HSE

Health and Safety Executive

An evaluation of the efficacy of safer sharps devices

Systematic review

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Research Report

HSE

Health and Safety Executive

An evaluation of the efficacy of safer sharps devices

Systematic review

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Sharps-related injuries carry the risk of serious blood borne infection. A systematic review was undertaken to consider the evidence related to safer sharps devices and their impact on needlestick injury reduction within the healthcare sector. The review sought to determine whether:

- the use of safer sharps devices could reduce the incidence of sharps injury;
- dedicated educational / training initiatives could reduce the incidence of sharps injuries;
- safer sharps devices were accepted by the hospital personnel asked to use them; and
- safer sharps devices had any proven impact on patient care outcomes.

The quality and quantity of evidence was limited, mainly due to study designs used by publishing authors. Despite this, there was sufficient published evidence to consider the use of safer sharps devices to reduce the incidence of sharps injuries amongst UK healthcare workers.

Studies showed that when educational programmes were implemented alongside a safer sharps device, lower rates of sharps injuries were sustained for longer. However, the benefit attributable to education alone could not be isolated from the impact of the introduction of the safer sharps device.

Few studies have investigated user acceptability of safer sharps devices and patient outcomes, and more studies are required to assess these areas with greater certainty.

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HSE Books

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CONTENTS

MAIN MESSAGES

This systematic review has considered the evidence related to safer sharps devices and their impact on needlestick injury reduction. The United States of America introduced legislation in 2000 to reduce sharps related injuries, and the European Union introduced a Directive in 2010 with similar aims. However, sharps related injuries persist within the healthcare sector with the risk of blood borne virus transmission, as well as infectious diseases caused by other viruses and bacteria. This issue therefore remains a concern for healthcare employers and occupational health professionals.

For the research questions considered, the quality and quantity of evidence was limited, mainly because of constraints on study design, for example, ethical considerations, insufficient statistical power, design rigour and the probability of bias.

Despite these constraints, taking into account the published studies included in this review there is sufficient published evidence to consider the use of 'safer' sharps devices to reduce the incidence of sharps injuries amongst United Kingdom healthcare workers.

Studies that examined the impact of 'specific' training (related to the use of safer sharps devices) were considered in this review. When educational programmes were implemented alongside a safer sharps device, lower rates of sharps injuries were sustained for longer. Training and 'worker attitudes' were integral to the success of these safer sharp device interventions. However, the benefit attributable to education alone could not be isolated from the impact of the introduction of the safer sharps device. More studies designed to assess the impact of educational programmes are required to demonstrate their benefit with greater certainty.

The review also considered evidence related to the acceptability of safer sharps devices by healthcare workers and whether using these devices affected the quality of care and patient outcomes. Few studies investigated these two research questions; because these elements were not central to the study design and the limited evidence was of low quality.

The reviewed evidence suggests that health care workers (HCWs) should be consulted about acceptability of new safer sharps devices before their introduction; also, younger HCWs were more accepting of their introduction.

Adverse outcomes for patients were not generally reported, but the risk for bacterial colonisation of the safer sharps devices is an important factor for patient safety and was considered by only a few studies.

EXECUTIVE SUMMARY

OBJECTIVES

To conduct a systematic review to provide the Health and Safety Executive with robust evidence about the use of safer sharps devices to reduce injuries amongst health care workers.

A systematic review of published literature (papers written in English only) from January 2000 to March 2010 was undertaken to assess the quality of the evidence about:

- Whether the use of safer sharps devices could be shown to reduce the incidence of sharps injury compared with the use of conventional needle systems?
- Whether any purpose-designed educational / training initiatives on the use of safer sharps could be shown to reduce the incidence of sharps injuries compared with previous working practices?
- Whether safer sharps devices were accepted by medical, nursing or paramedical personnel asked to use them?
- Whether safer sharps devices had any proven impact on patient care outcomes compared to devices previously used?

METHODOLOGY

The Scottish Intercollegiate Guidelines Network (SIGN) framework was used for this systematic review. SIGN was used to grade the published studies to reach conclusions based on the quality of this evidence. Occupational health studies rarely obtain the highest SIGN evidential gradings (level 1++). They tend to be studies of real working practices, which bring inherent constraints about sample size, the practicality of randomising participants and access to suitable control groups. The studies selected to develop evidence-based conclusions here were those of SIGN grade 2- and above; the 2- category reflecting some of the limitations surrounding the design of safety device studies. Non-analytical studies (level 3) and expert opinion (level 4) were excluded from the development of evidence-based conclusions (Table 2, page 11). However, some relevant content from level 3 studies provided useful background information for this report.

RESULTS

Following initial searches and sifts, 92 peer-reviewed papers were systematically examined to assess the quality of the evidence and their relevance to the study questions. Subsequently 82 papers required full review. Using the SIGN process only 41 papers were included in the evidence tables and those with evidence levels of 2- and greater were used to formulate evidence-based conclusions.

EVIDENCE-BASED CONCLUSIONS

- The use of safer sharps devices is considered to improve safety and reduce the incidence of healthcare worker needlestick injuries. However, their use is not regarded as a complete solution to reducing sharps related injuries amongst health care workers.
- Safer sharps devices should be introduced alongside appropriate educational programmes.
- Healthcare workers should be involved in evaluating products before safer sharps device are introduced.

MEMBERS OF THE LITERATURE REVIEW ASSESSOR GROUP

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Thanks also to Carol Wray (NHS Supply Chain) and Elizabeth Murphy (NHS Grampian OHS), who offered comment and support during the initial assessors' group meeting, but were unable to contribute to the literature review process.

Susan Cliff (Health Protection Agency) and Anil Adisesh (HSL) also contributed to the initial assessor group meeting and to the initial review process, but became unavailable for paper reviews at an early stage of the study.

Conflict of Interest

One external member identified his role in publications within a related topic area. This information was considered by the HSL research team but not deemed to be a source of conflict of interest.

1 INTRODUCTION AND CONTEXT

Injuries to healthcare workers from sharp medical instruments (sharps) contaminated with a patient's blood have the potential to transmit more than 20 infectious diseases; including blood borne viruses (BBV) that can have a serious impact on health (HSE, 2007). In addition to the health impact, the anxiety and side effects of post-exposure prophylaxis have a significant personal impact on healthcare workers, with an infection having the potential to limit their career in healthcare. Injuries involving chemical contamination of sharps are therefore a recognised hazard within the healthcare sector. Costs to health sector employers include lost time (for post incident investigation, treatment etc) and costs of prophylaxis pharmaceuticals.

There is no one reliable source of data on the number of sharps injuries. The Health Protection Agency (HPA) runs a well-used voluntary reporting scheme for incidents of significant occupational exposure to a blood borne virus from National Health Service (NHS) employers in England, Wales and Northern Ireland. It reported that between January 1997 and December 2007 there were 3,773 reported occupational exposure incidents. These involved exposures to blood or other body fluids from patients known (e.g., as a result of the incident) to be a high risk for three key blood borne viruses[i]. It includes both percutaneous (where the incident involves an injury through the skin of the person) or mucocutaneous (contact with eyes/mouth or an uncovered wound). The HPA report found that:

- Sharps injuries are the most commonly reported occupational exposures to infected blood or body fluids;
- Transmission rates remain low as a proportion of reported incidents;
- Injury from hollow bore needles remains the most common type of sharps injury, representing 68% of all percutaneous exposures[ii].

In 2000 the United States (US) introduced a Needlestick Safety and Prevention Act, which required that healthcare employers use safety engineered sharps in preference to traditional sharps, where they were available. Partly in response to this, there has been an increase in the availability of alternatives to traditional sharp medical instruments. Commonly known as 'safer sharps technologies' these include cannula and needles incorporating mechanical mechanisms that recap or otherwise eliminate the sharp point after use. There are two main types of safety engineered sharps devices, either active or passive. Active devices require healthcare workers to activate the mechanism, whereas passive devices deploy automatically. As these become available they have been taken up in hospitals and other health care settings in many countries, particularly those with well-developed healthcare systems.

In July 2009, The European Hospital and Healthcare Sector Social Partners[iii] signed a Framework Agreement, which aims to introduce harmonised measures across Europe to prevent sharps injuries in the health care sector. Since the 2009 European Agreement, the initiative was proposed as a European Union (EU) Directive to the Council of Ministers and subsequently adopted on the 8th March 2010. Implementation of the Directive in the UK is required by May 2013. The Health and Safety Executive (HSE) is leading the work to address how the Directive will be transposed.

HSE asked the Health and Safety Laboratory (HSL) to complete a systematic review considering the evidence related to use of safer sharps technologies and their impact on sharps injury reduction. The review is intended to provide HSE with evidence to inform the

[i] Hepatitis B Virus surface antigen, Hepatitis C Virus or Human Immuno Virus positive

[ii] Health Protection Agency Centre for Infections. Eye of the Needle - Surveillance of Significant Occupational Exposure to Blood Borne Viruses in Health Care Worker.. Available at:http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1227688128096

[iii] HOSPEEM (Health care employers) and EPSU (Healthcare Unions)

transposition of the Directive, prepare advice for the healthcare sector and inform potential enforcement decisions.

HSL were commissioned to undertake a systematic review of evidence concerning safer sharps technologies used in healthcare, and to assess whether the evidence supports their use as an effective means to reduce sharps related injuries. The review was required to assess:

- The setting of the research, i.e. acute care, mental health, primary care & community care.
- The level of training, information and instruction given to employees before the introduction of safer medical devices.
- The quality of existing safety policies and procedures.
- The level of reporting, before, during and after the implementation of safer medical devices.
- The overall impact of interventions to reduce sharp injuries.
- Other relevant factors

A particular concern was the extent to which the published studies provide robust evidence about the potential practical and cost implications of introducing safer sharps devices. Therefore a systematic review based on the Scottish Intercollegiate Guidelines Network (SIGN) methodology was undertaken with involvement of an assessor group composed of external and internal experts (see section 2).

The assessor group and the HSE technical lead agreed four 'Population Intervention Comparison Outcome' (PICO) questions:

- Whether the use of safer sharps could be shown to reduce the incidence of sharps injury compared with the use of conventional needle systems?
- Whether any purpose-designed educational / training initiatives on the topic of safer sharps use could be shown to reduce the incidence of sharps injury compared with the use of any previous working practice systems in place?
- If implemented, whether safer sharps devices were accepted by those medical, nursing or paramedical personnel asked to use them?
- Whether the introduction of safer sharps devices had any proven impact on patient care outcomes compared with any previous systems of treatment employed?

The systematic review assessed the amount and quality of evidence for these four questions. Relevant published studies and reviews were sifted and examined systematically to assess the quality of the study designs (e.g., type of intervention, size of the population(s), inclusion of a comparison control population, and outcomes measured).

It was decided from the outset that literature on the related topic of the safe disposal of sharp devices was outside the scope of the current review. To focus the literature search strategy, some topics were treated as secondary, e.g., the cost implications for safer sharps devices, or whether the devices were activated by active or passive means. Comments about these two issues are based only on the papers included within this review.

2 METHODOLOGY

2.1 AGREEMENT OF INITIAL APPROACH AND SCOPE

Following detailed discussions with HSE it was agreed that the most appropriate method of providing authoritative, informative advice for this review would be to undertake a systematic review of the available literature within a defined period of publication. This would ensure an unbiased assessment of the published literature not always provided by a standard (non-systematic) narrative review, and be based on a validated strategy to assess the quality of published evidence. This systematic methodology ensures consistency should reviews of this topic be required when new evidence is published.

A systematic review of clinical interventions is defined as "*an efficient scientific technique to identify and summarise evidence on the effectiveness of interventions and to allow the generalisability and consistency of research findings to be assessed and data inconsistencies to be explored'*, SIGN, 2011.

A number of systematic review methods are available but the SIGN methodology was applied here for the following reasons:

- It is capable of meeting the requirements described above, i.e., a defined process of unbiased literature assessment open to audit or reproduction at a future point in time.

- This review was required to reach clear, evidence-based conclusions, subject to the quality of the evidence, but it was not required to inform guidelines. The SIGN approach incorporates clear steps for such conclusions to be developed. Any subsequent provision of guidance or related initiatives is a separate issue for HSE to consider when it has consulted with duty holders and external partners in the healthcare sector.

- Groups working part time on projects within a limited timescale typically undertake SIGN reviews. This meant that the SIGN methodology was suited to the team undertaking this work and provided a structured framework to review the published studies.

- Although the SIGN approach provides a well evaluated and widely used methodology for reviewing health related research findings, its methods are under constant refinement to meet the needs of those using them. This point is discussed further elsewhere in this report.

