testing)

The safety feature is intuitive to use and no additional user input is required to activate the mechanism. Only a slight additional pressure is required to trigger the retracting spring mechanism.

The needle is activated insitu and the needle is immediately internalised to the syringe barrel. The safety feature does not impede the view of the syringe contents, and there is a smooth mechanism of activation, with only slight pressure to trigger retraction.

The needle and syringe is a fixed unit, with no opportunity to change needles.

There is no control over the speed of retraction of the needle, which could startle the patient. One can in theory withdraw the needle without activation of needle retraction if the plunger is not fully depressed.

DISCUSSION

Review of the Advantages and Disadvantages of Safety Syringes

Syringes using Needle Shielding Technology

Advantage

The safety feature is integral to the needle unit but separate to the syringe, this allows it to be attached to any size of syringe. It is possible to draw up medication with one needle, and switch over to another to inject the patient. Some staff still prefer to do this. The unit can be used for similar functions as the conventional hypodermic needle and syringe.

Disadvantage

The main disadvantage is that all are active devices requiring the user to manually deploy the safety feature; a concern would be that users may forget or opt not to use the safety feature. The external shield may get in the way when injecting.

Syringes using Retractable Needle Technology

Advantages

The needle safety mechanism is automatically activated once the syringe contents have been delivered; the needle retracts immediately into the barrel thus eliminating the exposure of needle to the user.

Disadvantages

The needles are fixed to the syringe, the hypodermic needles cannot be changed if needle becomes contaminated. The syringes cannot be used for aspiration of fluids in joints, or withdrawing blood. Active devices require the additional action to manually retract the needle. One concern is that the additional force needed to trigger the retraction may cause more pain to the patient.

CONCLUSION

With such a low return of evaluation forms these conclusions should be viewed with caution. However combined with a review of the syringe product literature and the ECRI product evaluations we are able to make the following recommendations:

Recommendations for Needle Shields

All of these devices are Active and require additional user input to activate the safety mechanism. We would recommend the use of the Magellan, Safetyglide (preferred) and Needle-Pro(adequate) devices as a safer alternative to the conventional needle and syringe.

- **Magellan: Preferred**

Easy to use.

Can be used for similar functions as a conventional hypodermic needle and syringe.

Single handed activation

- **Needle-Pro: Acceptable**

Easy to use.

Can be used for similar functions as a conventional hypodermic needle and syringe.

Needs to be activated on a flat surface.

Single handed activation

- **Safetyglide: Preferred**

Easy to use.

Can be used for similar functions as a conventional hypodermic needle and syringe.
Single handed activation

- **Monoject: Not Recommended.**

Awkward to use.

Can be used for similar functions as a conventional hypodermic needle and syringe.

Bulky for disposal.

Accidental locking prior to use.

Two handed use necessary.

Table 43. Summary Recommendations: shielded syringe and needle devices

Needle-Pro	Magellan	Monoject	Safetyglide
Adequate	Preferred	Not recommended	Preferred
12p	9.3p	13p	14p
Add syringe cost	Add syringe cost	Add needle cost	Add syringe cost

Recommendations for Retractable Needle Syringe Devices

The ideal safer mechanism is one that does not require any additional input from the user. Two of the retractable syringes fall into the category of Passive devices, however this automatic action is compromised by reduction in the range of applications for which the device may be used.

Retractable Syringe with Passive Mechanism

- **NMT Safety Syringe: Preferred**

Automatic deployment of safety feature.

Ease to use, intuitive to use

This syringe is now only available as a prefilled syringe.

- **Vanishpoint Syringe: Preferred.**

Automatic deployment of safety feature.

Ease to use, intuitive to use

Retractable Syringe with Active Mechanism

- **Securegard syringe: Acceptable .**

Manual activation of safety feature

One hand to hold the barrel, the other to retract the plunger.

- **Smartlock Syringe: Not recommended.**

Awkward to use. Bulky disposal.

Table 44. Summary Recommendations: Syringe devices with retractable needles

NMT Safety Syringe	Vanishpoint	Securegard	Smartlock
Preferred	Acceptable	Acceptable	Not Recommended
36p	39p	10p	18p

4.6 Evaluation of Theatre Devices intended to reduce sharps exposure incidents.

The Royal College of Nursing EPINet³³ data show that the operating theatre, which is second only to ward areas, is where approximately one-fifth of all reported sharps injuries occur. 10.2 % of reported injuries are attributed to sharps intended for suturing, with instruments used for cutting accounting for 6.2% of injuries.

Other sources of sharps injury (as identified in the RCN EPINet report) within the operating theatre include:

These injuries may be reduced through the modification of surgical practice and the use of safer devices.

In a review article, Loudon and Stonebridge⁴² outline modifications to surgical practice and identify safer instruments that may reduce risk of penetrating sharps injury. These include:

- No touch technique using forceps and needle holders.
- Hands free technique for passing instruments (use of instrument dish).
- Use of electrocautery for tissue dissection.
- Use of blunt-end surgical needles.
- Use of stapling devices.

During operating procedures sharps are not immediately disposed of as all instrumentation and swabs etc must be counted at the end of the surgical procedure.

i) Theatre sharps disposal devices

These are usually adhesive covered cardboard backed squares onto which sharps including scalpel blades and needles are placed for holding or disposal. The pad is folded over in half, encasing the sharp objects; it is then disposed of in an appropriate sharps container. Sharps injuries have been reported where needles have punctured sharps disposal pads. Literature and Internet searches revealed 5 sharps disposal devices that were promoted as safer alternatives.

Table 46. Safety Theatre Sharps disposal devices available to UK Healthcare market

Device	Manufacturer	Unit Cost
Disarmer*	Johnson & Johnson	£2.10
Disguard	SafeGuard Medical	£0.40
Medeurope Box*	SafeGuard Medical	£0.44
Puncture Proof Pad	Cory Bros	£0.73
Purple Turtle	Cory Bros	£0.51

*Both the Medeurope Box and the Disarmer are boxes (as opposed to pads) and incorporate a scalpel blade remover.

Literature searches revealed a lack of efficacy figures for any of these products. All devices were subject to Bench-top testing, all appeared suitable for their intended use.

Recruitment

Nursing staff from theatre departments within Lanarkshire Acute Hospitals Trust and North Glasgow University Hospital NHS Trust were approached to evaluate all 5 of the sharps disposal pads. A total of 27 theatre nursing staff were recruited from the following areas:

- Hairmyres Hospital
- Western Infirmary
- Stobhill Hospital
- Glasgow Royal Infirmary

Each product was used for a two-week period. Users were requested to achieve approximately 10 or more uses of the disposal pad during this time. At the end of each evaluation period staff were asked to complete an evaluation form.

RESULTS

Results for the Utility Evaluation forms are split by evaluation criteria Ease of Use, Safety, and Training. (Forms returned per device type in parenthesis). During the evaluation period staff were requested to attain 10 uses of each device. Anecdotal feedback from theatre nurses was staff did not like these, consequently uptake and use of these products was low. This is reflected in the mean number of uses for each pad type.

Ease of Use

Table 47. Ease of use : theatre sharps disposal devices

Ease of Use Issues	Disarmer (16)	DisGard (13)	MedEurope Box (8)	Puncture Proof Pad (13)	Purple Turtle (18)
Mean Number of Sharps pads used	5.0	4.75	5.13	5.17	4.11
Area adequate for disposal/storage of sharps	43.8%	23.1%	37.5%	69.2%	50%
Users comfortable with pad after one use	21.4%	54.5%	83.3%	63.6%	35.7%

Disposal Area

69.2% of the Puncture Proof Pad users and 50% of those evaluating the Purple Turtle indicated that the sharps pad had an adequate disposal area.

Less than half the users of the Disarmer, DisGard and MedEurope Box indicated the pad area was adequate for the disposal of sharps.

Time to Comfort

Users were asked to indicate the number of times they used the pad before feeling comfortable with it. As the overall number of uses was low we looked at the percentage of staff reportedly comfortable with the device with 1 use. Over 80% of users of MedEurope Box indicated comfort with one use, this was followed by 63.6% of Puncture Proof Pad users. Only 21.4% of Disarmer users felt comfortable with this device with one use.

Adhesive qualities of Evaluated Disposal Pads

Users were asked to grade the adhesive qualities of the pad ranging from 1 (satisfactory) to 5 (unsatisfactory). 38.5% of the Puncture Proof Pad users graded the adhesiveness of the pad as satisfactory. The only other pad graded as 1 for adhesiveness was Disarmer, 18.8%. 50% of the Purple Turtle users graded pad as a 5.

Table 48. Adhesive qualities

		User grading of the Adhesive Qualities of Sharps Disposal Pad				
		1	2	3	4	5
		Satisfactory				Unsatisfactory
PRODUCT	Purple Turtle (18)	0	3	0	6	9
	Puncture Proof Pad (13)	5	2	1	5	0
	DisGard (13)	0	3	4	5	1
	Disarmer (16)	3	3	5	4	1
	MedEurope Box (8)	0	5	1	2	0

Overall Grading:

Participants were asked to give an overall grading of the pad with 1=Poor ranging to 10=Excellent. The results for the individual disposal pads are shown in charts 2-6 below. The Puncture Proof Pad received the best overall grading with a mean grade of 7. Next in order of grade was the MedEurope Box with a mean of 5.13, the Disarmer (4.75) DisGard (4.38) and the Purple Turtle (4.06).

Figure 16. Overall grading of theatre sharps disposal devices (Charts 1-4)

Safety

Table 49. Safety issues :theatre sharps disposal devices

Safety Issues	Disarmer (16)	DisGard (13)	MedEurope Box (8)	Puncture Proof Pad (13)	Purple Turtle (18)
Incidents where 'sharps' punctured pad	0	2	1	2	2
-Type of Sharp (Suture Needle)	0	2	1	2	2
Pad offers adequate protection when closed	93.8%	92.3%	75%	92.3%	61.1%
Fluids retained by pad upon closure	63.6%	55.5%	50%	60%	58.3%
Confident that pad will reduce sharps injury	37.5%	66.7%	28.6%	83.3%	44.4%
Users preferring to use conventional pad	75%	92.3%	87.5%	38.5%	82.4%

There were no sharps injuries reported from using any of these sharps pads.

