

An evaluation of the efficacy of safer sharps devices

Systematic review

Prepared by the **Health and Safety Laboratory**
for the Health and Safety Executive 2012

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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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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.

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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 Adishes (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 virusesⁱ. 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 exposuresⁱⁱ.

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 Partnersⁱⁱⁱ 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 reviewsⁱ.

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.

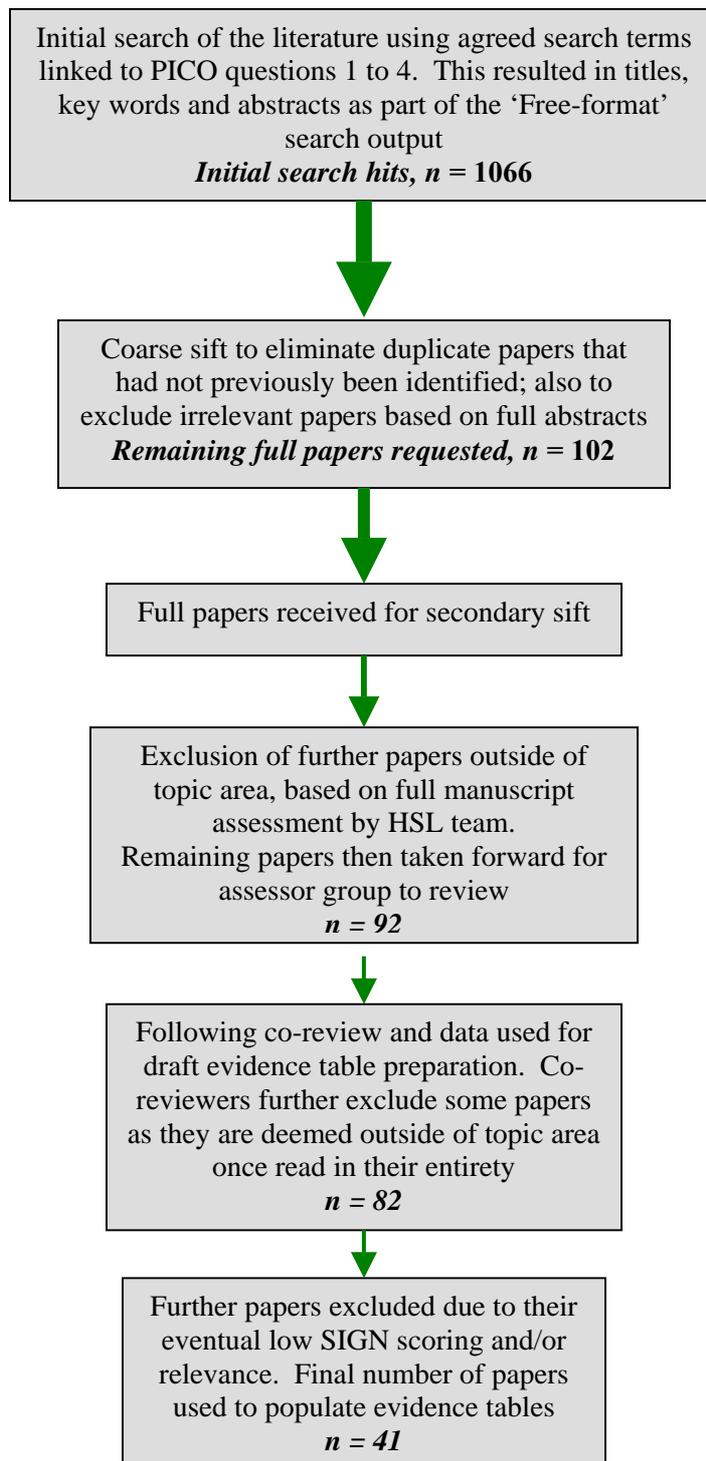
2.4.2 The search process

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 siteⁱⁱ, 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

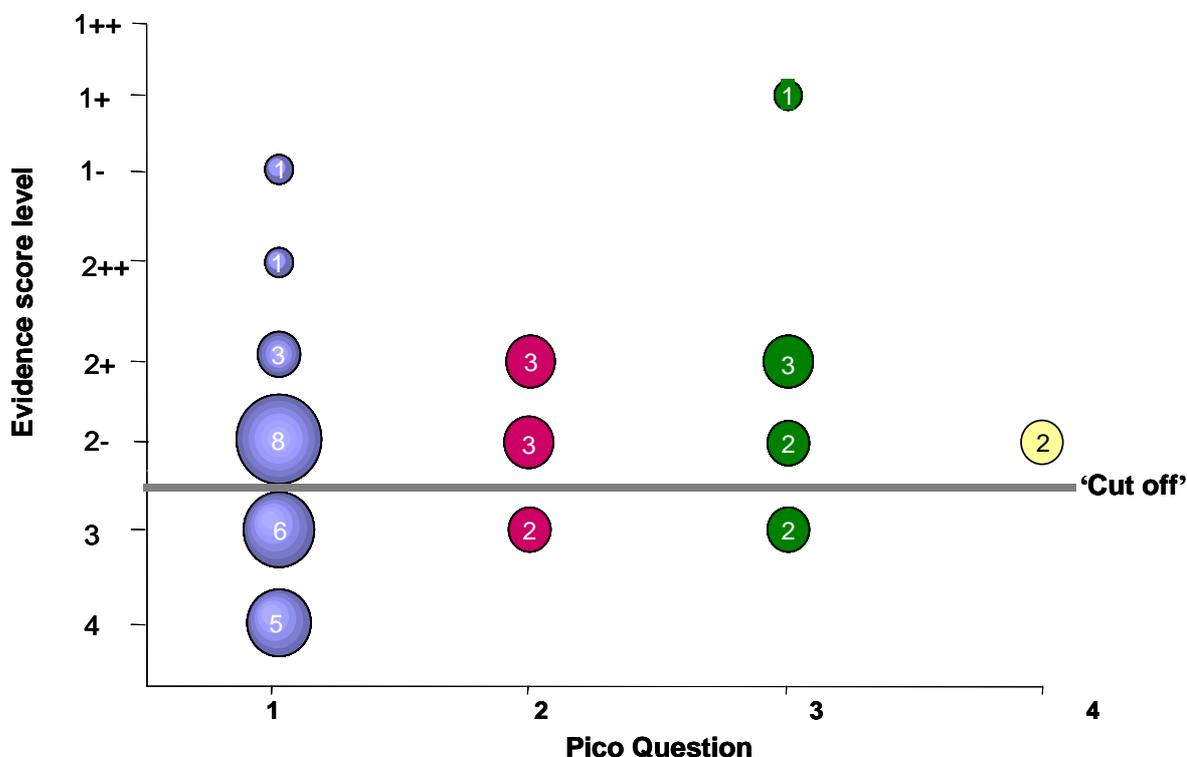
3.1 PRIMARY SEARCH OUTPUT AND PAPER EXCLUSIONS