2.2 EXTERNAL PARTNER INVOLVEMENT – THE ASSESSOR GROUP

The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) states that '*The members of the 'review team' are responsible for the day-to-day conduct of a review or series of reviews, and may come from a range of backgrounds, some with methodological skills in undertaking reviews and some with subject area expertise*'. In line with this principle an external group was asked to help with the development of the PICO questions, to review papers, and to comment on the draft report. This group represented organisations with relevant expertise or knowledge obtained from working in or with the healthcare sector. The individuals chosen possessed an appropriate insight about safer sharps and their details are listed on page vi of this report. Some members of the group had previous experience of preparing systematic reviews. For those group members that had not previously gained this experience, a tutorial session was completed at the inception meeting. In addition, the SIGN tutorial was circulated to the assessor members, should they require further clarification on the various stages of the review process (http://www.sign.ac.uk/methodology/tutorials.html).

2.3 DEVELOPMENT OF REVIEW QUESTIONS

An initial assessors' group meeting was held at HSL on the 22nd February 2010. This meeting covered the proposed methods including the scale of literature searching, appraisal and retrieval of data, assessing the impact of study findings and formulating the PICO questions. Those present developed the draft review questions on the day, and full minutes of the meeting were recorded and circulated.

Following the initial meeting in consultation with the assessor group four draft PICO questions were further refined and their final form agreed (Figure 1). The HSL project team then worked closely with the wider group of external assessors to refine the literature search to identify the most relevant set of publications for each question. Many of the search terms were agreed during the initial assessor group meeting, and all were tightly linked to the agreed PICO Questions, as detailed in Appendix 1. This process closely aligned to that described by SIGN for systematic reviews[i].

[i] *http://www.sign.ac.uk/guidelines/fulltext/50/section6.html*

Figure 1. Study questions and their PICO-format breakdown

1. Does the use of safer sharps devices compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

Population	Intervention	Comparison	Outcome
Employees of healthcare organisations including contractors	Provision and use of safer sharps devices	Use of standard sharp device	Rate of sharps injuries and blood/body fluid exposures

2. Does the provision of an education or any other training programme compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

Population	Intervention	Comparison	Outcome
Employees of healthcare organisations including contractors	Provision of an education or any other training programme	Usual education or training	Rate of sharps injuries and blood/body fluid exposures

3. Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?

Population	Intervention	Comparison	Outcome
Healthcare workers using sharp devices	Provision and use of safer sharps devices	Use of standard sharp device	Change in user acceptability characteristics (e.g. tactile properties, time for procedure etc.)

4. Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practices?

Population	Intervention	Comparison	Outcome
Patients of healthcare organisations	Subject to the use of safer sharps devices	Use of standard sharp device	Change in patient outcomes (e.g. infection rates, recovery time etc.)

2.4 SYSTEMATIC LITERATURE SEARCH

2.4.1 Agreed search boundaries

Safer sharps technology is relatively new and so the relevant period of publication was constrained to recent decades and consistent with the SIGN process this was discussed and

agreed by the study group. A ten-year retrospective search (2001-2010) was appropriate because the US initiative was implemented within the last ten years (OSHA, 2001) and the EU drive to reduce sharps injury has been considered for several years but is yet to be fully implemented. Experienced information retrieval specialists from the HSE's Infocentre undertook the literature search.

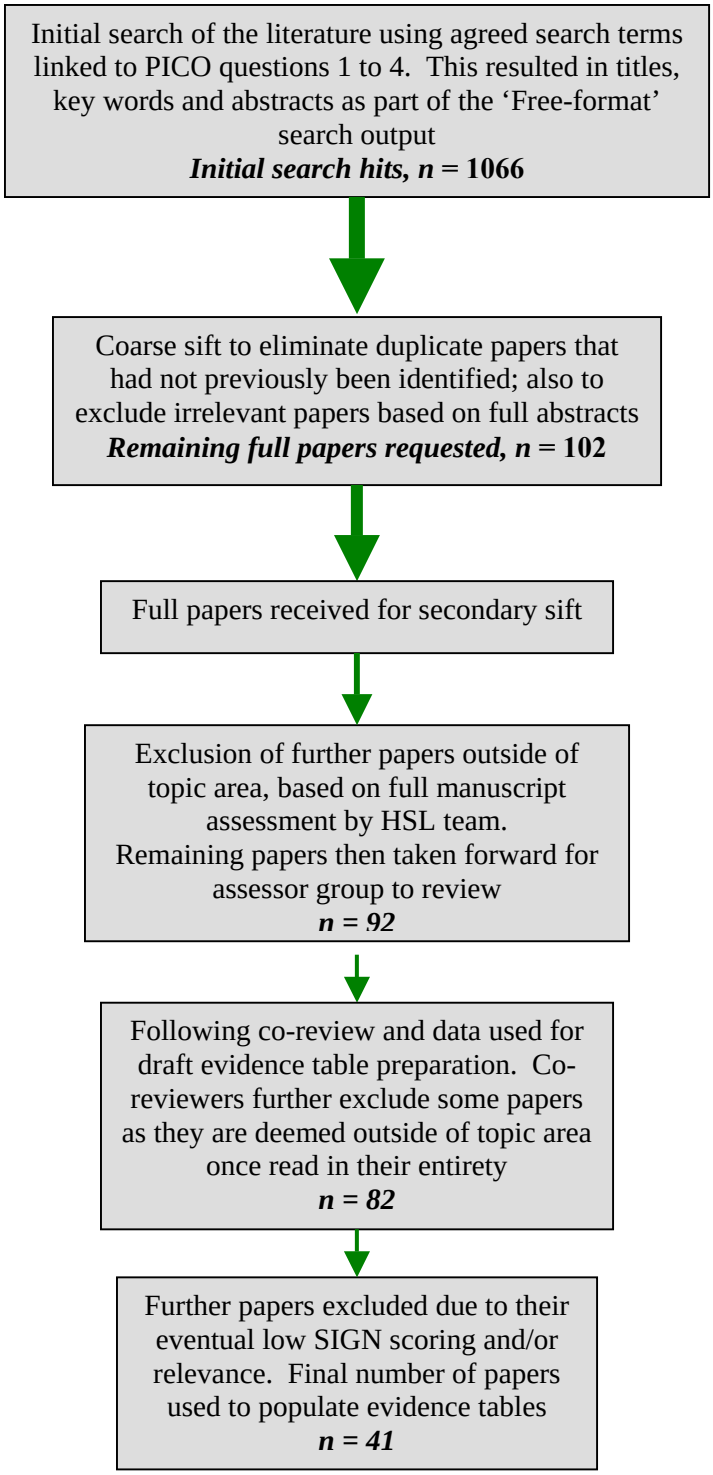
2.4.2 The search process

The agreed review questions and search terms were provided. Search algorithms were prepared by the HSE Infocentre (Appendix 1) and incorporated all of the terms requested, whilst being sufficiently selective to exclude papers outside of the topic areas and eliminate duplication. Database searches were undertaken by the HSE search team and included the EMBASE and MEDLINE databases. The use of two comprehensive search engines is consistent with recommendations given in a recent discussion paper about systematic reviews for occupational health research (Nicholson, 2011).

2.5 REVIEW OF ABSTRACTS AND OTHER RELATED OUTPUT

HSE Infocentre provided printed summaries of the publications and the HSL team undertook an initial sift of these papers to identify those most relevant to the subject of the review. Abstracts of the literature identified as relevant to the review were then requested. Following a further sift of the abstracts copies of the relevant papers were then requested. The full process and distillation of publications from the initial search to the paper reviewed is summarised in Figure 2, below.

Figure 2. Search and sift procedure undertaken for papers relating to PICO questions 1 to 4



2.6 CRITICAL APPRAISAL OF PAPERS

SIGN defines the quality of evidence as, '*the extent to which confidence in an estimate of the effect is adequate to support recommendations*'. To meet this requirement – in this case to draw up evidence-based conclusions - this review systematically examined the design of each of the sifted studies to assess the following.

- The design of the study (e.g., non-analytic studies, case reports; case control or cohort studies, systematic reviews of case control or cohort or studies, meta-analyses of such studies, and the results of randomised controlled studies).
- The likelihood that the results of these studies were confounded or biased (as a result of insufficient power, or poor design).

Other factors that were relevant in ranking the papers were:

- The size of the populations studied.
- The characteristics of the study population(s) (and controls if included).
- The nature of the intervention and follow up period in the study.
- The nature of the outcome measures (quantitative or qualitative) and any measurable effect size that resulted from the intervention.

Peer-reviewed publications, reports and other articles vary widely in terms of the research study design and how well this was implemented. In the context of occupational health research criteria that apply to the design of clinical studies (e.g., drugs or medical devices) cannot be applied easily to consider the risks to workers using safer sharps devices. For example, it has been stated, "*Since randomised control trials do not apply in many areas of occupational medicine, e.g. health surveillance, susceptibility to disease or the sensitivity and specificity of screening and diagnosis procedures, there is scarce level 1 evidence as defined by the SIGN grading system*"(Nicholson & Llewellyn, 2010). Tuma & Sepkowitz (2006) also observed that "*blinded, randomized, and controlled trials, which are considered the 'gold standard', cannot be used to assess device implementation because HCW must be appropriately trained in device use. Randomization of HCW is difficult in settings outside of the operating room environment, as are direct observations of compliance with device use and percutaneous injury event"*.

Another limitation of safer sharps device studies is the relatively low incidences of reported needle stick injuries (NSI) which impacts on the statistical power of study; requiring either very large populations or the use of surrogate measures of the potential for injury. These surrogates may not be an accurate reflection of the risk of injury. Due to this constraint many of the published studies have focussed on smaller populations in order to carry out practical interventions (Pugliese *et al*, 2001). For the current study the HSL review team recognised that most of the sifted papers employed study designs that could be evaluated using the SIGN data extraction checklist. This consists of asking questions about key aspects of the study design and the outcomes. For a few studies the SIGN Randomised Control Trial (RCT) checklists were used, which require more detailed extraction of study data. Both checklists are available via the SIGN website (http://www.sign.ac.uk/guidelines/fulltext/50/annexc.html). For the purposes of this occupational health research we have included studies of evidence level 2- or above in preparing evidence-based conclusions from the available information, although relevant background information at level 3 was also used to support more general comments.

2.7 EVIDENCE TABLES

Evidence tables were used to draw together the summaries of each of the papers reviewed. Two reviewers critically appraised each paper and the evidence table summarised their combined assessment of the study and the results. This process is explained on the SIGN web site[ii], which states: "*The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies"* (SIGN, 2011).

The study team used MS Word tables to summarise their comments and to help to prepare the considered judgement forms. The study grading was applied in most cases when the evidence table was compiled, but these gradings were agreed between the contributing assessors. During the review process it was recognised that some of the studies were equally relevant to another PICO question and so a reference to this has been placed in the evidence tables. Some papers had to be reviewed at a later stage in this process (e.g. papers not identified in the original searches) and the HSL team agreed the SIGN gradings. All external assessors were given the opportunity to review the SIGN gradings as listed in Table 1.

2.8 CONSIDERED JUDGEMENT FORMS

The evidence tables were used to populate the considered judgement forms and formulate evidence-based conclusions. When co-reviewers allocated different SIGN gradings to a paper these were discussed between the two reviewers and a consensus reached.

The criteria for grading evidence and related review output often rate RCTs as the highest level of evidence. However, RCTs do not apply to many areas of occupational health research and as a consequence in this review few SIGN graded evidence level 1 studies were encountered. For occupational health research it has been suggested that reviewers should, *"Avoid adhering rigidly to a hierarchy of evidence with the RCT at the pinnacle, since this concept neglects methodological appropriateness. Adopt a balanced approach, recognise the strengths and limitations of well-conducted observational studies"'* (Nicholson, 2011). For this review evidence-based conclusions were taken from the higher scoring studies. Where appropriate relevant information from lower graded studies has been taken to inform knowledge gaps and to support general comments.

The lack of RCT and systematic reviews for studies of safer sharps related issues has been raised as a limiting factor in other papers that were reviewed in this study and this is discussed elsewhere in this report.

[ii] www.sign.ac.uk/guidelines/fulltext/50/section7.html

Table 1: Levels of evidence based on the SIGN approach

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias.
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias.
2++	High quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal.
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal.
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal.
3	Non-analytic studies, e.g. case reports, case series.
4	Expert opinion.

2.9 EVIDENCE-BASED CONCLUSIONS

The nature and strength of any evidence-based conclusions from this review need to be assessed in terms of the importance that can be placed on them; for example, their use in any future decision or policy-making. The grading system (Table 2) is intended by SIGN to place appropriate emphasis on the quality of the evidence supporting each conclusion drawn, and as such a single study cannot support a conclusion. Where there is insufficient information to support an evidence-based conclusion within this review, a knowledge gap (KG) has been identified. More weight can be given to conclusions supported by good quality observational studies, e.g. where RCTs are not available. Through the considered judgement process, evidence may be down graded where there are inconsistencies in the evidence base, where the evidence is not generalisable or where it is not directly applicable to the target population. The following SIGN grading was applied to the evidence in the papers that were reviewed.

Table 2: Grades of evidence-based conclusions (based on SIGN)

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+.

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++.

D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+.

KG Knowledge gaps identified by the HSL team.