Table 50. Ability to prevent sharps protrusion

		Ability to Prevent Sharps Protrusion				
		1 Satisfactory	2	3	4	5 Unsatisfactory
PRODUCT	Purple Turtle	3	5	5	3	1
	Puncture Proof Pad	4	6	1	2	0
	DisGard	3	3	3	2	1
	Disarmer	4	8	2	1	0
	MedEurope Box	2	3	0	2	1

Pad Punctures

The Disarmer was the only pad with no reports of sharps puncturing the pad.

The DisGard, Puncture Proof Pad and Purple Turtle each had 2 reports of a needle penetrating the disposal pad, in all cases this was attributed to a suture needle.

The MedEurope Box had 1 report of a needle penetrating the pad, again by a suture needle.

Protection

Over 90% of the staff using Disarmer, DisGard and Puncture Proof Pad indicated the sharps pad offered adequate protection when closed. Only 61.1% of Purple Turtle and 75% of MedEurope Box indicated similar.

Confidence in injury reduction:

User confidence in the devices reducing needlestick injury was mixed. Only 38.6% of MedEurope Box users and 37.5% of Disarmer users felt they would help reduce sharps injury, this rose to 44.4% with Purple Turtle and 66.7% of DisGard users.

Over 80% of Puncture Proof Pads users felt confident the pad would reduce sharps injury.

Safety v Conventional:

Staff were not entirely won over by these devices. When given the option of using either the safer disposal pad or the normal pad over 75% would prefer to use their 'normal' disposal pad. The exception to this was with the Puncture Proof Pad, over 60% users would prefer to use the safety option.

Training

Participants were asked the level of training they thought necessary to ensure the safe and effective operation of these products.

Table 51. Training issues : sharps disposal devices

These pads are similar in design to the conventional sharps pads, it would therefore be reasonable to expect that staff would require only minimal training to use these. The MedEurope Box and the Disarmer incorporate the additional feature of a scalpel blade remover; staff may welcome a demonstration of this feature.

All of the staff using the Purple Turtle and Puncture Proof Pad reported that the devices were self evident to use and training would not be necessary. Three users of the DisGard and Disarmer felt that some training would be necessary to use this device; the remaining staff in this group graded these products as 'training not required'.

One user of the Disarmer felt that hands on training would be essential before using this product, however this device did incorporate a scalpel blade remover.

Comparison Form Results (11 product comparison forms returned)

Staff were asked to rate the devices used with 1 (most preferred device) to 5 (least favoured device) these ratings are outlined below.

Figure 17. Device ratings : sharps disposal devices

Once staff had evaluated all of the sharps pads they were asked to complete a comparison form identifying the product that was best with regards to adhesiveness, storage space and potential to reduce risk of sharps injury. Staff were also asked to indicate which device they would prefer to use.

Table 52. Device comparison results

	Disarmer	DisGard	MedEurope Box	Puncture Proof Pad	Purple Turtle
Which pad held sharps most securely	4	-	3	4	-
Which had the greatest storage area	3	-	2	5	-
Most likely in reducing sharps injury	4	-	3	4	-
Which would you prefer to use	3	-	3	5	-

In 10 out of the 11 forms returned the staff indicated the evaluation period was long enough to fully evaluate the product.

Overall Rating

Staff were asked to rate the disposal pads where 1 indicated their most preferred device through to 5 least preferred device. The products were rated as:

1. Puncture Proof Pad	2. Disarmer	3. Purple Turtle	4. MedEurope Box	5. DisGard
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Users comments:

CONCLUSION

All of the safer sharps disposal pads are used in a similar way to the conventional pads, they also have a stronger backing than the conventional cardboard pads and are in most cases are of equivalent size.

For these reasons we would grade all of the evaluated pads are suitable replacements for the conventional cardboard backed pads.

Summary Points of Disposal Pads

- **Disarmer** : Rated as **Acceptable**
According to staff the blade remover is only useful for size 23 blades.
Difficult to count blades once in the scalpel remover box.
- **DisGard** : Rated as **Acceptable**
Adhesiveness not great
- **MedEurope Box** : Rated as **Acceptable**
Difficult to remove and count scalpel blades.
- **Purple Turtle** : Rated as **Acceptable**
Pad size small, sutures not adequately secured by adhesive.
- **Puncture Proof Pad** : Rated as **Preferred**
Size could be bigger

Table 53. Conclusions : theatre sharps disposal devices

Disarmer (Johnson and Johnson)	DisGard (SafeGard Medical)	MedEurope Box (SafeGard Medical)	Puncture Proof Pad (Cory Bros)	Purple Turtle (Cory Bros)
£2.10	£0.40	£0.44	£0.73	£0.51
Acceptable	Acceptable	Acceptable	Preferred	Acceptable

ii) SCALPELS

Conventional scalpels are used for skin incision and tissue dissection and incorporate a metal scalpel handle with a disposable blade. Following use the blade is removed and disposed of, the handle is autoclaved. Alternatively for some applications disposable scalpels with a plastic handle and fixed scalpel blades are used, following use they are disposed of in their entirety.

Sharps injury may occur:

- During scalpel blade use, if surgeons or assistants hand is in operating field.
- Passing the scalpel between surgeon and scrub nurse.
- Removal of the scalpel blade from the handle.
- Prior to, or during disposal (potentially through sharps disposal pads).
- Inappropriate disposal.

Good practice dictates that sharp objects be passed not by hand but in a *kidney dish* or similar receptacle, or placed into a 'hands free' area.

Injury Incidence Data

The Royal College of Nursing UK EPINet data suggests 4.1% of injuries are attributed to disposable scalpels.

Safer Alternatives

At least 2 Scalpels with safety features are available to the UK healthcare market:

	Manufacturer	Unit Cost	Blade Sizes
Safety Scalpel	Personna International	£1.00	10, 11, 15
Safety Scalpel	Swann Morton	£0.66p	10, 11, 15

The Personna Safety Scalpel has a fixed blade covered by a clear plastic shield which can be moved back and forth, by the users thumb, to cover or expose the scalpel blade. The shield can be locked when the procedure is finished.

With the Swann Morton Safety Scalpel the blade is recessed into the handle and moved by side-mounted switch. The blade can be recessed when not in use but cannot be locked.

No efficacy figures were available from the scalpel suppliers, and literature searches did not demonstrate any published efficacy data for safety scalpels.

Recruitment

Safety scalpel suppliers were only able to provide 3 scalpel blades sizes. This impacted on recruitment as the limited blade sizes were not suitable for the needs of some surgeons. In order to achieve comprehensive scalpel usage recruitment was targeted at theatres with routinely high number of cases, e.g. day case, minor ops lists. Staff were recruited from the following areas:

- Western Infirmary Glasgow.
- Gartnavel Hospital.
- Hairmyres Hospital.
- St Johns Hospital Livingston.
- Glasgow Royal Infirmary.

Surgical staff in minor ops theatre lists are mainly middle grade medical staff, due to rotational commitments it was difficult to recruit and ensure the same surgeon used the safety scalpel during these lists. To facilitate scalpel use theatre nurses allocated scalpels to junior doctors to use for the duration of their operating list.

RESULTS and ANALYSIS

Only 8 completed forms were received from the above areas, 6 forms from Personna Safety Scalpel users and 2 from Swann Morton safety scalpel users. Additionally, four evaluation forms were received without device name or operator details. Without product identifiers we were unable to include this data in the evaluation results.

With so few forms returned it was not possible to fully examine the utility of these products, however reference is made to the sparse data to attempt to glean salient points of these products. This combined with bench-top testing and the review of the product literature we are able to make general recommendations.

Utility of Swann Morton and Personna Safety Scalpels

- Both of the Swann Morton users could activate the safety mechanism using a single-handed technique, 4/6 Personna scalpel users could activate using 1 handed technique.
- 1/6 Personna users and 1 of 2 Swann Morton users claimed additional dexterity was required to activate safety mechanism.
- Given the choice of using the trial scalpel or 'normal' scalpel both the Swann Morton users indicated a preference to use their normal scalpel. Only 1 of the Personna scalpel users would choose to use the trial scalpel over the conventional scalpel.

Safety Aspects of the evaluated safety scalpels

- There were no reported sharps injuries from staff using these devices and only one of the 6 users of the Personna Scalpel blood splash/splatter on activation of the safety shield.

Training

All 8 users of both safety scalpels claimed that the devices were self evident to use and did not require training.

User Comments

- Swann Morton Safety Scalpel: The scalpel is slightly longer than normal scalpel.
- Personna Safety Scalpel: 'Good Device, Safe and Effective, Excellent new safety product'. 'Poor handling, compromises safety. Sometimes the mechanism fails'.

Conclusion

Summary Points of Safety Scalpels. (from bench-top testing, product literature and ECRI publication)

We have graded the safer disposable scalpels as suitable substitutes for the replacement of conventional disposable scalpels. However the limited blade size availability may reduce the opportunity for use.

Swann Morton Safety Scalpel-Adequate

- Side mounted switch to retract blade is awkward for left handed operators.
- Cannot permanently lock blade.

Personna International Safety Scalpel-Preferred

- Top mounted shield can be used equally well by right and left-handed operators without any difficulty.
- Blade shielding mechanism can permanently lock.

iii) Blunt Suture Needles

RCN UK EPINet data show suture needles account for 8.8% of sharps injuries.

Wright et al⁴³ showed that 26% of sharps injuries were to the index finger tip of the non-dominant hand for operating room staff and occurred in 67% of hip arthroplasties. There are two types of conventional suture needle with attached suture material: the tapered end needle-point is less sharp than a cutting needle but will still penetrate certain tissue types.

Areas of Risk:

- Passing suture hand to hand
- Guiding through tissue using digital pressure
- Tying suture with needle attached
- Poking through sharps disposal pad
- Inappropriate disposal

Safer Alternatives:

A safer alternative to conventional cutting and tapered suture needles is the blunt end suture needle. The tip of the needle is blunter than conventional suture needles, however the tip can still penetrate tissue. These needles cannot be used for certain procedures for example, skin closure or bowel anastomosis, however they can be used to close fascia. The fact that it is very difficult for these needles to penetrate skin should reduce likelihood of needlestick injury.