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	
<i>Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.</i>	
<p>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.</p>	
2. Applicability	
<i>Comment here on the extent to which the evidence is directly applicable to UK practice</i>	
<p>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.</p>	
3. Generalisability	
<i>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.</i>	
<p>The majority of studies reported injury reduction where safety devices were introduced and whilst the working environments described differed, some general trends were identified.</p> <p>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).</p> <p>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.</p>	
4. Consistency	
<i>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</i>	
<p>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:</p> <p>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).</p> <p>Other studies have reported the following benefits:</p> <ul style="list-style-type: none"> • 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 effectⁱⁱⁱ – (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 <i>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.</i>	Evidence level
<p>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).</p>	<p>2++</p>
<p>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).</p>	<p>2+</p>
<p>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).</p>	<p>2+</p>
8. Evidence-based conclusion(s) <i>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.</i>	Grade of evidence-based conclusion
<p>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.</p>	<p>C</p>
<p>HCW's (users) of the devices, should be involved with the evaluation of new devices.</p>	<p>C</p>
<p>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.</p>	<p>KG</p>

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 <i>Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.</i>	
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 <i>Comment here on the extent to which the evidence is directly applicable to UK practice</i>	
The papers short-listed for full review were undertaken in well-developed healthcare environments relevant for UK practice.	
3. Generalisability <i>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.</i>	
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 <i>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</i>	
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 <i>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.</i>	
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 <i>Indicate here any other factors that you took into account when assessing the evidence base.</i>	
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 <i>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.</i>	Evidence level
Education and training were regarded as necessary to achieve the greatest preventative effect after the introduction of safer sharps devices. (27 / 31)	2+ / 2-
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-
8. Evidence-based conclusions <i>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.</i>	Grade of evidence-based conclusion
Safer sharps devices should always be introduced alongside appropriate educational programmes, as would be expected for conventional devices.	C
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).	C
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.	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 <i>Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.</i>	
Of the seven studies identified to address this question, only 5 were suitable to obtain evidence-based conclusions.	
2. Applicability <i>Comment here on the extent to which the evidence is directly applicable to UK practice</i>	
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 <i>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.</i>	
Generalisability is limited due to lack of volume in the evidence identified.	
4. Consistency <i>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</i>	
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 <i>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.</i>	
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 <i>Indicate here any other factors that you took into account when assessing the evidence base.</i>	
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 <i>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.</i>	Evidence level

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).	1+
Healthcare workers training and their involvement in the selection of devices had a beneficial effect on the activation rates for the safer devices – (37).	2+
8. Evidence-based conclusions <i>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.</i>	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 <i>Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.</i>	
Within the scope of this project and the selection/exclusion criteria, the evidence available was limited to two studies.	
2. Applicability <i>Comment here on the extent to which the evidence is directly applicable to UK practice</i>	
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 <i>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.</i>	
As only 2 papers were reviewed for this question the results cannot be generalised.	
4. Consistency <i>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</i>	
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 <i>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.</i>	
As only 2 quality studies were reviewed for this question, the clinical impact of cannot be generalised.	
6. Other factors <i>Indicate here any other factors that you took into account when assessing the evidence base.</i>	
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 needleless device) was reported as a risk factor for patient outcomes.	
7. Evidence statement <i>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.</i>	Evidence level
An association between primary bloodstream infection and needleless connector devices was observed - (40).	2-
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-
8. Evidence-based conclusions <i>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.</i>	Grade of evidence-based conclusion
The scarcity of data suggests that more research is required in this area.	KG
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