2.10 REVIEW OF ADDITIONAL PAPERS

Despite carrying out a thorough search of the published literature other published studies were identified when individual papers were reviewed and scrutinised. These new papers were checked to ensure that their content fell within the agreed criteria for the review (i.e., published in English, within the last ten years, relevant to modern healthcare systems and relevant to the PICO questions). When these studies met these criteria they were reviewed on the same basis as the previous studies but only the HSL team undertook the paired reviews.

3 FINDINGS

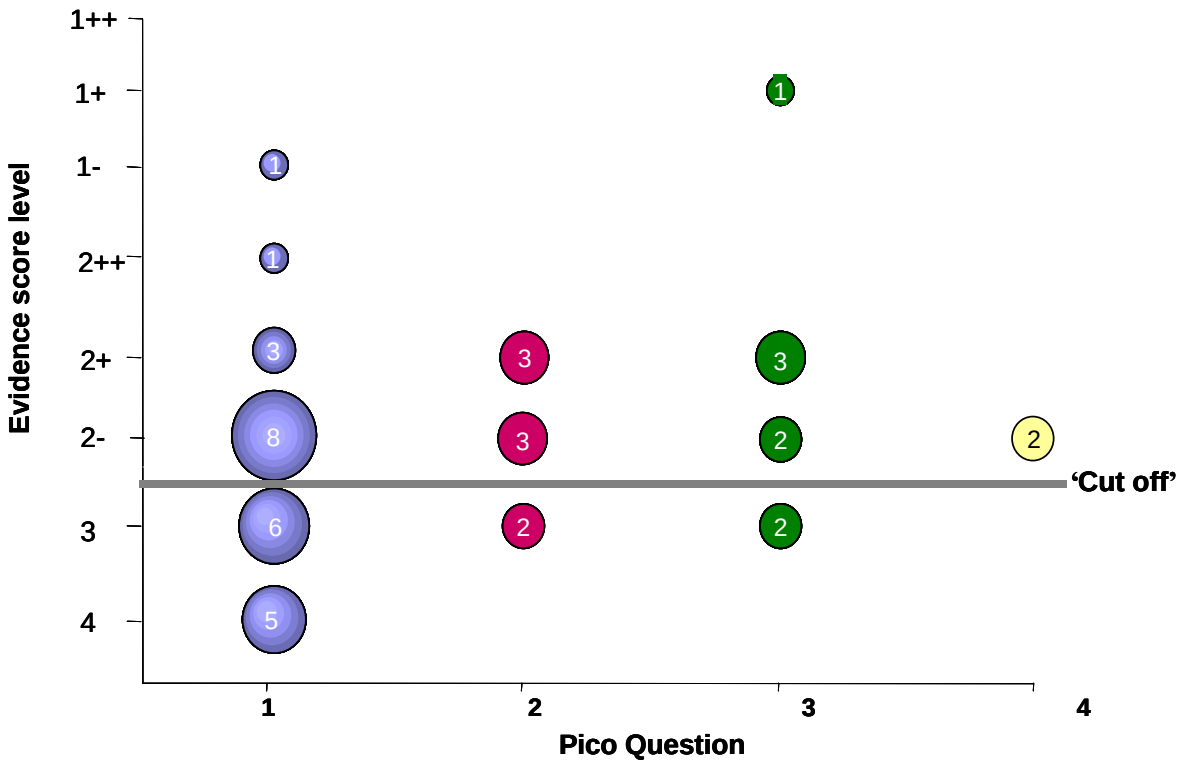
3.1 PRIMARY SEARCH OUTPUT AND PAPER EXCLUSIONS

Figure 2 summarises the different numbers of papers that were originally identified by the literature search and those that were retained through the different stages of appraisal and review. This figure also identifies the number of papers that were rejected during these stages based on their content (e.g., outside the topic area, short editorials only, or no data presented). Search results for PICO question 1 generated the largest number of relevant papers, followed by PICO question 2. Fewer papers were identified for PICO questions 3 and 4. The numbers of sifted papers and their allocated SIGN gradings for each of the PICO questions is summarised in Figure 3 (below).

3.2 EVIDENCE TABLES

All papers containing evidence of sufficient quality were incorporated into the respective evidence tables with the designated SIGN grading. Those papers of insufficient quality (i.e., mostly grading 4) were removed, based on collective discussions with the external reviewers and the HSL team. The completed evidence tables are included within Appendix 3.

Figure 3. Distribution of grading allocations and numbers of retrieved papers following literature review searches under the four separate PICO questions.



Note: The inserted number and size of each circle represents number of papers that met specific Pico scores. Recommendations were only made based on those studies of evidence grade 2 and above. Four papers were used to address two of the Pico questions see evidence tables references **(25)(27)(29)(32).**

PICO Question 1: Does the use of safer sharps devices compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

PICO Question 2: Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

PICO Question 3 Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?

PICO Question 4: Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practice?

3.3 CONSIDERED JUDGEMENT FORMS

N.B. The parenthesised reference numbers in the considered judgement tables below cross-refer to the papers also summarised in the evidence tables in Appendix 3.

Considered Judgement Form 1	
Key question 1: Does the use of safer sharps devices compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?	
1. Volume of evidence *Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.*	
This review question generated the largest number of relevant papers from the searches undertaken (*n* = 24). Following systematic review these publications produced a body of evidence that included papers offering well-conducted, relevant research designs although because of the variety of these studies the likelihood of bias and confounding cannot be ignored. Supportive information was also identified from less rigorously designed research and narrative reviews and these studies scored less highly and contributed to comments about knowledge gaps.	
2. Applicability *Comment here on the extent to which the evidence is directly applicable to UK practice*	
All of the papers identified were studies or reviews undertaken in modern healthcare facilities in developed countries, published in English and in environments where worker safety is important. The findings of these studies are meaningful for UK healthcare practices.	
3. Generalisability *Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.*	
The majority of studies reported injury reduction where safety devices were introduced and whilst the working environments described differed, some general trends were identified. For example, a beneficial impact of reducing needlestick injuries was observed across a range of safety devices (for example; IV Catheters, blunt needles and retractable winged steel (butterfly) needles). All the reviewed studies involved representative groups of HCWs and procedures using sharps devices that are applicable to the UK workforce considered within the scope of this review.	
4. Consistency *Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence*	
For some of these studies there was consistency in terms of the quality of evidence and the observed trends in injury reduction following the introduction of safer sharps device(s). Evidence from studies graded 2- and above includes the following: Rogers & Goodno's systematic review (**21**) of 11 studies which showed that 'safer device' interventions results in significant and reproducible reductions in NSI's (e.g., as measured by the number of glove perforations, skin perforations and percutaneous injuries). Other studies have reported the following benefits: • A statistically significant reduction in glove perforations was observed in HCWs using blunt needles. The study showed that blunt needles were protective against glove perforation (and probably needlestick injuries), especially for the assistant surgeons. However, the authors	

recognised that these reduced perforation rates compared to other studies may be due to the Hawthorne effect[iii] – (**3**)

- In the first 9 months following the introduction of the new retractable safety Winged Steel Needle (WSN) device the rate of needle stick injuries decreased by 60%, compared to the use of the manual re-sheathing WSN – **(4)**
- A 93% reduction in relative risk of percutaneous injury (PI) was observed in areas where safety devices were used. Healthcare worker behaviour was acknowledged as a risk factor for PIs but training was recognised as a means to address this risk – **(5)**
- For a specific type of safer sharps device (the IV catheter stylet) a significant reduction in sharps injuries was observed over a large HCW population using a defined 'before and after' assessment of the intervention, when compared directly with a non-safety control device - (**8**)
- Following a 3 year pre and post-interventional study of two sharps safety devices a 48% reduction in percutaneous injuries per 100,000 phlebotomies performed was observed, with no subsequent sero conversions to HIV, Hep B or C throughout the survey period – (**24**).

5. Clinical impact
Comment here on the potential clinical impact that the intervention in question might have - e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.

The majority of studies present significant and quantifiable benefits of using 'safer sharps' devices, compared with previously used sharps devices.

6. Other factors
Indicate here any other factors that you took into account when assessing the evidence base.

In view of the occupational nature of any trials involving safer sharps introduction, a number of other factors need to be considered when assessing the available data. In view of this some of the comments below were drawn from papers that scored less than 2-:

i) One cannot assume that all devices designed to reduce sharps injury will succeed in all contexts. For example:

The findings of these studies question the wisdom of a blanket approach to introducing safer sharps devices as well as their use in outpatient allergy clinics (practices). The study concluded that twice as many accidental needlestick injuries occurred in clinics administering immunotherapy using new 'safer' needle devices compared to older 'non safe' needles -(**11**).

ii) The design of sharps reduction studies is challenging due to the nature of the working environment where most sharps are used. As a result, evidence from RCT studies is rare and other studies need to be undertaken to provide a stronger evidence base about the value of interventions using safer sharps devices.

For example:

'*….blinded, randomized, controlled trials, which are considered the 'gold standard', cannot be used to assess device implementation because HCWs must be appropriately trained in device use. Randomization of HCW is difficult in settings outside of the operating room environment, as are direct observations of compliance with device use and PI events*' - (**12**).

Safer sharps devices vary considerably depending on their design and application. Designs are constantly evolving to improve their value to 'end users'. In view of the specific devices evaluated within these studies, newer devices may have superseded some and so knowledge about this new technology needs to be maintained to ensure that the benefits from using this technology can be gained.

[iii] *The Hawthorne effect is a form of reactivity whereby subjects improve or modify an aspect of their behaviour being experimentally measured simply in response to the fact that they know they are being studied, not in response to any particular experimental manipulation.*

7. Evidence statement *Please summarise the research group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level, which, applies.*	**Evidence level**
The study showed that the blunt needles were protective against glove perforation (and therefore probably needlestick injury), especially for the assistant surgeons. However, the surgeons overall were less satisfied using blunt-needles and rated them either as poor or offering no protection against glove perforation - (**3**).	**2++**
This study emphasised the importance of involving the user in the selection of the safety device. An audit investigated whether staff were activating the safety device on these needles including checks on phlebotomy sharps containers which showed that 100% of the devices had been retracted. Following the introduction of the new retractable safety WSN, the rate of needle stick injuries decreased by 60% compared to the use of the manual re-sheathing WSN - (**4**).	**2+**
This study stated that safety devices should not be regarded as an infallible solution as most of the devices they evaluated had to be activated to protect users and preventative injury (ie., reliant on user input) – **(5).**	**2+**
8. Evidence-based conclusion(s) *What conclusion(s) does the research group draw from this evidence? Please indicate the grade of conclusion(s) and any dissenting opinion within the group.*	**Grade of evidence-based conclusion**
Thirteen international, peer reviewed studies provided evidence that sharps devices designed for improved safety significantly reduced the incidence of healthcare worker needlestick injury. As such, safer sharps devices should be considered as part of an overall process to reduce sharps injury. These interventions should only be implemented alongside training of staff to use these device(s) effectively.	**C**
HCW's (users) of the devices, should be involved with the evaluation of new devices.	**C**
More research is required to ensure that the design of safer sharps devices is robust and reliable to achieve the desired outcome reliably. These devices are not risk free since some require manual activation to provide protection and to prevent injury.	**KG**

Considered Judgement Form 2	
Key question 2: Does the provision of an education or any other training programme compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?	
1. Volume of evidence *Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.*	
With respect to PICO 2, there was a small (n= 8) body of published studies, of which six were of sufficient quality to provide a SIGN grade range of 2- to 2+.	
2. Applicability *Comment here on the extent to which the evidence is directly applicable to UK practice*	
The papers short-listed for full review were undertaken in well-developed healthcare environments relevant for UK practice.	
3. Generalisability *Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.*	
Studies associated with successful outcomes were generally undertaken using structured and/or enhanced sharps awareness training and were delivered over extended periods. As the educational interventions took place over a long period of time, it was difficult to assess how many of the reported benefits were due to the gradual education of the staff or attributable to other changes. The studies reviewed did not provide evidence on the impact of specific types of educational intervention (nor were they able to quantify the impact of these interventions), but many of the studies concluded that safer sharps devices could not be introduced effectively without an educational programme. Safer sharps educational programmes rarely exist as standalone initiatives. The majority only occurred because of the introduction of new devices and the manufacturers often provided this training.	
4. Consistency *Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence*	
The majority of the identified papers had examined the impact of an educational intervention on needlestick related injuries. Most of the studies were based on 'before and after' educational interventions. These studies generally involved a wide range of HCWs and examined the impact of the educational intervention over years.	
5. Clinical impact *Comment here on the potential clinical impact that the intervention in question might have - e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.*	
Some authors considered that education may have a measurable impact, but other factors were said to account for the biggest reductions to reported injuries (e.g.: the use of a safety device). The magnitude of effect for an educational intervention was therefore difficult to establish.	
6. Other factors *Indicate here any other factors that you took into account when assessing the evidence base.*	
Some of the comments below drew from papers that may have been scored less than 2-. Following training interventions, injury-reporting rates may increase (**25 & 31**) due to raised awareness. Therefore, increases in the reported incidence of injuries after the introduction of a safer sharps device should not necessarily be taken as evidence that safety devices cause more injuries. Studies should be carefully designed (with appropriate controls) to ensure that educational initiatives are not simply increasing reporting rates. However, ethical considerations mean that untrained control	

groups are not likely to be included in training impact studies. On the grounds of sharps injury prevention, it would be difficult to justify training a study group and not a control group. It was noted that some of these studies highlighted the value of educational programmes to increase general awareness of sharps related injuries, irrespective of whether safer sharps devices are introduced (26, 31 & 32). They also noted the value of implementing this early in the training of all health care professionals.	
7. Evidence statement *Please summarise the research group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level, which, applies.*	**Evidence level**
Education and training were regarded as necessary to achieve the greatest preventative effect after the introduction of safer sharps devices. (**27 / 31)** As a consequence of limitations to the design of safer sharps interventions, measuring the impact of educational interventions alone has proved challenging. (**27 / 29**)	**2+ / 2-** **2+ / 2-**
8. Evidence-based conclusions *What conclusion(s) does the research group draw from this evidence? Please indicate the grade of conclusion(s) and any dissenting opinion within the group.*	**Grade of evidence-based conclusion**
Safer sharps devices should always be introduced alongside appropriate educational programmes, as would be expected for conventional devices. Education should be given to all groups of HCWs, including those reported to be less engaged by sharps training initiatives (e.g., surgeons and health care senior managers). There is a need for studies of robust design to demonstrate the specific benefits of educational training applied to the introduction of safer sharps devices.	**C** **C** **KG**

Considered Judgement Form 3

Key question 3: Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?