Several studies investigating the use of blunt tip needles during wound closure have found these needle types reduce needlestick exposures. For example, one study to evaluate blunt tipped suture needles as a replacement for conventional curved needles in gynaecological surgery found that the use of blunt tipped needles were associated with a statistically significant reduction in percutaneous injury rates and minimal clinically apparent adverse effects on patient care.⁴⁴

Overall the blunt tipped needles were generally well accepted by the gynaecology surgeons. However a small number of technical difficulties were reported with the use of these needles:

- Problems penetrating tissue
- Tearing of tissue
- Needle slippage
- Bleeding when needle entered tissue

(None of these were reported to be clinically important).

In a randomised trial of blunt tipped (n=46) versus cutting suture needles (n=39) to reduce glove puncture. Hartley et al⁴⁵ found 14 pairs of surgical gloves were punctured when using a cutting needle and three pairs were punctured when using blunt tipped needles. On no occasion did glove penetration give rise to needlestick injury. The results showed blunt tipped needles significantly reduced the incidence of surgical glove puncture ($p < 0.001$, Fisher's exact test).

Other studies^{58,59} have endorsed the potential for injury prevention and practicability of blunt-tipped needles.

Survey of Surgeons

2 Blunt suture needle products were identified:

- **Ethiguard (Ethicon)**
- **Bluntip (Tyco Healthcare)**

Blunt suture needles are very similar and bench top testing revealed no apparent difference between the products. Previous studies outlining the efficacy and utility of these products revealed that the blunt needles are well accepted. With the increasing popularity of their use, we opted to obtain feedback from surgeons on their experience with blunt suture needles used.

A survey was undertaken to identify current safer methods of clinical practice in the operating theatre and to determine surgeons views on the use of tapered needles.

Survey forms were sent to 60 Consultant surgeons in 9 NHS Scotland Trusts. (including the six study partner Trusts plus Borders General Hospital NHS Trust, Dumfries and Galloway Acute and Maternity Hospital NHS Trust, and West Lothian Healthcare NHS Trust,).

Survey forms were sent to all Consultant general surgeons within each Trust (Inclusive of general surgeons with colorectal and breast surgery interests).

21 (35%) survey forms were returned, 17 surgeons indicated current use of a blunt suture needle. Types of suture needle used are outlined below.

Figure 18. Blunt suture needles used by surgeons

Needles used.

7-Ethiguard

6-Bluntip

4-Other (not identified)

3-Don't use any

1 case missing

All of the surgeons using the Ethiguard needle gave a positive indication that the use of these needles would reduce needlestick injuries. Half of the surgeons using Bluntip needle indicated use of this needle would help reduce needlestick injury. Two surgeons were not convinced the needle would reduce needlestick injury, 1 case was missing.

All of the surgeons using the blunt suture needles identified mass closure of abdomen as the application where the blunt suture needles were routinely used (not surprisingly since general surgeons were surveyed). Additionally one surgeon used them for breast reconstruction using tissue expander.

Nine surgeons cited the reason for starting to use the tapered needles was to reduce or prevent needlestick injury, 1 surgeon used this needle to avoid damaging a breast prosthesis and 1 claimed to use the needle just because it was available. Surgeons identified that an increase in force may be needed to pass the needle through the tissue, however only 1 of the 7 surgeons using Ethiguard needle felt the needle may cause excess trauma to the tissue. None of the surgeons indicated any adverse effects from using this needles, but 1 suggested an audit should be carried out.

Overall for both blunt suture needles surgeons highlighted that ‘delicate surgery’ and patients with previous scar tissues were applications where blunt suture needle use was unsuitable.

Surgeons were asked to outline possible disadvantages to blunt suture needle use. The general consensus was that more force is needed to penetrate tissue and as a consequence the surgeons hand tires more easily. Some also identified a learning curve effect with the use of these and the ease of use is poor.

Surgeons also identified the following as possible barriers to widespread use of blunt suture needles:

- Blunt sutures cannot be used in delicate situations.
- The suture needles can be difficult to push through tissue.
- Less able to accurately place suture.

Summary of Other Safer Practices in Theatre:

- 14/21 surgeons indicated that they used electrocautery for tissue dissection either routinely or frequently.
- 10/21 used disposable safety scalpels on occasion 8/10 used a Swann Morton scalpel, 1 used a Bard Parker, 1 scalpel manufacturer not identified.
- 4 surgeons indicated routine use of tissue adhesive for wound closure, applications included closure of face and neck wounds, closure varicose veins incisions. 1 surgeon used tissue adhesive to close laparoscopic hernia cholecystectomy wounds.
- 81% of returns indicated that surgeons use stapling devices. Indications for use include: speedy closure for long wounds and major laparotomy wounds, especially emergency use.

Conclusion

There is good evidence for injury prevention and it would appear that surgeons accept blunt suture needles for appropriate surgical indications. These devices are recommended for use by surgical directorates for appropriate clinical uses.

5. Financial issues

Introduction

An important issue for purchasing Trusts is the relative cost of introducing devices with safety features compared with standard devices. Most safety devices cost significantly more and the cost-benefit calculations are complex, with several important variables proving difficult to estimate with any confidence. Some of the problems in cost calculations include :

- Uncertainty over the true proportion of injuries likely to be prevented by devices
- Uncertainty over estimation of the real costs of episodes of viral transmission, which are rare events (none recorded in the Scottish NHS over the last 5 years)
- Difficulty in estimating accurately civil liability and legal costs with a range from a few thousand pounds for all injuries in a year up to several hundred thousand pounds for one case
- Calculating accurately the number of devices used for specific tasks, especially percutaneous needle-and-syringe usages
- Estimating costs for professional time in aftercare of injuries

In this section the costs of introducing safety devices are presented, based on NHS procurement data from one Acute Hospitals Trust, costs of current devices and quoted costs from safety device manufacturers. There follows an attempt to estimate the direct realised costs arising from injuries in this Trust over one year, using a minimalist approach but attempting to estimate the likely real costs to employers. This is not presented as a complete societal cost benefit calculation or economic analysis which might include QALYs, future lost earnings, lifelong treatment costs or opportunity cost of staff time. In this way it is hoped purchasing Trusts will be given a clearer and realistic idea of the direct employers costs and possible savings from introduction of devices.

As a comparison, an alternative costs analysis is presented from one London Acute Hospitals Trust, with a higher incidence of reported injury and a greater number of HIV exposures.

5.1.The cost of using devices with safety features

Costs have been calculated based on procurement data obtained from Lanarkshire Acute Hospitals NHS trust.

Lanarkshire Acute Hospitals (LAHT) data (3 acute hospitals 1541 in-patient beds serving 560 000 population), subtracting devices purchased for this trial and used in other Health Board areas.

Estimated device use (from procurement data)

Vacutainer plus needle devices used p.a.	240 000
Butterfly (infusion and blood collection)	40 000
Cannulation devices used per annum	117 000
Lancets used per annum	100 000
Insulin syringes used per annum	110 000
Arterial blood gas syringes used p.a.	31 000
Disposable scalpels used p.a.	20 000
2ml syringes used p.a	650 000
21 gauge (green) needles used p.a	1 110 000

To compare these figures, the US General Accounting Office² estimates of device use per in-patient bed are included in Table 54.

Table 54. US General Accounting Office² data on device use compared to Lanarkshire data.

Device type	GAO estimate annual use per hospital in-patient bed	Lanarkshire procurement data use per in-patient bed	Lanarkshire usage as a % of GAO estimate
Blood collection	217	193	89%
IV cannula (catheter)	111	78	70%
Winged steel needle (butterfly)	56	27	48%
Hypodermic needle/syringe	367	Unknown	

The GAO data is broadly comparable to Lanarkshire usage for vacuum tube collection but significantly less for IV cannulae and butterfly needle usage. This may well reflect differing practices in US and British hospitals.

Percutaneous needle and syringe use is difficult to calculate from procurement data. It is known that around 650 000 2ml syringes were used in Lanarkshire and the 21 gauge (green) needle usage was around 1 100 000. However only an unknown proportion of these would be used for IM or SC injections or indeed for phlebotomy. Many for instance would be used for drawing up or administering via IV lines rather than percutaneous use. Calculating probable Lanarkshire percutaneous needle and syringe use from the GAO data would require an adjustment which can only be estimated: it is also unclear if the US data included insulin syringe use.

However, using an adjustment figure of 70% of the GAO estimate, this would equate to 257 devices per in patient bed. Likely usage extrapolated from this figure is 386 000 per annum. Allowing for an error of +/- 20% the range would be 310 000 – 460 000 as an “educated guess” of usage.

Based on the above procurement data and estimates of usage for syringe devices, the series of tables below estimate costs of LAHT converting universally to safety devices for each marketed product in the various device categories.

Table 55. Estimated LAHT costs for Phlebotomy Vacutainer/needle safety devices

Product	Standard vacutainer barrel plus needle	Product cost (as for holder plus needle)	Cost differential from standard device	Overall additional cost per annum for 240 000 devices
Portex Needle Pro	5.7p	13p	7.3	17 520
Pendell Vanishpoint	5.7p	37p	31.3	75 120
BD Eclipse	5.7p	21p	15.3	36 720
Greiner QuickShield	5.7p	19p	13.3	31 920
Safeguard secure guard	5.7p	7p	1.3p	3120

Table 56. Estimated LAHT costs for Butterfly vascular access/infusion safety devices

Product	Standard butterfly cost	Product cost	Differential cost	Additional cost p.a. for 43 000 uses
Tyco Angel wing	22p	92p	70p	£30 100
Terumo Surflew	22p	42p	20p	£8600
BD Safety-Lok	22p	40p	18p	£7740
Greiner Vacuette	22p	13p	-9p	-£3870

Table 57. Estimated LAHT costs for IV Cannulation safety devices.