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	Safe, Safe cannula (to pick up 'cannulae' also)		Retractable
Dentist	Safe cannulae + impact and/or assessment		splash
HCWs	Safe needle devices		Splash blood
Health	Safe needle devices + impact and/or assessment		stab
health care facilities	Safe needle disposal		stab wound
health care personnel	Safe needle disposal + impact and/or assessment		stab wounds
health care worker	Safer sharps bin		stick injuries
health care workers	Safer sharps device		stick injury
health careworker	Safer sharps device + impact and/or assessment		suture needles
health careworkers	Safer sharps disposal		syringe
health occupation	Safer sharps disposal + impact and/or assessment		viral infect
health occupations	Safe syringe + impact and/or assessment		virus
health personnel	Safe** sharps, safe/ty/r, safe/ty/r + engineered		virus disease
health worker	safe/ty/r/guard, Safer		virus transmission
health workers	Safer needle technology		winged steel
Health-Personnel	Safety engineered device		wound
hospital	Secretion; secretion fluid, fluid, fluids		wound penetrating
hospitals	Self blunting		wound stab; stab wound
human	Standard + syringe + sharps device		Wounds
humans	sharp, Blunt,		Exposed; exposure; exposures
nurse	sharp injuries; sharp injury		Eye; eye injuries; eye injury; eyes
nurses	sharp instrument; sharp instruments		penetrating; penetrating wound
nursing	sharp medical; sharp medical device;		penetrating wounds
nursing as a profession	sharp medical devices		percutaneous
medical personnel	sharp medical instrument;		percutaneous exposure
medical profession	sharp medical instruments; sharp-needle; sharp needles;		percutaneous exposures
medical students	single		percutaneous injuries
military-medical-	winged,		percutaneous injury
personnel	instrument		percutaneous trauma
Physician	Intervention, mask		arm; arm injuries; arm injury
Physicians	Design; device; Devices + safety features		blood, blood borne infection
professional	Needle; Needle shields; needle stick		blood borne/bloodborne virus
Psychiatric-Hospital-Staff	needle stick/exp; needle sticks; needle/stick		disease Transmission
Volunteer (not Animal)	Needless connectors/devices; needlestick		face injury, facial, Facial injuries,
volunteer	Needlestick injuries; needlestick injury		Facility, finger
Personnel	Needlestick prevention devices		finger injuries; fingers
phlebotomy	blood evacuation		forearm injuries
medical	cannula, catheter, hypodermic		hand, hand injuries or injury
clinic	injection, intravenous		injured, injuries, injury
Health	body fluid, body fluids, Body Secretions		occupational exposure/exposures
Services	prevention, Protected needle, protection/ive		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 intervention
 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 1 above

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.)

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.

INDEX Evidence Table Index

Paper Reference	Evidence Grade						
1	3	25	3	33	3	40	2-
2	3	26	2-	34	1+	41	2-
3	2++	27	2+	35	3		
4	2+	28	2+	36	2-		
5	2+	29	2-	37	2+		
6	3	30	2+	38	2-		
7	2-	31	2-	39	2+		
8	2-	32	3				
9	4						
10	4						
11	3						
12	3						
13	4						
14	4						
15	2-						
16	2-						
17	2+						
18	2-						
19	2-						
20	3						
21	1-						
22	4						
23	2-						
24	2-						

Key for table sections:

- A = Number of Healthcare Workers (HCW)
- B = Characteristics of HCW
- C = Intervention
- D = Comparison
- E = Length of follow up
- F = Outcome measure
- G= Effect size
- H = Main results

 SIGN	Evidence Table PICO Question One 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?
Reference: 1	Sossai D, Puro V, Chiappatoli L, Dagnino G, Odone B, Polimeri A, Ruzza L, Palombo P, Fuscoe MS, Scognamiglio P. (2010) Using an intravenous catheter system to prevent needlestick injury. Nurs Stand 24 (29): 42-46.
Evidence Level: 3	
Study Type: Before & After study: Case series (non-analytical) with a longitudinal follow up period of 3 years after the introduction of a Safety IV Catheter system (Introcan) and with comparison to data on needle stick injuries for the two years preceding the intervention when standard catheter needles were used.	
Source of Funding: Training sessions were carried out by manufacturers of the safety catheter and by members of the hospital's	
A	The paper does not focus on patients but on the number of reported needle stick injuries occurring amongst hospital staff when a safe design of catheter was introduced. The following numbers of catheter needles were used during this period: ➤ Conventional catheter (2 year period): 295,000 ➤ Safety needle catheter (3 year period): 512,000
B	Patients groups not included but the study involved hospital employees in 90 departments (outpatient clinics, operating theatres, intensive care units, day hospitals and surgery). The number of hospital employees suffering needle stick injuries was monitored and the total numbers of staff reported in employment during the study varied from 4,447 to 4,636 (between 2003 to 2007)
C	Safety catheter: The key intervention was the introduction (in 2005) of a safety catheter (Introcan Safety IV Catheter system manufactured by B. Braun) after an educational intervention to raise awareness (i.e. awareness campaign) of needle stick injuries (started in 2003). The safety catheter had a self-activating safety clip that automatically shields the needle's sharp bevel during retraction after cannula insertion. This safety catheter was described as identical to the conventional catheter used up until the introduction of the safety catheter. <p style="text-align: center;"><i>Note this paper also contains information relevant to Pico 2</i></p> The education intervention continued between 2005 and 2007. This involved practical training and courses (for long-term employed healthcare staff) on the biological risk of needlestick injuries. A monthly compulsory training course on the need for prevention and safety precautions related to needlestick injuries, and the correct practical application of safety devices was also introduced for all new employees. During this period, 596 of 3,392(8%) long-term employed physicians, nurses and technicians and 882 (100%) new employees received safety training.
D	Comparison of use of safety device versus non safety catheters by healthcare staff.
E	➤ The entire study lasted 5 years (2003 – 2007). ➤ After the introduction of the safety catheter hospital employees were followed for two years. ➤ 4 years for awareness campaign.