1. Volume of evidence
Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.

Of the seven studies identified to address this question, only 5 were suitable to obtain evidence-based conclusions.

2. Applicability
Comment here on the extent to which the evidence is directly applicable to UK practice

Whilst the evidence base was limited, the studies selected were included as they are applicable to the UK.

One US study had looked at a single IV catheter device (**33**) and concluded that the majority of nurses considered the device satisfactory to use and that no change in technique was required to use the new device.

3. Generalisability
Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.

Generalisability is limited due to lack of volume in the evidence identified.

4. Consistency
Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence

There was conflicting evidence even in the papers that were suitable for inclusion in the review.

There was one good quality study (**34**) but the investigation of 'user acceptability' for the devices was not carried out to quality applied to the primary subject of this paper, which examined the performance of the safety device.

In this study (**34)** safety catheters were not reported as superior in terms of failure rate for catheter placement and they were more difficult to use in terms of catheter insertion and needle withdrawal, although the users considered they were better protected using the safety device. However use of the safety device resulted in more blood splashes on the operator and around the sites of blood withdrawal. No needle stick injuries occurred in any of the three groups. The passive safety catheter was found to be more efficient than the active safety catheter and easier to introduce into the vein compared to the active device; it also reduced exposure to the patient's blood.

5. Clinical impact
Comment here on the potential clinical impact that the intervention in question might have - e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.

The small volume of evidence here makes it difficult to comment with certainty on clinical impact with regards worker acceptance of newly introduced devices. However, the small number of reviewed papers suggests that early staff involvement can support the introduction of safer sharps and their subsequent acceptance and uptake by the worker population.

6. Other factors
Indicate here any other factors that you took into account when assessing the evidence base.

Nurses who had worked at the hospital >1 yr were likely to be less accepting of the new device than those who had worked there for <1yr - (**33**).

Another study reported staff dissatisfaction with the use of safety devices - (**35**).

7. Evidence statement — **Evidence level**
Please summarise the research group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level, which, applies.

A passive safety catheter was found to be more acceptable because it was easier to introduce into the vein than an active device; it also reduced staff's exposure to patient blood - **(34).** Healthcare workers training and their involvement in the selection of devices had a beneficial effect on the activation rates for the safer devices **– (37)**.	**1+** **2+**
8. Evidence-based conclusions *What evidence-based conclusion(s) does the research group draw from this evidence? Please indicate the grade of conclusion(s) and any dissenting opinion within the group.*	**Grade of evidence-based conclusion**
Healthcare workers should be involved in the evaluation of products before any safer sharps device is introduced.	**C**
User acceptability is likely to be an obstacle to the uptake of safer sharps devices and given the lack of current evidence, this area requires further research.	**KG**
Future studies should consider carefully the nature of their design in order to determine the influence of staff attitudes on the effective introduction of safer sharps devices.	**KG**

Considered Judgement Form 4	
Key question 4: Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practice?	
1. Volume of evidence *Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.*	
Within the scope of this project and the selection/exclusion criteria, the evidence available was limited to two studies.	
2. Applicability *Comment here on the extent to which the evidence is directly applicable to UK practice*	
The results from the two US papers selected described studies of central venous catheters and a pain reducing syringe device with a safety needle; both studies were applicable to UK.	
3. Generalisability *Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.*	
As only 2 papers were reviewed for this question the results cannot be generalised.	
4. Consistency *Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence*	
The sift process highlighted 8 papers, of which 4 were rejected after a full assessment. Of the remaining 4, only 2 papers were of sufficient quality to be included as evidence under PICO Question 4.	
5. Clinical impact *Comment here on the potential clinical impact that the intervention in question might have - e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.*	
As only 2 quality studies were reviewed for this question, the clinical impact of cannot be generalised.	
6. Other factors *Indicate here any other factors that you took into account when assessing the evidence base.*	
In 1 of the 6 papers that were excluded (in this case due to a lack of comparison with a 'standard' sharps device), the use of needleless devices reduced the incidence of needlestick injuries, but the potential for bacterial colonisation (either externally or within the valve of the needless device) was reported as a risk factor for patient outcomes.	
7. Evidence statement *Please summarise the research group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level, which, applies.*	**Evidence level**
An association between primary bloodstream infection and needleless connector devices was observed - (**40**). Use of the conventional syringe resulted in significant pain in 53.5% ($p<0.001$) compared to 27.0% of procedures with the reciprocating procedure device (RPD) ($P<0.001$) i.e., there was ~50% greater prevalence of reported pain when the conventional syringe was used. In terms of immediate complications to the patients these were infrequent (1.4%) and equivalent in both the RPD and conventional syringe groups. After 2 weeks of use, no major complications were observed with either device, and the outcomes were good - (**41**).	**2-** **2-**
8. Evidence-based conclusions *What conclusion(s) does the research group draw from this evidence? Please indicate the grade of conclusion(s) and any dissenting opinion within the group.*	**Grade of evidence-based conclusion**
The scarcity of data suggests that more research is required in this area. More consideration should be given to the design of safety devices before they are introduced, specifically taking into account the risk for bacterial colonisation (externally or internally) within the device.	**KG** **KG**

3.4 EVIDENCE BASED CONCLUSIONS

Considered judgement forms (Section 3.3) were used to summarise the evidence reviewed, to identify other factors and to develop evidence-based conclusions. The process of completing the considered judgement forms was undertaken by the HSL team, following a round table discussion of the summaries of evidence for each PICO question. The tables provide a summary of the key findings supported by the given quality of evidence. Where levels of evidence were identified at evidence grade 2- or greater, evidence-based conclusions were developed. These had to reflect consensus results from at least several peer-reviewed papers.

To develop the conclusions based on the evidence collected in the considered judgement forms, key themes were collated to provide evidence-based conclusions or to identify knowledge gaps.

The evidence-based conclusions and knowledge gaps are summarised for each PICO question.

Please refer to Table 2, page 11 for explanatory information on grades of evidence.

Numbers in the table below refer to papers listed within the Evidence Tables (Appendix 3)

Evidence-based conclusion 1 [Grade C]: Safer sharps devices should be considered to improve safety and reduce the incidence of healthcare worker needlestick injuries.
Notes: There were sufficient international studies of adequate quality that demonstrate a consistent reduction in the incidence of percutaneous injuries (and other acceptable surrogate markers of injury) following the introduction of safer sharps devices. Thirteen international, peer reviewed studies provided evidence that sharps devices designed for improved safety can help to significantly reduce the incidence of healthcare worker needlestick injury. As such, safer sharps implementation should be considered as part of any process to reduce sharps injury. Such interventions should only be implemented alongside effective training of the staff that will use the device(s).
Related Evidence Table for PICO 1 Studies: Paper References: 3, 4, 5, 7, 8, 15, 16, 17, 18, 19, 21, 23 and 24.
Healthcare specialities providing source data (where stated): obstetrics & gynaecology; nurse led and specialist phlebotomy; neonatal intensive care; medical & surgical intensive care; cancer specialist treatment; dialysis unit; urban medical centre clinics and dental surgical units.

Evidence-based conclusion 2 [Grade C]: Safer sharps devices should always be introduced alongside appropriate educational programmes.

Notes: Such interventions should only be implemented alongside effective training of the staff that will use the device(s).

There are studies of adequate quality that demonstrate a consistent reduction in the incidence of percutaneous injuries (and other acceptable surrogate markers of injury) when other safety initiatives e.g. training were implemented before and during the introduction of safer sharps devices.

Consideration should be given to all existing groups of HCW, particularly those who have reported to be less engaged in sharps training initiatives, such as surgeons and health care senior managers.

It was noted that some of these studies highlighted the value of educational programmes to increase general awareness of sharps related injuries, irrespective of whether safer sharps devices are introduced. They also noted the value of implementing this early in the training of all health care professionals.

Related Evidence Table Paper References: 26, 27, 28, 29, 30 and 31 (also referred to as a secondary comment in many of the PICO 1 papers**).**

Healthcare specialities providing source data (where stated): all healthcare workers, obstetrics, surgical wards, medical wards, outpatient department and dental surgery.

Evidence-based conclusion 3 [Grade C]: Healthcare workers should be involved in the evaluation of products before any safer sharps device is introduced.

Notes: This should be done to improve user safety and acceptance of any newly introduced devices (this point is closely linked with evidence-based conclusion 1). There are some studies that adequately demonstrate the beneficial outcome of consulting with the 'end users' of these devices before they are introduced.

HCWs (users) of the devices should be involved with the evaluation process of any new devices.

Related Evidence Table Paper References: 34, 35, 36, 37, 38 and 39 (also referred to as a secondary comment in many of the PICO 1 papers).

Healthcare specialities providing source data (where stated): Cancer care; critical care and cardiac theatre anaesthetics; multi-centre phlebotomy.

3.5 KNOWLEDGE GAPS

There was insufficient published evidence of quality to provide evidence-based conclusions for PICO question 4. However, knowledge gaps were identified for each of the PICO questions as follows:

- Standardisation of study protocols would improve consistency in the design and collection of data related to incidence of sharps injuries, influence of education, user acceptability, and patient outcomes. Standardisation would enable meaningful comparison between different studies. For example, emphasis on large multi-centre studies is critical to provide the necessary statistical power, and could provide evidence that safer sharp devices can be effectively implemented by different health care disciplines across different settings.
- More research is required to ensure that the safer sharps devices are robust and reliable to achieve a consistent benefit for both the HCW and patient. Such research should also take into consideration the evolution of safer sharps product design.

More studies are required to investigate:

- Whether specific educational interventions related to sharps injuries and safer sharps devices are more effective than others; or which of these interventions are effective with particular healthcare professions.
- Whether consulting HCWs before safer sharp devices are introduced is beneficial and whether staff attitudes influence the effective introduction of safer sharps devices.
- The impact on patient safety when safer sharps devices are used.