Product	Standard cannula cost (£)	Product cost (£)	Cost differential from standard device (£)	Overall additional cost per annum for 117 000 devices
J&J Acuvance	0.57	1.75	1.18	£138 060
J&J Protectiv Plus	0.57	1.98	1.41	£164 970
NMT Vaxess	0.57	0.98	0.41	£47 970
BD Safelon	0.57	1.80	1.23	£143 910
BD Insyte Autoguard	0.57	1.16	0.59	£69 030
BD Saf-T-Intima	0.57	2.00	1.43	£167 310
BB Introcan Safety	0.57	1.09	0.52	£60 840
BB Vasofix	0.57	1.09	0.52	£60 840

Table 58. Estimated LAHT costs for Lancet safety devices.

Product	Standard lancet cost (p)	Product cost (p)	Cost differential from standard device (p)	Overall additional cost per annum for 100 000 devices
Owen Mumford Unistik 2	8.2	7.8	-0.4	-£400
BD Genie	8.2	9.7	1.5	£1500
Greiner Medlance	8.2	13.0	4.8	£4800
Tyco Monolettor	8.2	23.0	14.8	£14 800

Table 59. Estimated LAHT costs for Percutaneous Needle and syringe safety devices (range 310 000 to 460 000 used p.a.)

Product	Cost of standard 2ml syringe and 21 gauge needle (p)	Product cost (p)	Cost differential from standard device (p)	Overall additional cost per annum for 310 000 to 460 000 devices (£)	Midpoint cost (£)
Portex Needle Pro	2.9	12	9.1	28 210 - 41 860	35 035
NMT Safety Syringe	2.9	36	33.1	102 610 -152 260	127 000
Alaris Smartlock	2.9	18	15.1	46 810 – 69 460	58 135
Tyco Monoject	2.9	13.3	10.4	32 240 - 47 840	40 040
Safeguard Secureguard	2.9	10.2	7.3	22 630 - 33 580	28 105
BD Safetyglide	2.9	14.0	11.1	34 410 - 51 060	42 735
Pendell Vanishpoint	2.9	39	36.1	111 910 - 166 060	138 985
Tyco Magellan	2.9	9.3	6.4	19 840 - 29 440	24 640
G&N Stopstick	2.9	22.0	19.1	59 210 - 87 860	73 535

Table 60. Estimated LAHT costs for surgical scalpel safety devices

Product	Cost of standard disposable scalpel (p)	Product cost (p)	Cost differential from standard device (p)	Overall additional cost per annum for 20 000 devices
Personna Safety Scalpel	16.9	100	83.1	£16620
Swann Morton Scalpel	16.9	66	49.1	£9820

The table below gives the estimated overall cost of converting to safety devices in each category.

Table 61. Estimated overall costs (taking median value of costs within range of products)

Device type	Additional Cost per annum	%
Vacuum tube holder/needle	31 920	16.1
Butterfly	8170	4.1
Cannula	103 000	51.9
Lancet	Cost neutral or up to 1000	0
Needle and syringe	42 040	21.2
Scalpel	13 220	6.7
Total	198 350	100

It should be noted however that potentially acceptable devices in each category could bring this estimate down. For example, the Needle-Pro (rated preferred) would cost £17 520 per annum in the vacuum tube holder/needle category. The Vacuette (rated preferred) is costed at an overall saving of £3870 compared with conventional butterflies. The Magellan device (rated preferred) would cost £24 640 in the needle and syringe category.

5.2 Devices and injury incidence

Section 2 on Epidemiology will have presented fuller data on injury statistics. The key figures relating to incidence and distribution by activity and type of device are summarised below. Scottish data is incomplete but some data from Glasgow and Lanarkshire are included.

Table 62. Needlestick injury incidence by device category

	US Epinet	UK Epinet	Scottish
Recorded NSI per 100 beds	26 (teaching hospital) 18 (non-teaching)	11.6-12.7	Glasgow Royal Infirmary 8.8* Lanarkshire Acute Trust 7.9**
Activity			
Injection (IM/SC)	21	23	14 *
Venous phlebotomy	16	12	12*
Suturing	17	10	
IV cannulation	6	8	10*
Cutting	7		8*
Finger/heelstick	2	4	
ABG	2	2	
Device Type			
Syringe	36	26	
Suture needle	17	9	12*

Butterfly	7	6	4*
Needle/holder for phlebotomy	4	7	
IV cannula	4	6	11*
Lancet	2	3	
Scalpel (disp)	3	4	8*

*Curran et al. Report for OHSSIG group

**Lanarkshire Acute Hospitals NHS Trust Minimum Dataset report 2002/03

Under-reporting rates (derived from NaSH data –CDC) could be from 60-80%, that is, the true figure is 60-80% higher.

Analysis and Conclusion

- It is clear that the highest **numbers** of injuries are for **needle-and-syringe devices**. It is noticeable that a greater proportion of the total is for syringes than for the task of IM or SC injection. This suggests that a significant proportion of injuries with syringes may be during procedures such as phlebotomy: it is known anecdotally that clinicians continue to favour this method when veins are difficult to access. It is noted that the Glasgow data suggest a much lower proportion of incidents occurring during injection procedures.
- Phlebotomy (using either holder plus needle or butterfly) and suture needle injuries are next most common, followed by IV cannulation.
- Lancet and scalpel use account for a much lower number of reported injuries.
- It should be remembered that in terms of prevention of bloodborne virus transmission, the most important injuries are those where the volume of blood is highest, i.e. vascular access, particularly with a hollow bore needle and blade injuries, particularly in surgery. In terms of ranking highest risk types of injuries for volume of blood transmitted, this could read as follows :
 1. Blade injuries in surgery
 2. Phlebotomy or ABG collection
 3. IV cannulation
 4. Needle and syringe used for IM/SC injection
 5. Solid bore Suture needle/Lancet injuries

5.3 Direct Injury Costs to Employers

Two examples of cost calculations are set out below. The first is based on LAHT data and the second from the Royal Free Hospital in London.

Example 1. Estimate of Realised costs for one Scottish Acute Trust (Lanarkshire Acute Hospitals)

1. Treatment cost – immediate

HIV Post exposure prophylaxis (PEP)

Over 3.5 years the following data for LAHT staff started on HIV PEP were obtained :

- 7 people completed 1 month of PEP = 7 x £750
- 2 continued for up to 2 weeks = 2 x £375
- 11 continued for 48 hours or less = 11 x approximately £60

- Total drug costs of PEP were therefore £6660 over 3.5 years, or **£1900 per annum**. A total of 37 Health Care Workers were referred to the Aids, HIV and hepatitis advisory centre in the Area Infectious Disease Unit for counselling over 3.5 years = 10 per annum. No HCW seroconverted.

HBV PEP

- HBIG costs : The cost is £310 per dose (ref. Dr Peterkin, Scottish NBTS). As an estimate, from 115 injuries there will be 10% who are unimmunised or non-responders and therefore candidates for HBIG. If we assume that 50% received it (some will have been assessed as low risk sources not mandating HBIG), this approximates to a cost of **£1860 per annum**. The trust does not directly pay this cost as it comes from central funding.
- HB vaccine costs: at £14 per dose, assuming 70% receive a single booster (this is a generous estimate but in practice injured staff may often be boosted even if they already have a good immune response). This equates to **£1127 per annum**.

2. Laboratory costs

- The cost of HCV antibody, HBsAg and HIV antibody tests total £48 (ref. Monklands Laboratories).
- If all source patients are tested for HBV, HCV and HIV, for an annual total of 115 source patients this equates to **£5520 per annum**. This is likely to be an over-estimate since not all source patients will be available for, or consent to testing.
- For the injured HCW, although all are routinely offered post injury testing if desired, but only a minority will elect to proceed. An estimated proportion would be around 20% (or 23 persons per annum based on LAHT data). If each has HCV antibody and HIV antibody at 6 weeks, 3 months and 6 months, plus one HBsAg test, the cost per person would be £114. Again, this is a probable over-estimate since some low risk injuries would only require one test at 6 months and HBsAg may not be requested if the HCW is known to be immune. Total estimated cost is **£2622 per annum**.
- Therefore the **total estimated laboratory costs are £8142 per annum**

3. Civil claims

Precise figures could not be obtained but it is estimated from known Trust data that the total annual cost from sharps injury claims (principals and legal costs) is in the region of **£14 000 per annum**.

4. Professional time : Sickness absence

The true figure is not known but if all persons receiving PEP were on sick leave, this would equate to approximately 8.6 months of staff time lost over 3.5 years. (mid point E grade S/N is £18890, SHO1 basic is £23940) Salary costs assuming injured staff are 60% E grade staff nurse and 40% SHO1 would be £14 986, which equates to **£4282 per annum**. In reality staff on PEP often did continue at work though many could not. However, having the higher estimate of sick leave allows for some staff not started on PEP who were absent due to anxiety.

5. Future Rx for seroconversion

Costs of this are unknown; to date there have been no described cases in NHSiS over the last 5 years.

The table below summarises the overall estimated direct costs to LAHT.

Table 63. Summary of estimated direct costs to LAHT per annum

Cost Area	Estimated annual cost to Trust	Estimated annual cost of converting completely to safety devices
PEP treatment	£1900 (actual)	
HBIG treatment	£1860(est) but no cost to trust	
Additional HB vaccine booster	£1127(est)	
Sickness absence	£4282 (est)	
Civil claims	£14 000 (est)	
Lab Costs	£8142 (est)	
Total	£31 311	

Other cost calculations include some under the headings below but these have not been included in this calculation for the reasons set out :

- Staff replacement costs during initial follow up of needlestick injury
It is unlikely these would result in actual costs since staff away from their workplace for less than a shift would be unlikely to be replaced.
- Occupational Health/A&E/ID service staff time
Although there is a nominal opportunity cost associated with time spent by services treating staff, reductions in sharps injuries would not necessarily result in real financial savings to Trusts since such staff are already in place and the work is absorbed into their normal clinical workload. The costs are opportunity costs but for clinical staff this would not necessarily translate into real financial savings for employers (G Grade time = £22.75 per hour Consultant = £73.50 per hour).
- Pain and distress
This is clearly extremely important but is unquantifiable in financial terms and incurs no direct cost to employers.
- QALYs
Given the absence of described cases of BBV infection arising from sharps injuries in the Scottish setting, this is very difficult to quantify.