 SIGN	Evidence Table PICO Question One 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?
Reference: 1	Sossai D, Puro V, Chiappatoli L, Dagnino G, Odone B, Polimeri A, Ruzza L, Palombo P, Fuscoe MS, Scognamiglio P. (2010) Using an intravenous catheter system to prevent needlestick injury. <i>Nurs Stand</i> 24 (29): 42-46.
F	<p>The outcome of the study included</p> <p>Injuries data: Rate of occupational accidents, including sharps injuries involving catheters. Over the whole duration of the study, occupational injury data was collected from incident reporting data and analysed retrospectively. This data included all occupational incidents and percutaneous injuries caused by catheter needles and sharps. Needlestick injuries caused by catheters were investigated and the type of catheter, and occupation of the affected staff member were recorded. The total number of catheters used annually was used as the denominator. All hospital employees were included in the study.</p> <p>Other supporting data included</p> <ul style="list-style-type: none"> ➤ The time, location and accurate description of an accident. ➤ The profession, department, ward or operating unit of where the incident occurred. ➤ The type of device responsible for the sharps injury The use of any safety measures during the incident.
G	<ul style="list-style-type: none"> ➤ The authors do not carry out a statistical analysis of the results (probably because of the low number of needle stick injuries) and instead summarise the annual data as an incidence rate for injuries with either conventional or safety catheters. ➤ The number of needle and sharp injuries entailing biological risk reduced from 163 to 86 from the beginning (2003) to the end of the study (2007). The rate of needlestick injuries was 24.1 per 100,000 cases for use of conventional catheters and 0.4 per 100,000 for use of safety catheters. The incidents of sharps injuries involving catheters fell from 19 in 2004 to two in 2007. No cases were reported for use of safety catheters. ➤ The results indicate that for healthcare staff the risk of injury when using a conventional device was more than 25 times higher than the risk associated with the use of the safety catheter. From 2005 to 2007 (after their introduction) the total number of reported needle stick injuries decreased from n=10 (2005); n=3 (2006), and n=2 (2007). ➤ During the study period, the authors indicate that nurses were affected more often by needlestick injuries than physicians but they do not report on the total number of needle stick procedures carried out by both groups during this period. ➤ Additional data reported that sought to measure the other aspects of the study included: ➤ Educational/ training intervention: The number of injuries caused by catheters increased from n=10 (in 2003) to n=19 (in 2004), and the authors suggest this is because of the introduction of the sharps safety awareness campaign in 2003, resulting in a increased reporting of needle stick injuries. ➤ Use of safety devices: The number of needlestick prevention devices used by the hospital was 130,000 in 2005 and increased to 165,000 in 2006 but decreased to 163,000 in 2007.

 SIGN	Evidence Table PICO Question One 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?
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H	<p>Yes the study overall does help address Pico question 1</p> <p>There caveats in this study which need to be considered:</p> <ul style="list-style-type: none"> ➤ Only needle sharp incidents were reported and given the low prevalence pre intervention the overall results do not allow a robust statistical analysis of trends. ➤ The study does not report on the numbers and variety of staff that were involved in using the needles. How experienced were the staff in using the catheters and how were the numbers of staff carrying out most catheter insertions similar throughout the study? ➤ No evaluation of staff experience of using the safety devices was undertaken and this might have helped resolve the influence of the educational programme and that of the safety design. ➤ The period of study following the introduction of the safety device was only two years, which is insufficient to anticipate long-term trends. ➤ The study involved a large educational intervention before during and after the introduction of the safety catheter. This is understandable but at the same time the impact of the education versus the impact of the safety needle mechanism in reducing the incident of needle stick injuries is difficult to separate. The authors report an increased reporting of needle stick injuries after the start of the education and awareness raising. It is possible that the reduced injury rate after this period was due both to the design and a greater awareness of the problem. However, the authors note that only 18% of long-term staff received the safety needle training and all of the new employees from 2005 (but by 2007 they still only represented 25% of all employees).

 SIGN	Evidence Table PICO Question One 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?
Reference: 2	Jagger J, Berguer R, Phillips EK, Parker G, Gomaa AE. (2010) Increase in Sharps Injuries in Surgical Settings Versus Non-surgical Settings after Passage of National Needlestick Legislation. <i>Journal of the American College of Surgeons</i> 210 (4): 496-502
Evidence Level: 3	
Study Type: Before and after study: This study was a retrospective analysis (an incomplete case series) of sharps injuries reporting over a nine year period before and after the introduction of the Needlestick Safety and Prevention Act of 2000 in the USA. The study is similar to a 'before and after' series with the impact of the introduction of this legislation on the incidence of sharp injuries investigated for a period of ~7 years leading up to the changes and six years after the change.	
Source of Funding: Ethicon, Inc. & National Institute for Occupational Safety and Health (NIOSH).	
A	The paper only reports data on sharps related percutaneous injuries and during the period of the study (1993 to 2006) there were 24,138 percutaneous injuries reported in non-surgical settings and 7,186 injuries in surgical settings and in 87 US hospitals.
B	Surgeons, surgical residents and fellows, operating room nurses, surgical technicians, attendants and ward assistants; The data was gathered from 87 US hospitals voluntarily participating from 11 states, this included teaching and non-teaching hospitals, small and large, and public and private hospitals.
C	The implementation of the 2000 Needlestick Safety and Prevention Act: The authors note: " <i>The law has been associated with a marked increase in the hospital adoption of safety-engineered sharp devices.</i> ".
D	Comparison of the impact of the introduction of the NSPA legislation in the US on the incidence of percutaneous sharps injuries amongst healthcare workers
E	The study investigated percutaneous injury data from January 1993 through December 2006 (i.e., 14 yrs)
F	The Occupational Safety and Health Administration protocol for anonymous reporting of at-risk percutaneous injuries using the EPINet reporting format (Exposure Prevention Information Network sharps injury and blood and body fluid exposure surveillance system). <ul style="list-style-type: none"> ➤ Injuries occurring in the operating room or post-operative recovery area were analyzed separately from those occurring in all other hospital settings. ➤ Injury data was excluded if it occurred before the use of the sharp device or where there was no risk of blood exposure. Injuries to non-surgical personnel were also excluded. ➤ Hospital-wide rates of injuries were calculated as 'average daily census' for each year of participation in the network combined as the denominator for calculating injury rates. ➤ Injury rates in surgical vs non-surgical settings were calculated for the periods before (1993 to 2000) and after (2001 to 2006) enactment of the new law. The differences were assessed using a likelihood ratio test. ➤ The impact of device mechanism on specific injuries in different members of the surgical teams were assessed to identify causal factors.