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5 APPENDICES

5.1 APPENDIX 1 - AGREED SEARCH TERMS

1. Does the use of safer sharps devices compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

Population	Intervention	Comparison	Outcome
Employees of healthcare organisations including contractors	Provision and use of safer sharps devices	Use of standard sharp device	Rate of sharps injuries and blood/body fluid exposures

Clinicians
Dentist
HCWs
Health
health care facilities
health care personnel
health care worker
health care workers
health careworker
health careworkers
health occupation
health occupations
health personnel
health worker
health workers
Health-Personnel
hospital
hospitals
human
humans
nurse
nurses
nursing
nursing as a profession
medical personnel
medical profession
medical students
military-medical-personnel
Physician
Physicians
professional
Psychiatric-Hospital-Staff
Volunteer (not Animal)
volunteer
Personnel
phlebotomy
medical
clinic
Health
Services

Safe, Safe cannula (to pick up 'cannulae' also)
Safe cannulae + impact and/or assessment
Safe needle devices
Safe needle devices + impact and/or assessment
Safe needle disposal
Safe needle disposal + impact and/or assessment
Safer sharps bin
Safer sharps device
Safer sharps device + impact and/or assessment
Safer sharps disposal
Safer sharps disposal + impact and/or assessment
Safe syringe + impact and/or assessment
Safe** sharps, safe/ty/r, safe/ty/r + engineered
safe/ty/r/guard, Safer
Safer needle technology
Safety engineered device
Secretion; secretion fluid, fluid, fluids
Self blunting
Standard + syringe + sharps device
sharp, Blunt,
sharp injuries; sharp injury
sharp instrument; sharp instruments
sharp medical; sharp medical device;
sharp medical devices
sharp medical instrument;
sharp medical instruments; sharp-needle; sharp needles;
single
winged,
instrument
Intervention, mask
Design; device; Devices + safety features
Needle; Needle shields; needle stick
needle stick/exp; needle sticks; needle/stick
Needless connectors/devices; needlestick
Needlestick injuries; needlestick injury
Needlestick prevention devices
blood evacuation
cannula, catheter, hypodermic
injection, intravenous
body fluid, body fluids, Body Secretions
prevention, Protected needle, protection/ive

Retractable
splash
Splash blood
stab
stab wound
stab wounds
stick injuries
stick injury
suture needles
syringe
viral infect
virus
virus disease
virus transmission
winged steel
wound
wound penetrating
wound stab; stab wound
Wounds
Exposed; exposure; exposures
Eye; eye injuries; eye injury; eyes
penetrating; penetrating wound
penetrating wounds
percutaneous
percutaneous exposure
percutaneous exposures
percutaneous injuries
percutaneous injury
percutaneous trauma
arm; arm injuries; arm injury
blood, blood borne infection
blood borne/bloodborne virus
disease Transmission
face injury, facial, Facial injuries, Facility, finger
finger injuries; fingers
forearm injuries
hand, hand injuries or injury
injured, injuries, injury
occupational exposure/exposures
Occupational Hazards/Health

Additional relevant, general search terms that were included: doubl, dble, doubl blind, double blind, double, blind, blind procedure, Double-Blind Method Effect, evaluation, evaluation studies, evaluation study, comparative, comparative studies, comparative study, control, controlled clinical trial, controlled study, cross over, cross over studies, cross over study, cross sectional study, crossover design, crossover procedure, Crossover Studies, clinical trial, clinical trials, follow up, follow up studies, follow up study, followup, Follow-up Studies, research design, research, Randomized Controlled, random, random allocation, randomized controlled trial, risk, single blind, single blind procedure, Single-Blind Method, trebl, trial, Trials, tripl, triple blind, triple blind procedure, Verbeek, program, prospective, prospective studies, prospective study, Trials, non randomized trials, placebo, Placebos, latin square, latin square design.

2. Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

Population	Intervention	Comparison	Outcome
Employees of healthcare organisations including contractors	Provision of an education or any other training program	Usual education or training	Rate of sharps injuries and blood/body fluid exposures

As for PICO 1	Training Workplace training Training + package On the job training Ward + training Professional training Training program(me) Training + impact Training intervention Education Workplace education On the job education, Ward + education Education program(me) Education + package Educational impact Educational intevention e-learning + package Learning, Workplace learning Learning + regime, Learning package, Learning intervention Instruction Workplace instruction Instruction + package On the job Instruction Ward + Instruction Professional Instruction Workplace instruction Tuition Clinical tuition Tuition + package On the job tuition Workplace tuition Ward + tuition Professional tuition	**As for PICO 1**

Additional relevant, general search terms could include: As previously stated for PICO 1above

3. Does the use of safer sharps devices in healthcare affect user acceptabilty characteristics compared to standard practices?

Population	Intervention	Comparison	Outcome
Healthcare workers using sharp devices	Provision and use of safer sharps devices	Use of standard sharp device	Change in user acceptability characteristics (e.g. tactile properties, time for procedure etc.)
As for PICO 1	**As for PICO 1**		User + impact User + acceptability/acceptance User + difficulty User + characteristics User + perception Tactile Procedure Procedure + impact Procedure + difficulty Professional + acceptability / acceptance Medical + acceptability / acceptance Medical + impact Medical + difficulty Medical + perception Services Affect services Sensitivity Loss of sensitivity Culture Culture change Cultural change Implementation

Additional relevant, general search terms could include: As previously stated above for PICO 1

4. Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practices?

Population	**Intervention**	**Comparison**	**Outcome**
Patients of healthcare organisations	Subject to the use of safer sharps devices	Use of standard sharp device	Change in patient outcomes (e.g. infection rates, recovery time etc.)

Patient(s) Patient + population Hospital patient(s) Healthcare patient(s) In patient(s) In-patient(s) Treated patient(s) Treated individual(s)	**As for PICO 1**	Patient outcome Patient care Patient treatment Care outcome Clinical outcome Adverse outcome Undesirable outcome Treatment outcome Infection Infection rate + improved Infection rate + poor Infection control Infection control + improved Contraindicated Contraindication Recovery Recovery time Recovery period Prognosis + improved Prognosis + poor Impact Patient impact Treatment impact Effects Adverse effects

Additional relevant, general search terms could include: As previously stated above for PICO 1

5.2 APPENDIX 2 - SEARCH ALGORITHMS AND EXCLUSIONS RELATED TO HSE INFOCENTRE SEARCH

Searches were initially run on Medline from 1990 onwards and Embase from 1993 onwards but the final results were limited – by agreement within the assessor group - to papers published from January 2000 onwards (i.e. to March 2010). The searches were based on a standard search strategy employed by the HSE Info Centre and were limited to publications (i.e., at least an abstract) in English. Boolean search terms were used and included the proximity of key words and combining different key search terms (see below) relevant to each PICO question (see Appendix 1). The full details of these search combinations are available on request.

- SET 1: Population terms
- SET 2: Safer sharps device terms
- SET 3: Standard sharps terms
- SET 4: Blood/body fluid exposure
- SET 5: Sharps injuries terms
- SET 6: Occupational exposure terms
- SET 7: Education terms
- SET 8: Impact terms
- SET 9: Outcome terms

PICO Question 1. Does the use of safer sharps devices compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

The following sets were combined
SET 1 **AND** SET 2 **AND** SET 4
SET 1 **AND** SET 2 **AND** SET 5
SET 1 **AND** SET 2 **AND** SET 6
SET 1 **AND** SET 3 **AND** SET 4
SET 1 **AND** SET 3 **AND** SET 5
SET 1 **AND** SET 3 **AND** SET 6

PICO Question 2. Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?

The results from question 1 **AND** SET 7

PICO Question 3: Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?

SET 1 **AND** (SET 2 **OR** SET 3) **AND** SET 8

PICO Question 4. Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practices?

SET 9 **AND** (SET 2 **OR** SET 3)

5.3 APPENDIX 3 - EVIDENCE TABLES

The review evidence for individual papers is tabulated below, with related scoring of papers. The following scoring guide has been used to grade the documents and comprises the evidence statements and grades provided by the Scottish Intercollegiate Guidelines Network (SIGN).

KEY TO EVIDENCE STATEMENTS - LEVELS OF EVIDENCE

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++ High quality systematic reviews of case control or cohort or studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 Non-analytic studies, e.g. case reports, case series

4 Expert opinion

N.B. Studies where no comparison group has been used will normally constitute no higher than level 3 evidence.

Non-systematic reviews and consensus reports (including consensus guidelines) constitute level 4 evidence and do not normally require data extraction of this kind. However, for completeness, most papers falling in to this category have still been reviewed within this study by completion of a data extraction form.

SIGN	**Evidence Table PICO Question Two** Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?
Reference: 31	Yang YH, Liou SH, Chen CJ, Yang CY, Wang CL, Chen CY, Wu TN. (2007) The effectiveness of a training program on reducing needlestick injuries/sharp object injuries among soon graduate vocational nursing school students in southern Taiwan. J Occup Health 49 (5): 424-429
H	In part (with limitations) the study helps to answer the key question. The education programme was not related to the implementation of safer sharps devices. This study was purely related to a standard education programme on the prevention of needle stick injuries. The study included a pre and post assessment by questionnaire of the same group of nurses, the number of valid questionnaires fell by the time of the post-intervention group assessment, because, they had either not become a licensed nurse, were not working with needles or had not worked for 4 weeks from graduation. This is related to what happens to nurses when they graduate. Although this was a low number it did not affect the significance of the effectiveness of the educational programme. Potential for recall bias on details of NSI's on completion of both pre and post intervention questionnaires. The authors concluded that the education intervention significantly reduced the incidence of NSI injury, as well as improving the injury reporting rate amongst those worked. Lack of experience could have resulted in high average of NSI's. Highlighted lack of training in administrative managers about completing report forms and following up injuries.

SIGN	**Evidence Table PICO Question Two:** Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?
Reference: 32	Brusaferro S, Calligaris L, Farneti F, Gubian F, Londero C, Baldo V. (2009) Educational programmes and sharps injuries in health care workers. Occupational Medicine-Oxford 59 (7): 512-514. **ALSO USED TO ADDRESS PICO 1 QUESTION**
Evidence Level: 3	
Study Type: Interrupted time series. This is an interventional study that looked at an educational programme to reduce the incidence of needle stick injuries in a large university hospital in Italy over a nine-year period.	
Source of Funding: Not stated.	
A	The study was performed in a 350-bed university hospital with ~13,000 inpatients per year. The study population of HCWs varied between 708 to 768 staff during the period from 1998 to 2006.
B	Healthcare workers (Physicians; nursing personnel; technical personnel; ancillary operators). No other details about these groups are given.
C	The key intervention was the introduction of an educational programme. No changes were made to the types of needles used or changes in existing protocols or guidelines for preventing sharps injuries, use of vacutainers, system for venepuncture, gloves, masks, specific sharps waste bins etc). ➢ The education programme started during the baseline year in 1998 and took an 8-hour formative training course, which systematically covered a standardized approach to train HCWs about biological risks control and tools for correct disposal of sharps. The topics covered the importance and availability of protection devices, biological hazards for HCWs, and prevention of the most frequent behaviours that were related to injuries. The training was designed for physicians, nurses, laboratory technicians and supporting personnel. The study collated all of the hospital recorded sharps injuries, which were then classified as: ➢ operating room activities; ➢ routine assistance to the patient; ➢ syringe disposal; ➢ and laboratory procedures.
D	Comparison between standard education about needle sharps injuries and enhanced education programme on the subsequent incidence of sharps injuries
E	No patients were followed and no members of staff were followed up but the study did report the annual incidence rate of needle stick injuries over nine years.
F	All sharps injuries occurring and reported between January 1998 and December 2006 were included in the study. Data were collected from a variety of sources including the personnel department (working hours), the centre for education and training (trained employees) and the occupational medicine centre (notification of injuries). The data was collected as incidence of sharps injuries (density index = total number of sharps injuries per year/total number of actual working hours carried out in one year by the healthcare personnel x 1,000,000).