Example 2 : An alternative percutaneous injury cost estimate from a London Acute Hospitals Trust.

This estimate was prepared by and is reproduced with the permission of, Dr Paul Grime, Consultant Occupational Physician at the Royal Free Hospital London. The figures are based on 2001 costs. Dr Grime took a more liberal view of costs and included opportunity cost of OH staff time etc. The Trust had higher numbers of reported incidents overall and a higher number of blood borne virus exposures than the Lanarkshire example:

This trust employs over 4000 staff, including 1900 nurses, midwives and health care assistants and 530 doctors. Every year around 200-220 sharps injuries and body fluid exposures are reported to the Occupational Health & Safety Unit. Such exposures incur further costs, some of which are detailed below (based on 2001 prices) :

Table 64. Potential cost of dealing with an occupational exposure to HIV:

Source patient testing for HIV, Hepatitis B&C	£27
4-week course of post-exposure prophylaxis for HIV	£564
Staff blood tests	£60
Nurse manpower per sharps incident reported (30 minutes with the staff member, 60 minutes gathering relevant information)	£50
Doctor manpower time (4 X 30 minute follow up appointments)	£100
*Cost of absenteeism	£1427
Total per exposure	£2228
Annual total (25 exposures)	£55,701

*Staff taking anti-HIV drugs following an exposure to HIV are often too unwell to work, due to drug side effects. Local data suggest that 50% staff on PEP need time off sick, and that the average duration of absence is two weeks. The cost to the Trust of an “average” nurse (40% of exposures) absent for a week, and the cost of covering this absence (using Nightingale Agency rates) is £1346. The weekly cost of an absent doctor (23% exposures) would be £2255 (based on SHO band 3 with one on call). The 37% other staff exposed are student nurses (9%), phlebotomists (5%), domestics (3%), lab workers (2%) and others. The average weekly cost of absence for these groups is estimated at £1000.

Table 65. Potential cost of dealing with an occupational exposure to Hepatitis B:

Hepatitis B booster immunisation:	£15
Source patient testing for HIV, Hepatitis B&C (most exposures):	£27
Staff blood tests for Hepatitis B exposures	£8
Nurse manpower per sharps incident reported (30 minutes with the staff member, 60 minutes gathering relevant information)	£50
Total per exposure	£85
Annual total (15 exposures)	£1275

Table 66. Average cost of dealing with an occupational exposure to Hepatitis C:

Source patient testing for HIV, Hepatitis B&C (most exposures):	£27
Staff blood tests for Hepatitis C exposures	£92
Nurse manpower per sharps incident reported (30 minutes with the staff member, 60 minutes gathering relevant information)	£50
Total per exposure	£169
Annual Total (25 exposures)	£4225

Table 67. Average cost of dealing with other occupational exposures:

Source patient testing for HIV, Hepatitis B&C (most exposures):	£27
3-day starter pack of post exposure prophylaxis for HIV exposures (average 20 used per year)	£102
Nurse manpower per sharps incident reported (30 minutes with the staff member, 60 minutes gathering relevant information)	£50
Total (per exposure)	£179
Annual total (155 exposures)	£13,975

The potential cost of dealing with all these exposures comes to **£75,176 per annum**. While the two example costings use slightly different methods and assumptions one can see the likely range of costs involved – between about £30-40 000 per annum for a medium sized Scottish Acute Hospitals Trust and £70-80 000 for an equivalent London trust.

5.4. Summary

The cost of a Healthcare organisation converting to safety devices is substantial, particularly for the Acute Hospital sector. Procurement data for one Scottish Acute Hospitals Trust (3 hospitals, 1500 beds) has been presented and an estimate made of the cost of converting totally to safety devices as between £190 000 and £200 000. This can only be a broad estimate due to uncertainties over the number of needle-and-syringe devices used and the great range of prices for various safety devices. In addition, this figure would reduce substantially if certain lower cost but rated acceptable devices were used.

A simple and basic injury cost analysis has been presented derived from known data from the same Trust. It presents a minimalist approach to injury costs and is not a full societal cost-benefit analysis but is intended to reflect actual rather than theoretical cost savings that could be made by employers. The estimate of realised costs is approximately £30 000 per annum. This compares with a separate estimate of around £75 000 per annum from a London trust of similar size but with greater BBV exposure.

These costs could change significantly if there was a substantial increase in civil liability costs or there were even one or two instances of bloodborne virus transmission to staff in the organisation. However, the introduction of safer devices would reduce injury costs only by a proportion. This is difficult to estimate in totality but an assumption of a 30%-50% reduction may be reasonable.

Thus, from the financial estimates presented in this chapter, on present evidence, injury cost savings to employers would not approach the additional spend required to introduce **universal** use of safety devices. In the short term there is not a strong **financial** argument for universal purchase of these devices in all categories. The legal and moral arguments are of course different.

The cost-benefit equation becomes much more favourable if safety devices are only introduced to universally replace conventional devices in the less expensive categories, e.g. blood collection, lancets. Similarly, selective stocking of needle-and-syringe safety devices purchased and available as a proportion of all syringes and reserved for percutaneous use only would reduce projected costs. The highest cost category is that of intravenous cannulae. Here, projected costs could only be reduced by stocking smaller quantities of safety cannulae alongside conventional cannulae to be used at clinicians discretion where there are higher risk clinical situations.

6. Survey of Safer Device Use in the NHS in Scotland

In the UK there are now over 50 devices available which have a safety feature as part of their design. Many of these devices employ a blunting, shielding or retracting mechanism to render the sharp safe, others, as in the case of IV connectors offer an alternative to using a needle. Although many of these devices have been available for several years their acceptability and extent of use in the NHSiS is not known. A survey of NHS Scotland Trusts was undertaken to determine the extent of use of such devices in the NHS Scotland, which devices had been evaluated and the outcomes.

6.1 Method

Between January 2003 and March 2003 a pilot study was undertaken to examine the extent of safer device use in the NHSiS. Initial telephone interviewing revealed that in many Trusts there were no clearly identifiable persons with knowledge of which safer devices were routinely used, which safer devices had been evaluated and the outcomes from evaluation exercises.

It was therefore decided to undertake the survey by contacting staff who would be directly involved in the purchasing of safer devices, and also those who may be involved in the evaluation of safer products i.e. infection control nurses and health and safety staff.

All of the Trusts outlined in Table 68 were approached for contact details of the infection control nurse, health and safety officer and the procurement manager. Survey forms were sent to the above staff responsible for individual hospitals or departments within their Trust. The survey form contained a listing of all currently available safer devices. Staff were asked to indicate those used and whether their use was Trust wide or only in specific clinical areas.

Table 68. Trusts or Island Health Boards Surveyed to determine the degree of safer device use in NHSiS.

A list of UK available safer devices was constructed from Internet (sources in appendix) and literature searches. At the time of the survey this search revealed 52 safer devices from 24 device manufacturers

In addition to the staff survey each device manufacturer was asked to supply details on where their safety products were routinely used in the NHS in Scotland.

6.2 Scottish NHS Trust Survey

Completed survey forms were returned from 17 of the 30 Trusts/Island HBs (57% response). The data in some instances was sparse with some Trusts unable to supply information on where devices were used. In other returns, it was indicated that a device was used but the location was not specified.

Reported use by device category

a) Lancet devices

Unistick 2 (Owen Mumford)

- Greater Glasgow Primary Care*, All of North Glasgow Trust, Areas within SGH Trust *, Trust wide in Fife Acute Trust, some primary care areas* within Fife Primary care Trust. Grampian Acute-diabetic wards and clinics

Genie (Becton Dickinson)

- Ayrshire and Arran Primary Care, Trustwide. Grampian Acute and Primary care Trustwide, Highland Acute SCBU ward and haematology. Argyll and Clyde Trustwide, Dumfries and Galloway Trustwide.

Summary : 14 of the 17 Trusts (82%) who responded reported use of one of the above devices. In 8 of these Trusts usage was trustwide, while the remaining 6 reported only partial use.

b) Cannulation devices

Saf-T-Intima (Becton Dickinson)

- North Glasgow Trust, mostly by pain control nurses. Also used Trustwide in Highland Acute Trust by palliative care team with syringe drivers.

Insyte Autoguard (Becton Dickinson)

- Fife Acute had used this device only in the A&E department at Victoria Hospital.

Summary: There is extremely limited use reported, mainly with one device used for pain control.

c) Syringe based devices

Smartlock (Alaris Medical)

- One Shetland Health Board dental practice.

Monoject (Tyco Healthcare)

- Grampian University Hospitals reported use within a dental department.

Safetyglide (Becton Dickinson)

- Fife Primary Care, Trustwide. Highland Acute Trust, Haematology.

Summary: Extremely limited use apart from one primary care trust which is using a device trustwide.

d) Blood collection system devices

Eclipse (Becton Dickinson)

- Fife Primary and Acute Trust, Trustwide.
Grampian Primary Care and Acute Trust, Trustwide.

Safety-Lok (Becton Dickinson)

- Highland Acute, haematology unit,
Highland Primary Care, non-stock item used occasionally.
Fife Primary Care Trust.

Summary: Two health board areas have reported area wide use of these devices.

e) Needleless IV Connection Devices

Bionector (Vygon)

- Borders General Health Board, Trustwide. Shetland Health Board, Trustwide,
Dumfries and Galloway Acute, Trustwide. Highland Acute, Trustwide.

South Glasgow NHS Trust, not indicated where used. North Glasgow Trust, not indicated where used.

Smartsite (Alaris Medical)

- Lothian Acute, Trustwide. Forth Valley Trustwide, Borders Trustwide, North Glasgow Trust, not indicated where used. Fife Acute, not used Trustwide (Used at Victoria and Forth Park hospitals), Grampian Acute, paediatrics.

Clave (Kimal)

- Fife Acute, not Trustwide used in ICU at Victoria and Queen Margaret Hospitals. Argyll and Clyde, areas used unspecified.