 S I G N	Evidence Table PICO Question One 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?
Reference: 2	Jagger J, Berguer R, Phillips EK, Parker G, Gomaa AE. (2010) Increase in Sharps Injuries in Surgical Settings Versus Non-surgical Settings after Passage of National Needlestick Legislation. <i>Journal of the American College of Surgeons</i> 210 (4): 496-502
G	<p>General findings: The key findings were:</p> <ul style="list-style-type: none"> ➤ In non-surgical settings the pre-legislation injury rate of 24.1 per 100 occupied hospitals beds significantly reduced by 31.6% ($p < 0.0001$) to 16.5 per 100 beds after the introduction of the legislation. ➤ There was a corresponding increase in the proportion of injuries caused by use of safety devices reflecting the greater use of these devices by the non-surgical health care professionals. ➤ In the surgical teams the proportion of injuries attributed to use of safety-engineered surgical devices was less than 1.0% before and after passage of the law, reflecting a very low adoption of safety devices. ➤ The injury rate amongst surgical teams increased from 6.3 to 6.8 injuries per 100 occupied beds ($p < 0.05$) after the introduction of the legislation. When a subset of hospitals that reported data consistently throughout the study were analysed the increase in injury rate amongst surgical teams was highly significant after introduction of the legislation ($p < 0.0001$). ➤ Amongst the surgical teams, 15.6% of the injuries were to surgeons, 17.0% to surgical residents and fellows, 30.3% to operating room nurses, and 37.1% to surgical technicians ➤ 81.9% of surgeons and 67.3% of surgical residents were the originator of the problem; with nurses (77.2%) and surgical technicians (85.1%) most frequently injured by devices used by others. 75.3% nurses and 73.4% surgical technicians received injuries when devices were passed to them, or during the disassembly of devices, or their disposal. ➤ 71% of injuries to surgeons and to 66% surgical residents occurred during use of the sharps device. ➤ 72.7% of reported injuries were associated with use of 3 devices; suture needles (43.4% of all injuries); scalpel blades (17.1%); and disposable syringes (12.1%). These 3 devices ranked top irrespective of job description. 27.3% of injuries were caused by a wide array of devices, mostly solid sharps used for cutting, clamping, retraction, and fixation. ➤ The majority of injuries occurred during the use and disposal cycle for these 3 devices. 83.5% of suture needle injuries, 69.8% of scalpel blade injuries, and 51.9% of injuries from disposable syringes occurred during these use – disposal cycle. ➤ Other activities associated with injuries included attaching and removing blades from reusable scalpel handles (12.0%); in use or disposal injuries with suture needles and scalpel blades (11.3% and 14.4%, respectively); disposal of syringes (29.3%) and recapping of syringes (11.1%). ➤ Fewer than 4% of injuries occurred during disassembly of suture needles and syringes.

 S I G N	Evidence Table PICO Question One 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?
Reference: 2	Jagger J, Berguer R, Phillips EK, Parker G, Gomaa AE. (2010) Increase in Sharps Injuries in Surgical Settings Versus Non-surgical Settings after Passage of National Needlestick Legislation. <i>Journal of the American College of Surgeons</i> 210 (4): 496-502
H	<p>Yes: The study does not provide evidence that introducing specific safer sharps devices reduced injury rates but as a very large survey it provide robust evidence that sharp injuries decreased amongst one group of health professionals following the introduction of the Needlestick Safety and Prevention Act of 2000.</p> <ul style="list-style-type: none"> ➤ The study provides data about the types of sharps instruments that caused most injuries; which groups of health care workers experienced most injuries; and some of the reasons behind these injuries. The data also provided information about the lack of reductions in sharps injuries amongst surgical teams indicating behavioural or practical barriers to the uptake of safer sharps devices amongst this group. <ul style="list-style-type: none"> • The proportion of surgical injuries attributed to safety-engineered devices was less than 1% before and after the legislation, reflecting low adoption of safety devices. • The proportion of non- surgical injuries attributed to safety-engineered devices increased post legislation, indirectly reflecting adoption of safety devices. ➤ The study design is appropriate for a retrospective survey and on a large enough scale to provide robust data to analyse incident rates amongst different sub groups of HCWs. The results of the study are considered valid. <p>Caveats: The study does not provide details of the actual number of conventional vs safety devices used by non-surgical and surgical groups during each year of the study. Whilst summary data of the injury rate associated with conventional and safety devices are provided for non-surgical and surgical staff it is difficult to assess the incidence rate in relation to the number of conventional vs safety devices used. The summary date (Figure 1) is for injury rates per 100 occupied beds.</p>