SIGN	**Evidence Table PICO Question Two:** Does the provision of an education or any other training program compared with standard practice lead to a reduction in sharps injuries and blood / body fluid exposures for employees of healthcare organisations?
Reference: 32	Brusaferro S, Calligaris L, Farneti F, Gubian F, Londero C, Baldo V. (2009) Educational programmes and sharps injuries in health care workers. Occupational Medicine-Oxford 59 (7): 512-514. **ALSO USED TO ADDRESS PICO 1 QUESTION**
G	➢ The changes in the incidence of needle stick injuries were expressed as a density incidence of sharps injuries (this is the total number of incidents per year/ per million working hours). ➢ Over 9 years of the educational intervention the incidence of needle sharp injuries reduced significantly from 77/1,000,000 to 32/1,000,000 worked hours ($p< 0.01$). ➢ The risk of sharps injuries significantly lowered amongst the trained HCWs compared to those not specifically trained. For each occupational group staff receiving training the risks decreased significantly ($p<0.01$) from 1998 to 2006. ➢ The decrease in sharps injuries was mainly due to the improved processes related to syringe disposal ($p<0.01$). ➢ Assistance of the patients helped to significantly decrease ($p<0.05$) the incidence of needle stick injuries. ➢ Overall by 2006, the proportion of trained staff increased from 26% in 1998 to 69 % in 2006 ($p < 0.01$). ➢ Significant reductions ($p<0.01$) in needle stick injuries over this period occurred only amongst the nursing professions. ➢ Differences in the reported needle stick injuries were not significant for the physician, laboratory technicians and ancillary staff.
H	The study demonstrated the potential benefit of an educational intervention but did not directly investigate the impact of changing from standard needles (or other sharp devices) to safety devices. ➢ The strength of the study as an educational intervention is that no other parameters were changed during this period (i.e. no new safety devices or procedures introduced). However, the topics covered in the training included the importance of and availability of protection devices. It is not clear whether the hospital was only using standard sharps devices or had introduced any type of safety device. ➢ The authors also identified other limitations of the study namely the small number of HCWs included in the survey and the issue that under reporting could have affected their estimate of the benefit of the educational intervention. They point out that if under reporting had increased during this period the same trend should have been expected for other types of types of accident reporting.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 33	Rivers DL, Aday LA, Frankowski RF, Felknor S, White D, Nichols B: (2003) Predictors of nurses' acceptance of an intravenous catheter safety device. Nurs Res. 52(4): 249-255
Evidence Level: 3	
Study Type: Cross Sectional.	
Source of Funding: A research Enhancement Grant from Lamar University, Texas, provided partial funding. No other details provided.	
A	742 nursing staff were targeted by a 34-item questionnaire; 649 were returned, of which 620 were usable.
B	All were state licensed nurses in the US, involved in full time patient care and with experience of using the new Protectiv Plus IV catheter device, as used for initiating IV infusion.
C	The characteristics of use, potential improvements in user safety and user acceptance of the IV device are considered. Training was also provided at the time of intervention – and as part of that process – and is evaluated.
D	Not applicable. No comparison group was described.
E	This was a Cross-sectional survey conducted by questionnaire. Use of the Protectiv Plus IV catheter device was implemented in Sept 1999 and data was collected via questionnaire from Dec 2000. The period of data collection is not clear.
F	Satisfaction of the device. Extent to which device are used nurse recommendations over device.
G	76.1% of nurses either agreed or agreed strongly that the device was satisfactory to use. 82.8% of users ultimately felt comfortable with the device, though 17.1% did not feel comfortable. 73.9% of staff felt that no change in technique was required to use the Protectiv Plus IV catheter device. Mean summary acceptance score 19.0 (17.5 and above would signify favourable acceptance): $p<0.001$. Mean summary recommendation score of 3.8 (3.5 and above would signify favourable recommendation): $p<0.001$
H	Nurses generally felt comfortable with the training they received for the device. Safety climate was a significant predictor of device acceptance. Significant predictors of compliance were: Increased length of time using device. Low and medium intensity of use on the units. Favourable safety climate - Safety climate was a significant predictor of acceptance of device. Nurses who had worked at the hospital >1 yr were likely to be less accepting of the new device than those who had worked there for <1yr.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?					
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158					
Evidence Level: 1+						
Study type: A Prospective Randomized Trial.						
Source of Funding:						
	Section 1					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	The study addresses an appropriate and clearly focused question. Comments: the main objective of the study was to assess the ease of insertion of safety needles compared no conventional needles. The question of impact of use on user acceptability was a secondary question addressed by the survey. This influenced the design of the study and potentially the interpretation of the user acceptability characteristics.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	The assignment of subjects to treatment groups is randomized. Comments: This was chosen on the basis that the study design was appropriate to the issue of ease of insertion of the needle not the question of user acceptability. The overall design of the study was a randomised prospective survey. Immediately before every procedure the type of peripheral venous catheter to use was determined randomly. Only if the operator considered the patient's veins unsuitable for placing an 18-G catheter, the patient was excluded from the protocol.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	An adequate concealment method is used. Comments: Not possible with this study since the operators have to handle the device under conditions which require safe use for each subject.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	Subjects and investigators are kept 'blind' about treatment allocation. Comments: This is not relevant, as the investigators could not use the device without recognising it. However the allocation of the different needles was randomly allocated and therefore not influenced by the operator. The design of the study ensured that an equivalent number of the different needles were examined.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	The treatment and control groups are similar at the start of the trial. **Comments:** This is not a comparison with a 'control' untreated group; three separate groups were used to test three different needle devices; two of these groups provided data on the two safety catheter devices and the comparator group provided data on the conventional 'non-safety' needle device. However, the number of patients allocated to each group was very similar and their demographics matched well.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	The only difference between groups is the treatment under investigation Comments: Yes.					

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?					
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	All relevant outcomes are measured in a standard, valid and reliable way. Comments. Outcome measured were; insertion failures (up to 2); difficulty introducing the catheter; difficulty of needle withdrawal; abnormal blood reflux into the catheter delivery system; needle stick accidents, staff exposure to blood, blood splashed to the environment; and staff sense of protection. These are relevant measures for the primary study objective. The endpoints were dependent on operator judgment based on analog scale, which will be very dependent on user experience. The study did not employ an expert view assessment of the reliability of this scoring system. It should be noted that the operators were anaesthetist's physicians and anaesthetists-nurses in the operating room and not phlebotomists. The authors of the paper states that "All personnel were educated on how to place the different catheters, thanks to specific posters provided by the manufacturers". This does not address the capability of these staff to make experienced judgments about these endpoints, which is likely to depend on the frequency of catheterisation procedures undertaken by these staff. This issue is not addressed in the paper. It is likely that this group of operators represented an experienced group, but, no evidence is provided. The endpoint most relevant to this review 'user acceptability characteristics' was based on a Visual Analog Scale (VAS), more dependent on personal experience of catheterisation					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? Comments: Not relevant but procedures put in place to exclude patients with unsuitable peripheral veins for 18 gauge needle catheterisation.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis) Comments: Yes.					
	Well covered	Adequately addressed	Poorly addressed	Not addressed	Not Reported	Not applicable
	Where The Study Is Carried Out At More Than One Site, Results Are Comparable For All Sites. Comments: Not Applicable.					
	Section 2					
	How well was the study done to minimise bias? Code ++, +, or -	+				
	Comments:					
	Not a conventional 'intervention' study design but the design of the study is adequate to address the effectiveness of "ease of insertion of safety needles compared no conventional needles" but reliability of the outcome measure "user acceptability characteristics" will be dependent on the experience of the operators for catheterisation.					
	Yes in the sense but in that the study examined safer needles in the context of patients requiring peripheral intravenous catheterisation.					
	Section 3					
	Supported by Sainte Anne Hospital and Department of Anesthesiology.					
	Funding□	**Academic□**	**Institution□**	**Healthcare Industry□**	**Government□**	**NGO □**	**Public funds□**	**Other□**
	One centre.						
	Scotland	**UK**	**USA**	**Canada**	**Australia**	**New Zealand**	**France**
	Germany	**Italy**	**Netherlands**	**Scandinavia**	**Spain**	**Other:**	

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?			
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158			
	Urban	**Rural**	**Mixed**	
	To be qualified for the protocol, adult patients had to enter the operating room or the emergency department during the study period and require peripheral intravenous catheterisation.			
	Exclusion based on peripheral veins unsuited to 18-gauge needle catheterisation.			
	Difficulty in placing the catheter (failure rate, difficulty introducing catheter, difficulty withdrawing needle, abnormality of blood reflux in catheter delivery system). Staff exposures to patients' blood, environmental blood splashes, and staff sense of protection against the risk of accidental needlestick injury.			
	A comparison between two safety use catheter needles and a conventional 'non-safety' catheterisation needle.			
	3-ball ballot box for selection of device. Once randomisation allocation made, no blinding of operator or patient. ***Notes:*** *The survey continued until at least 250 informed assessment for each type of needle had been undertaken. Patients not randomised but the use of the catheters randomised at each patient recruited.*			
	Not relevant. Time fixed by the recruitment of fixed number of patients for each group.			
	Not relevant.			
	Adult patients entering the operating room or the emergency department and requiring peripheral vein catheterisation. Average age 54 years with a 3:7 ratio of females to males. ~81% of the patients in each group were treated in the operation room and ~19% in the emergency room. ~76 of the patients were seem as programmed admissions and ~24% as emergency admissions. No significant differences between the three study groups. *Very similar patient characteristics between the three study groups: age, gender, weight and height (almost too similar).*			
	Record the basic data for each arm of the study. If there are more than four arms, note data for subsequent arms at the bottom of the page.			
	Arm 1: **Treatment: Non safety** catheterisation needle**.** **Sample size:** 254 **No. analysed:** 254 **With outcome:** NA **Without outcome:** NA	**Arm 2:** **Treatment: Safety** catheterisation needle (Passive safety catheter). **Sample size:** 251 **No. analysed:** 251 **With outcome:** NA **Without outcome:** NA **Primary outcome?** Ease of insertion of safety needle.	**Arm 3:** **Treatment: Safety** catheterisation needle (Active safety autoguard catheter). **Sample size:** 254 **No. analysed:** 254 **With outcome:** NA **Without outcome:** NA **Primary outcome?** ease of insertion of safety needle.	Arm **4:**

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?			
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158			
	Record the basic data for each IMPORTANT outcome in the study. If there are more than four, not data for additional outcomes at the bottom of the page.			
	Outcome 1: Failure to insert needle attempt 1 **(Arm 1)** **Value:** 8.7% **Measure:** **P value: NS** **Upper CI not given** **Lower CI not given** **Primary outcome? NA**	**Outcome 1:** Failure to insert needle attempt 1 **(Arm 2)** **Value:** 8.4% **Measure:** **P value: NS** **Upper CI not given** **Lower CI not given** **Primary outcome? NA**	**Outcome 1:** Failure to insert needle attempt 1 **(Arm 3)** **Value:** 9.4% **Measure:** **P value NS** **Upper CI not given** **Lower CI not given** **Primary outcome? NA**	**Outcome 4:**
	Outcome 2: Failure to insert needle attempt 2 **(Arm 1)** **Value:** 7.1% **Measure:** **P value:** NS **Upper CI not given** **Lower CI** not given **Primary outcome?**	**Outcome 2:** Failure to insert needle attempt 2 **(Arm 2)** **Value:** 3.6% **Measure:** **P value:** NS **Upper CI not given** **Lower CI** not given **Primary outcome?**	**Outcome 2:** Failure to insert needle attempt 2 **(Arm 3)** **Value:** 7.5% **Measure:** **P value** NS **Upper CI not given** **Lower CI** not given **Primary outcome?**	
	Outcome 3: Difficulty to introduce the catheter **(Arm 1)** **Value:** 1.0 **Measure:** Visual analog scale **P value:** **Upper CI** not given **Lower CI** not given **Primary outcome?**	**Outcome 3:** Difficulty to introduce the catheter **(Arm 2)** **Value:** 1.2 **Measure:** Visual analog scale **P value: NS** **Upper CI** not given **Lower CI** not given **Primary outcome?**	**Outcome 3:** Difficulty to introduce the catheter **(Arm 3)** **Value:** 1.74 **Measure:** Visual analog scale **P value <0.05** ***Vs outcome 1 & outcome 2*** **Upper CI** not given **Lower CI** not given **Primary outcome?** More difficulty in introducing catheter.	

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?			
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158			
	Outcome 4: Difficulty of needle withdrawal **(Arm 1)** **Value:** 0.5 **Measure:** Visual analog scale **P value:** **Upper CI** not given **Lower CI** not given **Primary outcome?**	**Outcome 4:** Difficulty of needle withdrawal **(Arm 2)** **Value:** 1.8 **Measure:** Visual analog scale **P value:** <0.05 ***Vs outcomes 1 & 3*** **Upper CI** not given **Lower CI** not given **Primary outcome?** Greater difficulty withdrawing this needle.	**Outcome 4:** Difficulty of needle withdrawal **(Arm 3)** **Value:** 1.3 **Measure:** Visual analog scale **P value** <0.05 ***Vs outcome 1*** **Upper CI** not given **Lower CI** not given **Primary outcome?** Greater difficulty withdrawing this needle.	
	Outcome 5: Abnormal blood reflux in the catheter delivery system **(Arm 1)** **Value:** 2.8% **Measure:** **P value:** **Upper CI not given** **Lower CI not given** **Primary outcome?**	**Outcome 5:** Abnormal blood reflux in the catheter delivery system **(Arm 2)** **Value:** 7.2% **Measure:** **P value:** <0.05 Vs outcome 1 & outcome 3 **Upper CI not given** **Lower CI not given** **Primary outcome?** More abnormal blood flow in the catheter delivery system	**Outcome 5:** Abnormal blood reflux in the catheter delivery system **(Arm 3)** **Value:** 16.1% **Measure:** **P value** <0.05 Vs outcome 1 **Upper CI not given** **Lower CI not given** **Primary outcome?** More abnormal blood flow in the catheter delivery system.	

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?			
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158			
	Outcome 6: Staff exposure to blood **(Arm 1)** **Value:** 6.3% **Measure:** **P value:** **Upper CI not given** **Lower CI not given** **Primary outcome?**	**Outcome 6:** Staff exposure to blood **Value:** 7.2% **(Arm 2)** **Measure:** **P value:** NS **Upper CI not given** **Lower CI not given** **Primary outcome?**	**Outcome 6:** Staff exposure to blood **(Arm 3)** **Value:** 15.4% **Measure:** **P value** <0.05 Vs outcome 1 & 2 **Upper CI not given** **Lower CI not given** **Primary outcome?** More staff exposed to blood	
	Outcome 7: Blood splashes in the environment **(Arm 1)** **Value:** 3.9% **Measure:** **P value:** **Upper CI** not given **Lower CI** not given **Primary outcome?**	**Outcome 7:** Blood splashes in the environment **(Arm 2)** **Value:** 8.4% **Measure:** **P value:** <0.05 Vs outcome 1 **Upper CI** not given **Lower CI** not given **Primary outcome?** More blood splashes using this catheter.	**Outcome 7:** Blood splashes in the environment **(Arm 3)** **Value:** 11.8% **Measure:** **P value** <0.05 Vs outcome 1 **Upper CI** not given **Lower CI** not given **Primary outcome?** More blood splashes using this catheter.	
	Outcome 8: Staff sense of protection **(Arm 2)** **Value:** 3.4 **Measure:** Visual analog scale **P value:** **Upper CI not given** **Lower CI not given** **Primary outcome?**	**Outcome 8:** Staff sense of protection **(Arm 2)** **Value:** 1.7 **Measure:** Visual analog scale **P value:** <0.05 Vs outcome 1 **Upper CI not given** **Lower CI not given** **Primary outcome?** More abnormal blood flow in the catheter delivery system	**Outcome 8:** Staff sense of protection **(Arm 3)** **Value:** 1.6 **Measure:** Visual analog scale **P value** <0.05 Vs outcome 1 **Upper CI not given** **Lower CI not given** **Primary outcome?** More abnormal blood flow in the catheter delivery system	

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 34	Prunet B, Meaudre E, Montcriol A, Asencio Y, Bordes J, Lacroix G, Kaiser E. (2008) A prospective randomized trial of two safety peripheral intravenous catheters. Anesth Analg 107 (1): 155-158
	Notes. Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question.
	Yes Safety catheters are not superior with regard to failure rate in the catheter's placement. The safety catheters were more difficult to use in terms of catheter insertion and needle withdrawal, and generated more environmental splashing than standard devices, but users feel better protected. Operators reported they were better protected using safety device needles but also found using these safety catheters more difficult. Their use resulted in more blood splashes on the operator and around the sites of blood withdrawal. No needle stick injuries occurred in any of the three groups. The passive safety catheter was found to be more efficient than the active safety catheter and easier to introduce into the vein than the active device; it also reduced staff's exposure to patient blood. The specific element of this study that addresses PICO question 3 was not the primary objective of this study, furthermore the operator evaluation of the safety needle devices may depend on the level of experience of the operators but this was not defined in this study. Well-reported relatively large randomised three-way comparison. Study groups similar in terms of numbers and patient characteristics. No baseline analysis of staff perception of safety, for post study comparison. No needlestick injuries reported so the reduction in NSI cannot be assessed. However, PICO question about comparative user acceptability is answered. Conflicts of interest and funding for study not declared.