Clearlink (Baxter Healthcare)

- Argyll and Clyde, areas not specified

Posiflow (cant remember)

- Fife Acute Trustwide

Summary: 11 of the 14 Acute Trusts indicated some use though this was patchy and sometimes limited to single departments.

f) Theatre Sharps Disposal devices

Disarmer (Johnson and Johnson)

- Highland Acute, Bedford Hospital Theatres.

Puncture Proof Pad (Cory Bros, distributor)

- Highland Acute, Bedford Hospital Theatres.

Summary: Reported use by only one hospital in Scotland.

6.3 Local Device Evaluations and Outcomes

The second part of the NHS Trust survey asked for details of any local evaluations of the listed safer devices, which clinical areas were involved and the outcome of the evaluation exercise. Only 5 Trusts reported they had previously evaluated safer devices.

- **Fife Primary Care** evaluated the Zerostick Syringe (New Medical Technology) in psychiatric and rehabilitation departments. The outcome was that the device was not introduced. Staff were not convinced of its safety and did not like the device.
- **Grampian University Hospitals Acute Trust** trialled the Zerostick syringe in an Accident & Emergency department, and the Infectious Diseases Unit. The device was not introduced for cost reasons.
- **Lothian University Hospitals Trust** evaluated the Zerostick syringe in the regional Infectious diseases unit. The device was not introduced as it received an unfavourable evaluation. Also evaluated was the Vanishpoint (ITC, Pendell Medical) syringe. This also received an unfavourable evaluation and its higher cost resulted in this product not being introduced.
- **Argyll and Clyde** evaluated the Safety Monovette (Sarstedt) blood collection system. The results of the evaluation are not available.
- At the time of the survey **Forth Valley Acute** were conducting an evaluation of the Saf- T-Intima (Becton Dickinson) in Paediatric ITU area.

6.4 Device Manufacturer Survey

All companies that supply or manufacture safer devices replied to our request and were able to give information on where in the NHSiS their devices were being used. Two companies recommended contacting their distributor for confirmation of their sales to NHS Scotland. Feedback from the 24 device companies revealed 18 of the 52 listed safer devices were supplied to NHSiS. As some companies did not wish this information reported in detail, the information is presented in summary form.

LANCET

Four products were reported as being supplied to Scottish Trusts; Genie (Becton Dickinson), Unistik 2(Owen Mumford), Quikheel(Becton Dickinson), and Tenderfoot (LDH Distribution –check).

Overall 14 Trusts were using these devices, with 3 further carrying out evaluations. By far the commonest devices in use were the Genie and the Unistick 2.

BLOOD COLLECTION

Two Vacutainer based devices, the Eclipse (BD) and the Vacuette (Greiner Bio-One) were supplied to 3 and 1 Acute Trusts respectively. The Safety Monovette (Sarstedt) was used by community nurses in one island Health Board.

One butterfly system (Safety-Lok, BD) was supplied to four acute Trusts.

One ABG system (Pulsator Liquid heparin and ABS, Sims Portex) was supplied to 10 Trusts.

INTRAVENOUS CANNULAE

Only the Saf-T-Intima (BD) was notified as being supplied to 4 acute Trusts for sub-cutaneous fluid administration and pain control.

SYRINGE

Only the Vanishpoint (Pendell) was notified as being supplied to the State Hospital, Carstairs.

NEEDLELESS IV CONNECTORS

Four products were supplied, Smartsite (Alaris Medical), Clearlink (Baxter Healthcare), Clave (Kimal) and Bionector (Vygon). In general, the Smartsite and Bionector products were more widely used. In total, 13 acute Trusts were supplied with this category of device.

SHARPS DISPOSAL PADS

Two products, the Purple Turtle (Cory Bros, distributor) and the Puncture Proof Pad (Cory Bros, distributor) were notified as supplied. These were used by 4 Acute Trusts.

The combined Trust and Manufacturer/Supplier information is summarised overleaf.

Table 69. Summary of Safer Device Usage in the NHSiS

Device Category	Trust information (57% response)		Manufacturer Information		Overall estimated number of Trusts using devices		
	Products	Trusts using	Products	Trusts using	Acute Trusts (15)	Primary Care Trusts (14)	Others* (3)
Lancets	Unistik2 Genie	14	Unistik2 Genie Quikheel Tenderfoot	14 3 further evaluati ng	13 (87%)	4 (25%)	
Cannulation	Saf-T-Intima Insyte Autoguard	3	Saf-T-Intima	4	4 (27%) for very limited use	N/A	
Blood collection	Eclipse	4	Eclipse Vacuette Monovette	5	5 (33%)	3 (19%)	
Blood collection (butterfly)	Safety-Lok	1	Safety-Lok	4	5 (33%)	2 (13%)	
Syringe	Safetyglide Monoject Smartlock	4 (3 very limited use)	Vanishpoint	1	2 (13%)	1 (7%)	2
IV Connectors	Bionector Smartsite Clave Clearlink Posiflow	11	Bionector Smartsite Clave Clearlink	13	14 (93%)	N/A	1
Sharps Pads	Disarmer Puncture Proof Pad	1	Purple Turtle Puncture Proof Pad	4	4 (27%)	N/A	

*Orkney and Shetland Health Boards, State Hospital

ANALYSIS

There were some discrepancies between the Trust and Supplier datasets, but combining the two gives us a reasonable idea of the extent of device usage at present. It is clear that Lancet devices are already widely used in Acute Trusts (though sometimes only in single departments) but only a minority of Primary Care Trusts have converted. Safer cannulation devices are hardly used at all : the one device named (Saf-T-Intima) is in the main used subcutaneously for the specific purpose of pain control. Blood collection devices are used by a minority of Acute and primary care Trusts, the active shielding system used in the Vacuette and Eclipse devices being employed. Safety syringe devices are used to any degree in only one main Trust, Fife Primary Care, the other 3 Trusts usages being extremely limited. IV connectors are very widely used in all Acute Trusts except one, but several different devices are used with no standardisation. Unfortunately this was not one of the categories of device evaluated in this project.

Only 5 Trusts claimed to have previously evaluated safer devices. This number appears low, anecdotally it is understood that many more informal evaluations have taken place though the results have not been recorded.

CONCLUSION

The only categories of device in widespread use are lancets and IV connectors. Safety cannulae and syringes have not gained acceptance to any degree. There is some trend to blood collection devices being used more extensively.

7. Discussion

The aims of this project were to assess current usage of sharps devices with an engineered safety feature in NHSiS, to review the devices currently available to the UK market and to assess their utility by means of user evaluations. In addition, some of the epidemiological data and the published device efficacy data has been reviewed. An estimate has been made of the costs of introducing devices versus injury costs. The project was not designed to evaluate the devices' capability for injury prevention as, with 50 types of device, this would have required a very large study conducted over a long period of time. The subject of needlestick prevention and use of engineered safety devices is complex, but there are two practical questions for NHS Scotland Trusts: should such devices be purchased and if so, which products?

7.1. Should Safety Devices be purchased, universally or selectively?

This question rests on issues of device effectiveness at preventing injuries, rates of injury/risk of injury by device type, cost and user acceptability.

7.1.1 Evidence for Efficacy in Injury prevention.

One of the major problems in this field is to estimate how effective individual devices might be in preventing injuries. Most of the marketed devices do not have published original data that demonstrates they are effective at injury prevention. There have been a few published studies which, if their results are extrapolated to similar devices suggest they have some efficacy. The overall number of studies however is small, virtually all were undertaken in the US and these have mainly ceased since legislation that mandated the introduction of such devices. In addition, even the published studies are mainly uncontrolled and involve "before-and-after" assessments of injury rates when new devices are introduced, bringing the potential for several biases. However, if these results are true and if they can be extrapolated to non-research settings, an approximate reduction in injury rate of around **50-60% might be possible with phlebotomy devices and safety butterflies**^{35,46,47} with a reduction of around **80% for cannulae**.^{36,48,49} A recently completed Scottish report for the Chief Scientists Office concluded that 61% of venepuncture related injuries were "probably" preventable by safety device use and 21% were "definitely" preventable.⁶⁰

There is little published evidence for needle and syringe devices.⁴⁰ One study of a shielded safety syringe suggested an approximate 86% reduction in injuries³⁹. A study of safety syringes in a dental setting reduced the injury rate to zero.⁴¹ An extrapolation from the similar shielding technologies used for phlebotomy devices would suggest up to 50% of injuries associated with IM injections drawn up with needle-and-syringe might be preventable. The Scottish Chief Scientist Office study concluded up to 78 % of injection related injuries might be preventable.⁶⁰ At present, there appear to be few pre-filled syringe products with engineered safety features.

There is very little published on automatically retracting lancet devices but due to their design, intuitively these ought to have a very high rate of injury prevention. Needleless intravenous devices have many studies⁵⁰⁻⁵⁷ showing large reductions in injuries associated with accessing IV lines (**70-80%**). In the UK this technique has perhaps not been as widely practised as in the US where it has been a significant cause of injury. In addition, the injuries sustained virtually never involve blood contamination and are therefore low-risk. There is good evidence for the effectiveness of **blunt suture needles**^{43,44,45,58,59} in operative surgery, with injury reductions of **70-80%** published. We could find no published evidence on efficacy concerning sharps pads in theatre nor for safety scalpels.

7.1.2 Injury rates and risk of injury by device category

While needle and syringe devices cause the largest number of injuries, the devices with the highest rate of injury are IV cannulae. Solid bore needlesticks from suture needles or lancets are relatively low risk in terms of capability for viral transmission, as are needles used for SC or IM injection. In contrast, hollow bore needles used for vascular access, or blade injuries in surgery carry the highest risk of viral transmission due to the volume of blood involved. A review of HIV transmissions (below) found that in the 94% of cases of transmission arising from needlesticks, all had been with hollow-bore needles. In addition, needles used in vascular access held an odds ratio of 5.1 for HIV seroconversion.

Table 70. Risk factors for HIV infection in health-care workers after percutaneous exposure to HIV-infected blood, based on a case-control study -- France, United Kingdom, and United States, January 1988-August 1994

Risk factor	Adjusted odds ratio *	(95% CI)
Deep injury	16.1	(6.1-44.6)
Visible blood on device	5.2	(1.8-17.7)
Procedure involving needle placed directly in a vein or artery	5.1	(1.9-14.8)
Terminal illness in source patient	6.4	(2.2-18.9)
Postexposure use of zidovudine	0.2	(0.1- 0.6)

- * All were significant at p<0.01.