 SIGN	Evidence Table PICO Question One 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?
Reference: 3	Sullivan S, Williamson B, Wilson LK, Korte JE, Soper D. (2009) Blunt needles for the reduction of needlestick injuries during cesarean delivery: a randomized controlled trial. <i>Obstet Gynecol</i> 114 (2): 211-216
Evidence Level: 2++	
Study Type: A Prospective Randomised Controlled Trial (device test sharp vs blunt needles) Note Clinical Trial Registration: NCT00844636 [Level of evidence 1]	
Source of Funding: Does not state source of financing.	
A	194 patients with 97 patients in the control group (sharp needle) and 97 in the study group (blunt needle). No 'dropouts' from the study
B	<ul style="list-style-type: none"> ➤ All patients requiring non-emergent caesarean deliveries from January 2005 to September 2006 were eligible and there were no exclusion criteria ➤ Data collected for the groups included: patient demographics included age, race, weight, height, parity, HIV status, and multiple gestations. ➤ There were no significant differences between the demographics for both groups (maternal age (y) ~ 27; body mass index ~33; gestational age (wk) ~36; nulliparity (%) 24.2; birth weight ~2.7Kg.
C	The introduction of blunt needles compared to sharp needles for caesarean surgical procedures (entry and closure of the abdominal cavity)
D	Comparison between use of blunt needles versus sharp needles on the incidence of needle sharp injuries and glove perforations
E	Not relevant to this study design
F	<ul style="list-style-type: none"> ➤ The primary outcome measure was surgical glove perforations as a surrogate measure of needle stick injuries. This was measured for all gloves used in both arms of the study and involved a physical test of glove integrity (water leak test) ➤ The second outcome was self reported glove perforations and injuries as well as satisfaction with the blunt needle compared to the sharp needle. ➤ This was based on a questionnaire employing a 5 point Likert rating scale for questions related to satisfaction / preference for needle type and the perceived likelihood of NSI. ➤ Other supporting data collected (not outcome measures directly related to the aim of the study): Included estimated blood loss, total surgery time, experience level of surgeon, type of anaesthesia, and neonatal weight and Apgar scores; types of incisions (skin, hysterotomy) and additional procedures performed, including tubal ligation.



Evidence Table PICO Question One

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?

Reference: 3

Sullivan S, Williamson B, Wilson LK, Korte JE, Soper D. (2009) Blunt needles for the reduction of needlestick injuries during cesarean delivery: a randomized controlled trial. *Obstet Gynecol* 114 (2): 211-216

G

Primary outcome measure (glove perforations):

A statistically significant reduction in glove perforations was observed in the blunt needle group with an estimated relative risk of 0.66 (CI-95%, 0.49-0.89).

This represented the following numbers of glove perforations for each group:

- 24 glove perforations in total representing a rate of 12.3% for both arms of the study.
- 17 perforations occurred with use of the sharp needles (a rate of 17.5%)
- 7 perforations occurred in the blunt-needle group (a rate of 7.2%)
- The number need to treat to avoid one glove perforation was 9.7 (CI = 5.1-864)

With respect to the level of surgical experience:

- 15 perforations to the gloves were noted for the primary surgeon group (7.7%). This was a non-significant reduction – relative risk of 0.8 (95%-CI 0.53, 1.2).
- 9 perforations to the gloves for the assistant surgeon group (4.6%).
- 1 glove perforation amongst the surgical assistant groups (1.03%). This represented a significant reduction amongst the surgical assistant using blunt needles with a relative risk of 0.54 (95%-CI 0.41, 0.71).

Other findings:

- 16 out of the 24 (66%) perforations were detected by the surgeon, or assistant, at the time of the surgery.
- There was a poor correlation between reported perforations and the perforations detected by physical examination both for the primary surgeons ($R^2=0.3$) and assistant surgeons ($R^2=0.37$).
- Surgeons for whom glove perforations were detected had operated for significantly longer times than did those without glove perforations (72 vs 63.1 minutes: $p=0.03$).
- The average duration of procedures were as follows: for perforation events = 70 min (median range 49-104); for no perforations = 64.9 min (median range 44-89). This was a significant difference ($p=0.03$)
- No additional differences in glove perforation rate were observed among the other clinical or demographic variables
- Primary and asst surgeons both reported less satisfaction with blunt needles cf sharp ($p<=0.001$)
- For the primary surgeons 92% rated blunt needles as likely to decrease the risk of needlestick.
- For the assistant surgeons 93% rated blunt needles as likely to decrease the risk.