Note: Table cell key not applicable to this table (see Pico Methodology Checklist 2: Controlled Trials template)

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 35	Bamberg R, Rivers C, Moore C. (2003) Use of needle safety devices by clinical laboratories in North Carolina hospitals. Clin Leadersh Manag Rev 17 (1): 21-25
Evidence Level: 3	
Study Type: Survey.	
Source of Funding: No evidence of funding. Student research.	
A	Clinical Laboratory Managers.
B	North Carolina Hospitals (varying bed size), 124 contacted, 87 replies. (70% response rate). 3 excluded for different reasons N=84.
C	Survey.
D	Use of safety needle devices (available at the time of the survey).
E	N/A as this was a survey. First mailed 10/1/01, second mailing 12/2/01.
F	Use of safety devices. Type(s) of device. Reasons for non-use. Needle stick injuries. Perceived advantages and disadvantages of devices. Number of hours education in needle safety over last year.
G	Only %'s reported. No statistics used.
H	Marginally answers key question - survey of use and satisfaction. 70% response rate (n=87 but only 84 useable). 10 hospitals (12%) didn't use safety devices and only 2 of these had no plans to use them. 50% using modified vacuum holder for needle retraction; 34.5% same, but, for 1 handed release; 25% using needle clip for vacuum holder or syringe. Reasons for non use: 70% not clear devices would < NSI; 33% cost of devices; 21% staff find device difficult to use. Needle stick injuries over past year: 40% zero; 49% 1-3. Primary reason staff rushing/ careless. N.B. results not reported related to device. Advantages of safety devices 76% phlebotomy staff safety. Disadvantages 46% higher costs, 35% staff dissatisfaction. Limitations: No statistical significant associations reported by bed size or those using, or not using, devices. The survey included phlebotomists, not nurses or doctors.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 36	Casey AL, Elliott TS. (2007) The usability and acceptability of a needleless connector system. Br J Nurs. 16 (5): 267-271.
Evidence Level: 2-	
Study Type: Intervention followed by survey.	
Source of Funding: Educational grant from Baxter.	
A	50, HCW's. 35 nurses and 15 anaesthetists.
B	HCW's worked at a City Foundation Trust hospital in the UK. HCW's were based in either a critical care ward or a cardiac theatre.
C	Training sessions were provided by the device manufacturer at the beginning of the 12-month trial of the new product. The training related to the use of a new needless connector (Clearlink).
D	No comparison.
E	12-month trial of new product followed by distribution of a questionnaire to HCW's.
F	A questionnaire was used which consisted of 14 questions. 11 of the questions were yes/no responses and the 3 remaining questions users selected from different options. Space for comments were provided for each question. 4 of the questions specifically related to user acceptability of the new device. Two questions asked the user to state which of the devices (Clearlink™ or the standard device) were preferred.
G	No statistics presented, just % (see section H).

H	The results of this study are based on a small sample size, which consisted of 29 nurses and 11 anaesthetists. The study did not include a non-intervention arm. No statistical analysis of the data was carried out. Other information is also missing from the paper such as the number of those participating in the trial who undertook the training provided by the device supplier, and the number of Clearlink devices used throughout the study. ➢ 40/50 completed questionnaires were returned. ➢ 29 (72.5%) from nurses and 11 (27.5%) from anaesthetists. ➢ 34/40 (85%) felt confident to use the device after caring for 3 patients, which suggests, the device is intuitive to use. ➢ In the questions (9) related to usability a positive response was given to each question of more than 85% for all questions. ➢ With regards to acceptability 34/40 (85%) considered the device to be suitable for every day practice and had no concerns about the use of the device. ➢ 1 respondent noted a tendency for the device to 'pop off' when used with a luer lock syringe. ➢ 28/40 (70%) preferred to use the safer sharps device rather than a conventional luer cap. ➢ 6/40 (15%) would use either, only 6/40 (15%) preferred the conventional luer cap. ➢ 100% (40) responded that they were able to disinfect the needless device and 97.5% (39) were able to adequately hold the needless device. ➢ No data presented regarding reduction in needlestick injury numbers. ➢ This study reports on other studies concerns of septicaemia and use of needless devices. ➢ The results suggested that training and support both before and after device introduction are critical for success (no data presented to back up this finding). ➢ The results suggested the value of having a defined usability questionnaire that could be adopted for other needles connector systems (no evidence presented). ➢ No data on needle stick injuries (or relevant surrogate measures of this) or of incidents with microbial infection of the lines was given but this was probably because of the small size of the study. ➢ The survey indicated that most respondents preferred to use standard 3-way stopcocks than the Y –type extensions sets that were provided with the Clearlink™ needleless connectors.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 37	Alvarado-Ramy F, Beltrami EM, Short LJ, Srivastava PU, Henry K, Mendelson M, Gerberding JL, Delclos GL, Campbell S, Solomon R, Fahrner R, Culver DH, Bell D, Cardo DM, Chamberland ME. (2003) A comprehensive approach to percutaneous injury prevention during phlebotomy: Results of a multicenter study, 1993-1995. Infection Control and Hospital Epidemiology 24 (2): 97-104
Evidence Level: 2+	
Study Type: Multi-centre before and after intervention study.	
Source of Funding: Not stated.	
A	Personnel from 10 university-affiliated hospitals in Minneapolis–St. Paul, USA. (nb: 4 of the 10 dropped out of the study at Phase 2). The data and analysis was performed on 1,630 percutaneous injuries reported to the surveillance systems at the 10 participating hospitals. For Healthcare Worker Acceptance: During phase II of the study, 1,108 (65%) of 1,705 healthcare workers responded to the survey. For Underreporting survey: The overall response rate for each of the two worker surveys was approximately 75%: 1,697 of 2,157 healthcare workers responded in phase I and 1,246 of 1,705 responded in phase II.
B	Personnel from 10 university-affiliated hospitals of the 1,630 injuries, 42% were sustained by nursing staff, 26% by physicians, 4% by medical students, 4% by phlebotomists, and 24% by healthcare workers in other occupations .For Underreporting survey: population included phlebotomists (reporting 91% of their injuries); nurses (68%); medical students (35%); and residents (31%).
C	Introduction of sharps safety devices: Re-sheathable winged steel needles - Safety-Lok, Becton Dickinson Corp., Franklin Lakes, NJ (at six Hospitals). Bluntable vacuum tube blood-collection needles - Punctur-Guard, Bioplexus Inc.,Tolland, CT (at three hospitals). Re-sheathable vacuum tube blood collection needles - Venipuncture Needle-Pro, Portex, Inc., Keene, NH (at four hospitals).
D	Evaluation of devices rather than comparison.
E	Phase I was the baseline period and lasted a mean of 10 months (range 9-12 months) and Phase II, the intervention period, when safety engineered devices were employed, lasted a mean of 12 months (range 6-15 months).
F	The number of sharps injury by device type (unadjusted and adjusted for under-reporting by occupational groups) and the estimated number of percutaneous injuries per 100,000 phlebotomy procedures.
G	Reductions in the percutaneous injury rates varied from 23% for the Safety-Lok (p=0.07), 76% for the Punctur-guard (p=0.003) and 66% for venipuncture Needle-Pro (p=0.003) when compared with conventional devices.
H	Specific to 3 particular devices and focused on their use in phlebotomy as a procedure only, the article concludes that the device features, healthcare worker training and their involvement in the selection of devices has an impact on the activation rates for the safer devices, and therefore, their efficacy. Data were based on self-reported estimates so likely to have been underreported. Also, not all non-safety engineered devices were replaced, so post intervention injuries will be in part due to the use of those devices still in circulation. Recall bias was recognised as a limitation because subjects were asked to report on procedures over the previous 12-month period.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 38	Clarke SP, Rockett JL, Sloane DM, Aiken LH. (2002) Organizational climate, staffing, and safety equipment as predictors of needlestick injuries and near misses in hospital nurses. Am J Infect Control 30 (4): 207-216
Evidence Level: 2-	
Study Type: Retrospective cohort survey.	
Source of Funding: National Institute for Nursing Research.	
A	2287 nurses in 22 US hospitals surveyed by questionnaire with one repeat distribution of questionnaires.
B	Mean age of 2287 nurses was 37.3 years (SD 9.9), 63% held a higher nursing degree or baccalaureate, 6% were men. Average nursing experience was 10.8 years (SD 9.2). 48% had had a sharps injury in their career.
C	Safety devices, organisational culture, workload. relationship between nurse and hospital characteristics, safety equipment and risk of needlestick injuries.
D	No direct comparison, rather an examination of the determinants of needlestick risks.
E	One year retrospective survey of sharps injuries risk factors.
F	Perceptions of risk using 2 types of safety device. Overall 56% response rate (varying from 43.1% to 81.4%. across hospitals). Other factors include; Nurse experience and length of employment; Frequency of risky tasks performed; Self reported incidence of needlestick injury or near miss (and details of these events).
G	4085 eligible nurses surveyed – 2287 useable returns (56% response rate). Users of safety equipment (capless valve IV sets and protective devices for IV insertion) for phlebotomy showed a 31% lower risk of sharps injuries in the previous year (OR 0.69, 95%CI 0.49-0.96).
H	Key questions revolve around staff perceptions, attitudes and relationship with organizational factors rather than the impact of safer sharps devices. Information on organisational factors is interesting and there is good background info on the issues, which may be of value. Based on a retrospective survey, with a low response rate of nursing staff in 22, non-randomly selected, hospitals. Protective devices reduced the risk of sharps injuries in the previous twelve months: the range of protective devices in use precluded identifying which devices were most effective. Indeed it is not known whether safety devices were actually in use when individuals sustained sharps injuries. Other limitations exist, for example the sample selection (e.g., bias towards high achieving hospitals with good safety records); also the overall sample size was small.

SIGN	**Evidence Table PICO Question Three:** Does the use of safer sharps devices in healthcare affect user acceptability characteristics compared to standard practices?
Reference: 39	Adams D, Elliott TSJ. (2003) A comparative user evaluation of three needle-protective devices. Br J Nurs 12 (8): 470-474
Evidence Level: 2+	
Study Type: Comparative Study.	
Source of Funding: Educational grant from Becton Dickinson.	
A	50 nurses.
B	Nurses were from a range of specialities within one Birmingham NHS Trust.
C	User evaluation of three needle safety devices using a standardised use evaluation questionnaire. There were three evaluation criteria, safety, usability and compatibility.
D	The comparison was against the routine practice for administering intramuscular and subcutaneous injection with a standard green needle and slip lock syringe. Five different combinations of the three needle protective devices (Eclipse, SafetyGlide and SafetyGlide Insulin) with two types of syringe (slip and luer lock) were used in a randomised (by computer) way. The devices were tested by drawing up 2ml of sterile water and then injected in to a simulated dummy model.
E	This was a one off evaluation with no follow up.
F	A Likert scale was used by participants within an evaluation questionnaire – scale as follows: strongly agree=1, agree=2, ambivalent=3, disagree=4, strongly disagree=5. Mean scores used.