Reproduced from MMWR 1995;44(50);929-33

7.1.3 Cost

Lancet devices are almost cost neutral, while phlebotomy (7-15p midrange additional per device) and needle and-syringe (6-10p) devices have intermediate cost premiums. IV cannulae are substantially more expensive with additional costs ranging from 41p-£1.23 per device. Cannulation devices would represent 53% of the cost of converting to safety devices across the board, according to the model outlined in section 5. The other device category relative costs are listed below.

Table 71. Relative cost of devices

Device Category	Estimated % of total cost of conversion to safety devices
IV Cannulation	52
Needle and syringe	21
Vacutainer barrel + needle	16
Scalpel	7
Butterfly	4
Lancet	0-0.5

As outlined in section 5, there would not seem to be strong evidence that real savings would be made by a universal conversion to safer devices. However, conversion in the lower cost categories (Lancet, Butterfly, Scalpel and Vacutainer barrel + needle) would account for only 25% of this cost, which does approach the injury costs as calculated in section 5. For the more expensive device categories, selective stocking of safety devices may be an approach that is worth considering.

7.1.4 User acceptability

Users are generally somewhat resistant to changing from the devices with which they are familiar. In our evaluations, users consistently preferred their conventional device even if they rated the safer device highly. In published studies however, there is evidence that safety devices can be used with no change in technique or increase in the number of occasions the procedure is attempted. There is some evidence that investing time in training and gaining user acceptability results in better acceptance and improved rates of injury prevention.

7.1.5 Current use of safety devices in NHSiS

Safety devices are not at present widely used in the NHSiS apart from two types of device: needless IV connectors and lancet devices. These have been adopted by a significant number of acute Trusts, though in some only in certain clinical settings. In primary care trusts, lancet devices appear to be less commonly used though our data may be misleading if the Trusts obtain their supplies via the local acute Trust. This suggests that the safer alternatives in these categories are widely accepted and as such their use ought to be standardised across NHSiS. In one other category, blood collection devices, there was some evidence of introduction of safety devices in some Acute Trusts, but only in a minority. We did not systematically assess blunt suture needle use, but anecdotal evidence suggests this is used for specific surgical indications by a significant proportion of surgeons. Formal evaluations of devices to date appear to be few with even fewer having a written output. Those that were conducted were often unfavourable or the devices were not introduced due to their cost.

7.1.6 Summary

Given the relative lack of published evidence of efficacy for injury prevention it is reasonable to take account of cost issues in the various device categories and products. In light of this, the information presented creates something of a dilemma, since the devices with a high rate of injury and relatively increased risk of transmission are IV cannulae, yet these are by far the highest cost devices.

However, a policy of using safer devices universally in the lower cost categories (phlebotomy, lancet, butterfly) is worth serious consideration. In addition, a policy of stocking needle-and-syringe safety devices in all clinical areas only for IM drug administration use would reduce costs and confine device use appropriately. The precise costs of this are unknown due to uncertainties over the number of devices used for this purpose. For IV cannulae, it is suggested that a policy of selective use in high-risk areas or clinical indications may be justified. This would be against the accepted practice of universal precautions but would allow the appropriate use of a high cost device in known high-risk clinical settings.

7.2. Which Products are Best?

7.2.1 Range, availability of devices and customer support

We identified 50 products available to the UK market. Some suppliers proved extremely helpful, others less so. In some instances there were problems in the companies supplying the devices timeously and arranging appropriate training. As this number of devices offers some choice to NHS purchasers and greater competition, it is possible that price reductions could follow with bulk orders.

7.2.2 Field evaluations by users

The principal aim of this project was to evaluate each device in terms of its utility by a range of health care workers in differing clinical settings. We found this difficult to achieve in practice for a number of reasons. Users, even after committing to use the devices sometimes did not do so, or failed to complete evaluation forms. In some cases, there proved to be fewer opportunities to use the devices than first thought. In particular, for the needle and syringe category of devices, feedback from clinical staff across a variety of settings suggested they rarely gave IM injections, these being largely replaced with IV drug administration. When drugs were given by the IM route, this was often with pre-filled syringes. As a result in some categories of device we have supplemented device evaluations by users with benchtop evaluation by the researchers.

7.2.3 Recommendations in Device Categories

7.2.3.1 Lancet Devices

Two products, the **Unistik 2** (Owen Mumford) and **Genie** (BD) are preferred. The products are of similar cost or less compared to conventional devices.

7.2.3.2 Blood collection devices

The types of device most favoured by users were shielded devices. Two products for Vacutainer barrel/needle use are preferred: the **Eclipse** (BD) and the **Needle-Pro** (Portex). For winged needles (butterfly) use two products are preferred: the **Safety-Lok** (BD) and the **Vacurette** (Greiner).

7.2.3.3 Cannulation devices

There were no clear preferred products in this category. For non-ported devices (which are in themselves unpopular with staff) the **Saf-T-Intima** (BD) is the most favoured device, however the main use for this product would seem to be for sub-cutaneous infusion where it was very popular with users. The **Acuvance** (Johnson and Johnson) and **Safelon** (BD) products were similar in evaluation; both would be acceptable devices to users, but the Acuvance was marginally preferred. The two bBraun products, **Introcan Safety** and **Vasofix** could not be fully evaluated but appeared promising.

7.2.3.4 Syringe Devices

Results in this category must be treated with caution due to the poor number of evaluation forms returned and the lack of comparative data between all devices. Combining some of the user evaluation with the researchers' benchtop assessment of the devices however, we are able to make some suggestions. For the shielded devices, the **Safetyglide** (BD) and **Magellan** (Tyco) devices are preferred, though it must be noted that there was very little user feedback on the Magellan device. The **Needle-Pro** (SIMS Portex) is rated acceptable. For the retractable needle devices, the **NMT Safety Syringe** (NMT) is preferred, the **Vanishpoint** (Retractable Technologies) is acceptable. With a cost differential of 3-4x for the retractable devices compared to shielded devices, it is suggested the shielded devices be considered.

7.2.3.5 Theatre Sharps safety disposal devices

Use of these products in preference to conventional pads would only be based on an intuitive evaluation of greater safety, as there is no published evidence for injury prevention. Of the five products tested, the **Puncture Proof Pad** (Cory Bros) is rated as preferred, whilst the other products are all rated acceptable.

7.2.3.6 Blunt Suture Needles

Blunt suture needles were not formally evaluated in this project since there are only two manufacturers with similar products, **Ethiguard** (Ethicon) and **Bluntip** (Tyco). A small survey of surgeons showed that the needles are acceptable to many surgeons for certain

clinical uses though some surgeons dislike them. Studies have demonstrated they can reduce surgical glove perforation rates and injury rates by up to 80%. Published studies suggest the needles are acceptable to surgeons and result in no detriment to patient care. It is recommended that surgical directorates in Trusts review their use of blunt suture needles and consider if there are opportunities to use them more routinely where clinicians consider appropriate.

7.2.3.7 Scalpels

Two products were evaluated, but due to a low rate of user feedback recommendations are based on benchtop evaluation along with limited user feedback. The **Personna** is preferred, whilst the Swann Morton is rated as acceptable. Use of the scalpels is likely to be limited due to the small range of blade sizes.

7.2.3.8 Use of cutting diathermy for dissection is a technique that may be increasing in popularity amongst surgeons and reduces sharps injury risk, though it may bring the additional hazard of increasing surgical smoke levels.

7.3 Conclusion

Safety devices offer another means to reduce the number of sharps injuries in the NHSiS and improve workplace safety. The financial case for wholesale introduction of engineered safety devices is probably not favourable and at present it seems unlikely that savings to employers from injury costs would cover additional procurement costs completely. This equation could change if there were more instances of viral transmission, an increase in civil liability costs, a selective approach to the introduction of devices, or a reduction in device costs.

However, financial issues must be weighed against the potential reduction in harm to healthcare workers, that is, post-injury anxiety and side effects from drug treatment, since fortunately, viral transmission appears to be rare in Scotland. The devices themselves vary significantly in quality, in user acceptability and in cost. In addition to information on individual products, the following general recommendations are made:

1. On the basis of efficacy and cost, NHS Trusts should consider further widespread introduction of safety devices for the categories of lancets, blood collection devices, needleless IV connection systems and sharps disposal pads.
2. In contrast, for the same reasons, limited stocking of syringe devices should be considered, for the sole purpose of percutaneous use. Replacement of all standard syringes and needles is not necessary since some of these will not be used for a percutaneous procedure.
3. In the category of peripheral intravenous cannulation devices, users were equivocal about the safety devices and due to the high cost, we cannot make a positive recommendation that all NHS Trusts convert to safety cannulae. However, they should be considered for use in clinical settings with a higher proportion of patients with risk factors for BBV carriage and for use where patients are known to be carriers of BBV. This would mean most clinical areas having small stocks of these devices available for selective use, but the standard IV cannula would remain the main stock item. We recommend that Trusts consider this approach.
4. The use of blunt suture needles in operative surgery should be reviewed by surgical directorates with a view to maximising their use for appropriate indications.
5. Scalpels with safety features have limited applications but should be considered for use where clinically appropriate.