 SIGN	Evidence Table PICO Question One 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?
Reference: 3	Sullivan S, Williamson B, Wilson LK, Korte JE, Soper D. (2009) Blunt needles for the reduction of needlestick injuries during cesarean delivery: a randomized controlled trial. <i>Obstet Gynecol</i> 114 (2): 211-216
H	<p>Yes in relation to one type of ‘safe’ device blunt needles used in the specific context of surgery for caesarean sections. The study has a randomised selection for the intervention and the two patient groups were comparable. However, it needs to be noted that the surgeon and surgical staff could not be blinded to the device and that this may have influenced the self-reporting data on preference.</p> <ul style="list-style-type: none"> ➤ It should be noted that the primary endpoint measured (glove perforations) provided only a small handful of outcomes (perforated gloves); furthermore the choice of glove type, number of gloves worn, and needle size was left to each surgeon’s individual preference. These variables may have influenced the reporting of perforations to gloves. The authors state that the method for testing glove perforations had been validated for the use of needles of 25-gauge or larger needles. However a non standard method for testing gloves was used. It should also be borne in mind that as a surrogate measure of NSI the use of glove perforations may over report the likely incidence of skin perforations. ➤ The advantage of the physical testing for perforation is that is provided objective data. It should be noted that self-reporting of perforations by the surgical team correlated poorly with the physical tests of perforations. Only 66% of the physical perforations were self reported and perforations were reported that could not be detected. The authors took account of the background frequency of perforation that can occur in gloves during manufacture. ➤ The authors concluded that the lower overall perforation rate compared to other studies may be due to the Hawthorne effect but despite this the study shows that the blunt needles are protective against glove perforation (and therefore probably needlestick injury), especially for the assistant surgeons. <p>Secondary outcome measure (self reported glove perforations and needle preference)</p> <ul style="list-style-type: none"> ➤ 100% of the physician completed the self-assessment survey. ➤ No instances of crossover following the randomized allocation of needle assignment occurred during the study. ➤ Primary surgeons said overall they were less satisfied with using blunt needles during the procedure compared with sharp needles (P<0.001) ➤ Assistant surgeons reported a similar decrease in global satisfaction (p=0.001). ➤ 92% of primary surgeons and 93% of the assistant surgeons rated the blunt needles as "acceptable" or higher. ➤ Neither the primary nor assistant surgeons reported that blunt needles reduced their risk of needlestick injuries during the procedure (p=0.33 & p=0.66) ➤ The secondary outcome suggested that surgeons' were overall less satisfied with using blunt-needles but they did not rate blunt needles as either poor or offering no protection against glove perforation.

 S I G N	Evidence Table PICO Question One 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?
Reference: 4	Hotaling M. (2009) A retractable winged steel (butterfly) needle performance improvement project: Jt Comm J Qual Patient Saf 35 (2): 100-105
Evidence Level: 2+	
Study Type: This is a summary of a retrospective and prospective study looking at the outcomes from several interventions to reduce the occurrence of needle stick injuries associated with the use of a safety needle device (steel butterfly needle) at one hospital	
Notes: <i>This is a discussion paper</i> and provides insufficient data on which to judge the reliability of the outcomes of the interventions introduced to reduce needle stick injuries. The study was implemented because the hospital had noted that six months after the introduction of the safety winged steel needles there had been an increase in reported needle stick injuries. This data indicated that reported needle stick incidents from use of WSNs were three times as frequent (3.4 versus 1.1 per 100,000 devices purchased) when compared with the conventional (non-safety engineered) vacuum-tube blood collection needles previously used.	
Source of Funding: No external funding reported.	
A	The number of staff participating in the study is not recorded but some information is provided that those participating included clinical laboratory phlebotomy staff and during the pilot study of the alternative needle devices nursing staff from the neonatal intensive care and emergency department departments. The information about the evaluation stage of the two alternative safety needles notes “a 100% response rate, the <u>seven</u> staff’s ratings averaged 1.6/5.0”.
B	Nursing staff and phlebotomists hospital staff, staff-registered nurses and emergency department technicians. Laboratory phlebotomists in a single hospital.
C	<ul style="list-style-type: none"> ➤ There were two interventions, the replacement of the safety winged steel needle (WSN) with two other devices (one a self-blunting needle technology, and the other a retractable-needle technology). ➤ The second intervention involved product training from the manufacturers of these devices. This training involved information to handle and assemble the equipment through to its use, safety feature activation, and disposal.
D	Comparison between non safe and ‘safe’ needle devices used by healthcare workers on reported incidence of NSI
E	The study examined two years of retrospective reports on NSI reports (from 2000 and 2001) and then prospectively examined over four years (2002-2007) the incidence of needle stick injuries following the periods in which training was introduced and two new safety devices piloted, one of which was then selected and for which data on needle stick injuries is reported in comparison to data obtained before this period using the winged steel safety needle.
F	<ul style="list-style-type: none"> ➤ The primary endpoint is reported needle stick injuries <p>Needlestick incidents were followed up by the laboratory safety officer, and ‘one-on-one’ interviews conducted with injured staff members to collect details about the circumstances of each incident. Re-enactment of the incidents helped to identify the root cause of the injury. All hospital staff laboratory who sustained WSN needle stick injuries, including nursing department staff-registered nurses and emergency department technicians were interviewed. The aim was to identify inherent design flaws, device failure, or user errors (e.g., failure to activate safety features).</p>



Evidence Table PICO Question One

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?

Reference: 4

Hotaling M. (2009) A retractable winged steel (butterfly) needle performance improvement project: Jt Comm J Qual Patient Saf 35 (2): 100-105

- G
- In first 9 months following the introduction of the new retractable safety WSN the rate of needle stick injuries decreased from 3.76/100,000 to 1.5/100,000 per retractable WSNs purchased. This was a 60% decrease compared to the use of the manual re-sheathing WSN.
 - Of two needle stick injuries reported to involve the retractable safety WSN both involved phlebotomists during blood collection where a sudden movement of the patient caused the needle to pull out of the vein resulting in it sticking into the operators finger or hand. Nursing staff reported no needle stick injuries using the retractable WSN needle sticks during the same nine-month period.
 - For the 31 months period (March 2006-October 2008) following implementation of the retractable WSN needle stick injuries reduced overall by 88% ($p<0.001$) from 3.76 to 0.47 per 100,000 WSNs purchased.
 - In the last 21 months of this period, no needle sticks injuries related to these devices were reported.
 - The authors noted that the 88% reduction in WSN needle sticks injuries related to the device's in-vein safety feature activation, in which the contaminated needle is retracted before needle withdrawal. This reduction was equivalent size to the proportion of injures attributable to use of the first winged steel safety needle.
 - An audit investigated whether staff were activating the safety device on these needles. Checks on some phlebotomy sharps containers showed that 100% of the devices had been retracted.