G	50 nurses completed user evaluation questionnaires. The users considered that the three devices met the safety standard criterion, mean score range 1.78 – 1.88. Ability to be aware that safety device activation - all nurses considered the devices allowed for you to see when activation had occurred, mean score range 1.30 – 1.58. Ability to deactivate safety device – the mean score range 1.60 – 1.74 demonstrated that even when reasonable force was applied none of the safety devices could be deactivated. Failure rate - 2 out of 50 (4%) for the SafetyGlide and 1 out of 50 (2%) for Eclipse was observed; the three needles involved had been attached by a right hand nurse with a push-on rather than a push-and-twist action. Analysis of attaching slip lock syringe and conventional needle concluded that 26 out of 50 (58%) of nurses used a 'push on' method. 20 out of 50 (40%) considered that a luer lock syringe would be safer than a slip lock syringe as it was less likely to disconnect even with a standard needle. Splashing (production of a spray of liquid from the needle when safety device activated) – 3 out of a 100 (3%) of the SafetyGlide needles evaluated were associated with splashing. No splashing associated either with the SafetyGlide insulin or Eclipse devices. **Usability** - easy to assemble, use, techniques should be similar to that of standard practice. The nurses concluded the devices were easy to activate, mean score range 1.58 – 1.78. Also that they did not hinder routine use, mean score range 1.70 – 1.80. Lastly that they did not require detailed training, mean score range 1.60 – 1.74. **Compatibility** - should be able to be used in all circumstances and be used with devices from other suppliers. The nurses concluded that the safety feature did not hinder the products' use, mean score range 1.70 – 2.1. Only 3 out of 50 (6%) of the nurses considered whether the devices were suitable for phlebotomy.
H	The nurses involved in this comparative study concluded that all of the safety criteria specified in the questionnaire were met. The nurses rapidly adapted their practices to using the safety devices. No training (by study design) was given prior to the nurses using the safety devices. The study revealed 'failure rates' where the safety device became disconnected from the slip lock syringe. - This could be addressed by training for staff or the use of Luer lock syringes only. It was felt that training could also address the issue of splash occurring, by teaching staff to activate devices smoothly. This study demonstrated the importance of an end-user evaluation process prior to the introduction of safety devices in a clinical setting, in order to assess ease of use of safety devices and acceptance by nurses. Also importantly the issues surrounding the best type of syringe to use with the safety device in order to improve performance and acceptability when introduced into a clinical setting.

SIGN	**Evidence Table PICO Question Four:** Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practice?
Reference: 40	Rupp ME, Sholtz LA, Jourdan DR, Marion ND, Tyner LK, Fey PD, Iwen PC, Anderson JR. (2007) Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. Clin Infect Dis 44 (11): 1408-1414
Evidence Level: 2-	
Study Type: Surveillance based report - Historically controlled study.	
Source of Funding: Not stated.	
A	Not given precisely, though a total of 466 hospital beds were studied in order to generate central venous catheter (CVC) data described below. The study involved >100,000 central-venous catheter (CVC) days.
B	All patients with CVC's in 3 types of clinical settings – critical care and transplantation units, in-patient nursing units, and co-operative care transplantation units.
C	The rates of bloodstream infection over time in each of the 3 clinical settings, before (baseline), during, and after introduction of (and then withdrawal) a new needleless connector device were derived retrospectively.
D	Comparisons were drawn between periods of use of a new CVC device and those periods when the device was not in use. In addition, comparisons were drawn between bloodstream infection rates between different hospital departments where the devices were in use.
E	A baseline period of two years was initially monitored, followed by a period of 6 months when the new device was employed. The follow-up period after the device was withdrawn was an additional 6 months.
F	The rate of blood stream infection - as expressed using infections per 1000 catheter days or infections per 1000 patient days.
G	The relative risk of bloodstream infection for the time period in which the suspect connector valve was in use, compared with baseline, was 2.79 (95% CI 2.27 – 3.43). This was similar across all 3 clinical settings. For example, in the critical care unit the rate of bloodstream infections rose with the introduction of the suspect connector system from 3.87 infections per 1000 catheter days to 10.64 3.87 infections per 1000 catheter days (P< .001); it then decreased in the 6-month period following the catheter removal from the unit.
H	This paper provides substantial data supporting the argument that introduction of new devices is associated with risks other than their effect on needlestick injury i.e. in this case, an increase in the number of bloodstream infections. Here, the authors conclude that '*A significant association between primary bloodstream infection and a needleless connector device was observed*'. This provides an answer that in certain circumstances the use of safer sharps devices in healthcare may affect patient outcomes compared to standard practices?

SIGN	**Evidence Table PICO Question Four:** Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practice?
Reference: 41	Moorjani GR, Bedrick EJ, Michael AA, Peisajovich A, Sibbitt WL, Jr., Bankhurst AD. (2008) Integration of safety technologies into rheumatology and orthopedics practices: a randomized, controlled trial. Arthritis Rheum 58 (7): 1907-1914
Evidence Level: *2-*	
Study Type: A Randomized, Controlled Trial**.** **Note:** This study compares the efficacy of a pain reducing syringe device with a safety needle across three groups of patients. This is not a time series study and is comparable to a cross sectional study comparing the performance of the device and patient responses to he different combinations of syringes and safety needle.	
Source of Funding: Not stated (One of the authors (Sibbitt WL) was the inventor of the reciprocating procedure device (RPD) (commercially produced by a company and part owned by the University of New Mexico). Another author, Dr Bedrick EJ was a founder stock holder in the company making the RPD device)	
A	With respect to testing the alternative safety needle device compared to a conventional needle the study population was thirty-seven physicians (2 attending physicians and 35 resident physicians) who performed 566 separate procedures on the 141 outpatient (who all required procedures involving syringe-and-needle devices): For testing the 141 patients who were divided by a randomization process into one of three groups. Use of the safety needle & conventional syringe. Use of the safety needle & RPD. Use of the safety needle the RPD and the conventional syringe.
B	All patients required musculoskeletal procedures (arthrocentesis, intra articular joint injections, or peri-articular intra-articular anesthesia) for their medical care. The three groups were equivalent in terms of their characteristics: The patient mean age between the groups varied between 51.6 and 51.9 years; Between 78 and 97% of the patients were females with underlying diagnoses of: Rheumatoid arthritis (44-65%); Systemic Lupus Erythematosus (5.6-8.8%); Osteoarthritis 5 (7.3-22.2%; Single other diagnosis 10 (14.7- 25.5%; multiple diagnoses (4.4-11.1%). No other patient demographics were provided.
C	The safety needle had an off-axis rotating safety sheath (25-gauge 1-inch & 22-gauge 1.5-inch). This needle has 2 sheaths, a conventional sheath that is removed to expose and use the needle; and a lateral rotating sheath, which is pushed with the finger to enclose and inactivate the used needle. The needle has a luer fitting and an external housing used as a grip so that the luer fitting is not contaminated during syringe exchanges. It is suited for use in joint-related procedures (e.g., injection pharmaceutical agent, or removal of fluid, from a joint space). This device was not compared to a conventional needle in this study. The second intervention involved the use of a reciprocating procedure device, which is a safety syringe to improve physician control of needles and syringes reducing procedural times and patient pain. The RPD is formed around the core of a conventional syringe barrel with a parallel accessory plunger and barrel.
D	Comparison between use of non safe and safety needle devices (including reciprocating procedure device) on reported NSI or pain relief
E	The study examined only short terms responses (either needle stick injuries, or patient pain relief) immediately following the use of these devices.

SIGN	**Evidence Table PICO Question Four:** Does the use of safer sharps devices in healthcare affect patient outcomes compared to standard practice?
Reference: 41	Moorjani GR, Bedrick EJ, Michael AA, Peisajovich A, Sibbitt WL, Jr., Bankhurst AD. (2008) Integration of safety technologies into rheumatology and orthopedics practices: a randomized, controlled trial. Arthritis Rheum 58 (7): 1907-1914
F	Real time operator observed patient pain and needle stick injuries were recorded. Needle stick injuries were mandatory to report. After the procedure the physicians were questioned about their satisfaction with the conventional syringe or RPD syringe. Patient pain was determined with the standardized and validated visual analog pain scale (VAPS). Operator satisfaction with the syringe devices was determined using a visual analog satisfaction scale (VASS).
G	**Primary measure 'sharp injury'**: With regard to the primary measure of interest 'sharp injuries' during 566 procedures using the safety needle no needle sticks injuries HCW occurred. One physician who did not follow the protocol and used a conventional needle suffered a NSI. **Secondary measures:** Use of the RPD resulted in a reduction in patient-assessed pain scores of 35.4% ($p<0.001$). Use of the conventional syringe resulted in significant pain in 53.5% ($p<0.001$) compared to 27.0% of procedures with the RPD ($P<0.001$) i.e., ~50% greater prevalence of reported pain with the conventional syringe. In terms of immediate complications to the patients these were very infrequent (1.4%) and equivalent in both the RPD and conventional syringe groups. At 2 weeks, no major complications were observed with the use of either device, and outcomes were good. Physician acceptance of the RPD was improved compared with satisfaction with the conventional syringe ($P< 0.001$). The performance of attending physicians and resident physicians using the conventional syringe was almost identical (both pain scores and significant pain). Resident physicians and attending physicians performed significantly better with the RPD compared with the conventional syringe. The performance of attending physicians with the RPD was considerably better than that of resident physicians in terms of both reduced pain scores and a reduction in the number of patients experiencing significant pain.
H	**Limited value:** The safety needle use in this study was not compared to a conventional standard needle and so the results of the study are of limited value as a primary outcome. The affect on patient outcomes was a secondary measure.

5.4 APPENDIX 4 - OTHER CONSIDERATIONS

5.4.1 Financial costs of safer sharps introduction

N.B. The parenthesised reference numbers in the text below cross-refer to statements made in the papers summarised in the evidence tables, Appendix 3.

Cost analysis and cost effectiveness were not included as Pico questions in the review process. To add value to the review, summarised below are conclusions from papers (nine) included in the evidence tables that made reference to the cost implications for introducing safer sharps devices. No references were made to costs in the papers reviewed for PICO question 4.

"Higher costs are associated with the use of safety engineered devices (direct cost of devices). When costs are evaluated in terms of number of patients, by patient days stay, the investment is smaller. The cost burden varies across different departments across hospitals, e.g. emergency department versus wards" - (**5**).

"Although costs can be an obstacle in regards to the implementation of safety engineered devices, the balance should be offset against the financial costs of NSI and the impact of the human costs if staff contract blood borne pathogen's - (**7***).*

"This study reviewed other studies that had looked at costs associated with the use of safety-engineered devices. The costs were broken into direct and indirect costs, education costs and production lost time costs. Estimates of cost effectiveness averted are dependant on a variety of factors, including management protocols, cost of devices, costs associated with education and training" - (**12**).

"The cost associated with the implementation of safer systems is a concern for hospitals faced with budget cost's - (**16***).*

"The cost of introducing safety-engineered devices has to be weighed against the costs of allowing staff to be injured and potentially infected following an occupational exposure. Higher costs associated with providing a safer working environment is not a new occurrence" - **(39**).

"Due to the costs associated with the implementation of safety-engineered devices and scarceness of evidence available validating their benefit, many healthcare settings have refrained from introducing them" - (**17**).

"The cost of the safety-engineered device implemented compared to the non-disposable device traditionally used was comparable. The cost of a NSI is not insignificant, even when no treatment is required. Psychological effects on staff can be considerable and should not be underestimated" - (**19***).*

"The introduction of safety-engineered devices should be considered as an investment in improving the health and safety of HCW. In a recent court ruling any decision made by employers not to introduce safety equipment should not be based on cost alone" - (**28**).

5.4.2 Active *vs.* passive devices

A number of papers (15, 16, 17 and 24) included in the review, made reference to, and described the difference between, active and passive safer sharps devices, though this topic did not fall within the remit of the agreed Pico questions. It was therefore not part of this review to assess whether one type of device was superior to another, or to determine the benefits of either of these types of devices.

5.4.3 Disposal of sharps

This is large topic area in its own right and did not fall within the remit of the Pico questions agreed for this review. It was agreed at the outset by the assessor group that sharps disposal devices would justify a separate and dedicated review in order to assess the impact of such devices. One 'disposal' study (Grimmond *et al*, 2003) was recovered from the current literature search and subsequently removed during the sifting process for this review.

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An evaluation of the efficacy of safer sharps devices

Systematic review

Sharps-related injuries carry the risk of serious blood borne infection. A systematic review was undertaken to consider the evidence related to safer sharps devices and their impact on needlestick injury reduction within the healthcare sector. The review sought to determine whether:

- the use of safer sharps devices could reduce the incidence of sharps injury;
- dedicated educational / training initiatives could reduce the incidence of sharps injuries;
- safer sharps devices were accepted by the hospital personnel asked to use them; and
- safer sharps devices had any proven impact on patient care outcomes.

The quality and quantity of evidence was limited, mainly due to study designs used by publishing authors. Despite this, there was sufficient published evidence to consider the use of safer sharps devices to reduce the incidence of sharps injuries amongst UK healthcare workers.

Studies showed that when educational programmes were implemented alongside a safer sharps device, lower rates of sharps injuries were sustained for longer. However, the benefit attributable to education alone could not be isolated from the impact of the introduction of the safer sharps device.

Few studies have investigated user acceptability of safer sharps devices and patient outcomes, and more studies are required to assess these areas with greater certainty.

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