8. References

1. Needlestick Injuries: Sharpen Your Awareness. Report of the short life working group on needlestick injuries in the NHSScotland.
www.scotland.gov.uk/library3/health/nisa-oo.asp
2. US General Accounting Office Report. Occupational Safety: Selected Costs and Benefit Implications of Needlestick Prevention Devices for Hospitals.
<http://www.gao.gov-new.items-d0160r.pdf.url>
3. Simultaneous Infection With HIV and Hepatitis C Virus Following Occupational Conjunctival Exposure. Ippolito G. et al JAMA Vol 280 (1) pp28-29
4. UK Health Department (1998) Guidance for Clinical Healthcare Workers: Protection Against Infection with Bloodborne Viruses. Recommendations of the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis. London Department of Health. <http://www.open.gov.uk/doh/chcguid1.htm>
5. <http://hsc.virginia.edu/medcntr/centers/epinet/estimates.html>
6. Surveillance of occupational exposure to bloodborne pathogens in healthcare workers: the Italian national experience. Ippolito G et al. Eurosurveillance 1999 4:33-36
7. A Case-Control Study of HIV Seroconversion in Health Care Workers after Percutaneous Exposure. Cardo DM et al. The New England Journal of Medicine 1997;337:1485-90).
8. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. Mast ST, Woolwine JD. Gerberding JL. Journal of Infectious Diseases Vol 168 (6) (pp1589-92), 1993.
9. Stability and Activation of HTLV-111/LAV under clinical and laboratory environments. Resnick L et al, JAMA 1986;255(14):1887-91.
10. Needlestick transmission of HTLV-111 from a patient infected in Africa. Anon (1984) Lancet 2:1376-7
11. Surveillance of Occupational Exposure to Bloodborne Virus in Healthcare Workers. www.hpa.org.uk/infections/topic_az/bbv/data.htm
12. Scottish Centre for Infection and Environmental Health-Personal Communication
13. Hepatitis C Surveillance in Scotland (Results to 30 June 2002)
<http://www.show.scot.nhs.uk/scieh>
14. Quarterly HIV and AIDS Report. <http://www.show.scot.nhs.uk/scieh>
15. http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/hiv/occupational.htm
16. Solving the Needlestick Nightmare. R Munro. Nursing Times. 97 (24): 12, 14 June 2001
17. Underreporting of accidental exposures to blood and other body fluids in healthcare settings: An alarming situation. Roy E, & Robillard P. Advances in Exposure Prevention 1995;1:11
18. A survey of percutaneous/mucocutaneous injury reporting in a public teaching hospital. D.J Haiduven et al. Journal of Hospital Infection (1999) 41:151-154)
19. <http://www.med.virginia.edu/medcntr/centers/wpinet/subpage2.html>
20. www.pasa.doh.gov.uk/medsurg/intravenous/needlestick/epinet_Figures_2002.ppt
21. Continuous Quality Improvement Research Programme Aimed At Reducing Sharps Injury Within Glasgow Royal Infirmary: First Feedback to All Divisions IN GRI. Curran et al
22. A G Elder, Personal Communication
23. EPINet Report Uniform Needlestick and Sharp Object Injury Report 21 Hospitals 1999. <http://hsc.virginia.edu/medcntr/centers/epinet/soi99.html> accessed 25/07/2002
24. EPINet Report: 2001 Percutaneous Injury Rates. Advances In exposure Prevention Vol.6, No. 3 2003 (Jane Perry, Ginger Parker, Janine Jagger)
25. Device-Specific Risk of Needlestick Injury in Italian Health Care Workers. G Ippolito et al. JAMA, August 24/31, 1994- Vol 272, No8
26. Rates of Needlestick Injury Caused By Various Devices In A University Hospital. J Jagger et al. N Engl J Med 1988; 319:284-8

27. http://www.doh.gov.uk/HPSSS/TBL_D1.HTM
28. http://www.pasa.doh.gov.uk/medsurg/intravenous/needlestick/EPINET_preliminary_report_Jan_2002.doc
29. HIV transmission in the healthcare setting .Robert L.M and Bell D.M. Infectious Disease Clinics of North America 1994; 8, 319-329.
30. Sharps Safety & Needlestick Prevention. An ECRI Resource for Evaluating and Selecting Protective Devices. (ECRI Europe, Welltech Centre, Ridgeway, Welwyn Garden City, Hertfordshire AL7 2AA)
31. <http://www.tdict.org>
32. Lancing devices for multi-patient capillary blood sampling: avoidance of cross contamination by correct selection and use. Anon. Safety Action Bulletin; 65: November 1990.
33. Royal College of Nursing 'Be Sharp Be Safe' Campaign
www.pasa.doh.gov.uk/medsurg/intravenous/needlestick/epinet_figures_2002.ppt
34. Lancet as a source of sharps injuries (letter). M.J.Weinbren, A.Hardwick, R.M. Perinpanayagam, A.S Thayalan. The Journal of Hospital Infection 1998; Volume 38, Number p235-236
35. Mendelson M, Lin-Chen B, Kogan G, Goldbold J. Evaluation of a safety resheathable winged steel needle for prevention of percutaneous injury associated with intravenous access procedures among healthcare workers. Infection control and hospital epidemiology, 24(2);105-112, February 2003 .
36. Mendelson MH, Chen LBY, Finkelstein LE, Bailey E, Kogan G.Evaluations of a safety IV catheter (Insyte Autoguard, Becton Dickinson) using the Centres for Disease Control and Prevention (CDC) National Surveillance System for Hospital Healthcare Workers Database. Mount Sinai Med Centre, New York. Abstract 4th Decennial International Conference on Nosocomial and Healthcare Associated Infections.
37. Asai T, Hidaka I, Kawashima A, Miki T, Inada K, and Kawachi S. Efficacy of catheter needles with safeguard mechanisms. Anaesthesia 2002, 57, pages 572-577
38. Asai T, Matsumoto S, Matsumoto H, Yamamoto K, Shingu K. Prevention of needlestick injury:Efficacy of a safeguarded intravenous cannula. Anaesthesia Volume 54 (3). March 1999. 258-261
39. Younger B, Hunt E, Robinson C, McLemore C. Impact of a shielded safety syringe on needlestick injuries among healthcare workers. Infection Control Hosp Epidemiol 13 (1993), pp349-353
40. Orenstein R, Reynolds L, Karabic M, Lamb A., Markowitz SM, Wong ES. Do protective devices prevent needlestick injuries among healthcare workers? Am J Infect Control 23 (1995), pp344-351
41. Zakrzewska JM, Greenwood I, Jackson J. Introducing safety syringes into a UK dental school--a controlled study.Br Dent J. 2001 Jan 27;190(2):88-92.
42. Loudon MA, Stonebridge PA. Minimizing the risk of penetrating injury to surgical staff in the operating theatre: towards sharp-free surgery. J.R. Coll. Surg. Edinb.,43,February 1998, 6-8
43. Wright KU,Moran CG,Briggs PJ.Glove perforation during hip arthroplasty.A randomised prospective study of a new taperpoint needle. J Bone Joint Surg Br.1994 May;76(3):505
44. Evaluation of Blunt Suture Needles in Preventing Percutaneous Injuries Among Health-Care Workers During Gynecologic Surgical Procedures-New York City, March 1993-June 1994. [From the Centres for Disease Control and Prevention] JAMA, Volume 277 (6). February 12, 1997.45-452
45. Hartley JE, Ahmed S, Milkins R, Naylor G, Monson JRT, Lee PWR Randomized trial of blunt tipped versus cutting needles to reduce glove puncture during mass closure of the abdomen.. British Journal of Surgery 1996, 83, 1156-1157
46. Alvarado-Ramy F, Beltrami E M, Short L J, Srivastava PU, et al. A comprehensive approach to percutaneous injury prevention during phlebotomy: Results of a multicenter study, 1993-1995. Infection Control and Hospital Epidemiology. Feb 2003. Vol. 24, Iss. 2; p. 97

47. Billiet LS, Parker CR, Tanley PC, Wallas CH . Needlestick injury rate reduction during phlebotomy; a comparative study of two safety devices. *Lab Med* 1991. 22(2):122—123.
48. Jagger J . Reducing occupational exposure to bloodborne pathogens: where do we stand a decade later? *Infect Control Hosp Epidemiol* 1996;17(9):573—575.
49. O'Connor RE, Krall SP, Megargel RE, Tan LE, Bouzoukis JK. Reducing the rate of paramedic needlesticks in emergency medical services: the role of self-capping intravenous catheters. *Acad Emerg Med* 3 (1996), pp. 668–674.
50. Lawrence LW, Delclos GL, Felknor SA, et al. The effectiveness of a needleless intravenous connection system: an assessment by injury rate and user satisfaction, *Infect Control Hosp Epidemiol*. 1997; 18:175-182.
51. L'Ecuyer P.B., Schwab E.O., Iademarco E., Barr N., Aton E.A. and Fraser V.J., Randomized prospective study of the impact of three needleless intravenous systems on needlestick injury rates. *Infect Control Hosp Epidemiol* 17 :12, p 803(1996)
52. Yassi A, Mc Gill M, Khokar J. Efficacy and cost-effectiveness of a needleless intravenous access system. *AJIC Am J Infect Control* 1995;23:57-64.
53. Van Keuren M, Cunningham C, Hackham B, Steinberg J. Impact of a needleless system (NLS) for connecting intravenous tubing on the incidence of needlestick injuries [abstract]. *AJIC Am J Infect Control* 1992;20:110.
54. Mendelson MH, Short L, Shecter C, Meyers BR, Rodriguez M, Cohen S. Study of a needleless intermittent intravenous access system for peripheral infusions: analysis of staff, patient and institutional outcomes. *Infect Control Hosp Epidemiol* 1998;19:401-6
55. Gartner K. Impact of a needleless intravenous system in a University Hospital. *AJIC Am J Infect Control* 1992;20:75-9
56. Rutowski J, Peterson SL. A needleless intravenous system: an effective risk management strategy. *Infect Control Hosp Epidemiol* 1993;14:226-7.
57. Skolnick R, LaRocca J, Barbra D, Paicius L. Evaluation and implementation of a needleless intravenous system: making needlesticks a needless problem. *AJIC Am J Infect Control* 1993;21:39-41.
58. Mingoli A., Sapienza P., Sgarzini G.*et al.*, Influence of blunt needles on surgical glove perforation and safety for the surgeon. *Am J Surg* 172 (1996), pp. 512–517.
59. J.J. Rice, J.P. McCabe and F. McManus, Needlestick injury: reducing the risk. *Int Orthop* 20 (1996), pp. 132–133
60. Genasi F, Goldberg D, Henry M, Symington IS, Bagg J, McCreddie M, Taylor A. Gordon B. Occurrence and prevention of reported occupational needlestick injuries within the National Health Service in Scotland, with particular reference to the role of safety devices. Report for Chief Scientist Office, Scottish Executive Health Department. 2003

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