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- Yes but only in general terms.** A good case study showing that in-vein retractable devices which can be activated single-handedly can be effective in reducing one of the most common needlestick injuries. This is not a randomised study but is design as a pre-post comparison it does not report the total number of procedures only rates per 100,000 procedures. The paper summarises different aspects of the replacement of one type of needle with a safer design. Its descriptions of the process are informative covering root cause analysis and evaluation of alternative devices. It also provides evidence of a significant reduction in needle stick injuries after 32 months use of the retractable safety needle.
- It emphasises the importance of involving the user in the selection of the safety devices (4 were considered – one rejected due to inability to use single handed, another because the users felt their fingers were placed unreasonably close to the needle when activating). Of the two considered there was a preference for the retractable device compared to the self-blunting device.
 - Overall the paper provides insufficient detail to know how large a number of staff were involved in this evaluation and the uncertainties surrounding these estimates. The paper does not consider whether some of this change could have resulted from the training interventions or other awareness raising activities.
 - A cost effectiveness analysis for replacement with the retractable safety device is provided.

 SIGN	Evidence Table PICO Question One 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?
Reference: 5	Valls V, Lozano MS, Yanez R, Martinez MJ, Pascual F, Lloret J, Ruiz JA. (2007) Use of safety devices and the prevention of percutaneous injuries among healthcare workers. <i>Infect Control Hosp Epidemiol</i> 28 (12): 1352-1360
Evidence Level: 2+	
Study Type: Before and after study trial (intervention evaluation)	
Source of Funding: Direccion General de Salud Publica de la Generalitat Valenciana Comunidad Autonoma de Valencia - Spain	
A	75 nurses participated in the study – these were part of a work force of ‘about 1000’ staff based at the 350-bed general hospital
B	The HCWs were all based in either the emergency dept., medical intensive care unit or half of the hospitalization wards (surgical and medical).
C	The use of safety-engineered devices was implemented in the above areas. The 75 HCWs based in these areas also received educational training – a 3hr slide review of risk factors and epidemiology and prevention of injury + 2hrs of hands on training and 15 minutes on site training with each new device being trialled. Education only in the intervention group. Nurses were involved in selection process of SEDs; Controls used a vacuum device to withdraw blood. Intervention with safety engineered device for phlebotomy, intra-muscular / sub-cutaneous injections, intravenous access, including blood gas devices. Lancets, and blunt needles for drawing up medication– (e.g. safT, EZ BD, Surshield, Provent, Preserts, Genie Surgilance, Protective plus, Versatus S, Insyte Autoguard eclipse). Voluntary reporting of sharps injuries for 6 months occurred prior to the intervention and 6 months after the intervention; the study included controls and an intervention arm.
D	The rate of percutaneous injuries (PIs) pre- and post- intervention;
E	The study was a ‘before and after’ study: Before = Oct 2004 to March 2005 (6 months); After = Oct 2005 to March 2006 (6 months)
F	Measures used were PIs per 100,000 patient days or PIs per 100,000 patients (Emergency unit only). The number of PIs that occurred and the number of devices used were monitored. Injury reporting was voluntary in the pre-interventional period but was nurse led using active surveillance during the post-interventional period.
G	A 93% reduction in relative risk of PI was observed in areas where the safety devices were used (14 vs. 1 PI). This compared to 11 prior to intervention and 13 during intervention period in the control group. A&E = 18.3 injuries (95% CI, 5.9 – 43.2 injuries) to 0 injuries/100,000 patients (P = 0.002) Hospital wards = 44 injuries (95% CI, 20.1 – 83.6 injuries) to 5.2 injuries (95% CI, 0.1 – 28.8 injuries) per 100,000 patient days (P = 0.007). Injury rates remained stable in the non-intervention wards 40.7 prior to intervention and 48.8 post-intervention.

 S I G N	Evidence Table PICO Question One 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?
Reference: 5	Valls V, Lozano MS, Yanez R, Martinez MJ, Pascual F, Lloret J, Ruiz JA. (2007) Use of safety devices and the prevention of percutaneous injuries among healthcare workers. <i>Infect Control Hosp Epidemiol</i> 28 (12): 1352-1360
H	<p>The control areas used (non-interventional areas) and the before and after data confirm that the safety devices did reduce sharps injury rates in the areas studied. The study design was sound and the data valid. The authors emphasise that <i>‘education and training are key to achieving the greatest preventative effect’</i>. <i>‘Provision of safety devices should not be regarded as an infallible solution as most of the devices evaluated had to be activated to provide a protective or preventative effect’</i> (so reliant on user input). Incorrect HCW behaviour is acknowledged as a risk factor for PIs and training can address this. The authors acknowledge some study limitations:</p> <p>It was a before and after study with historical controls so no randomisation</p> <p>It was limited to 6 months before and after so there was no opportunity to assess the duration of the intervention efficacy</p>

 S I G N	Evidence Table PICO Question One 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?
Reference 6	Little MA, Hussein T, Lambert M, Dickson SJ. (2007) Percutaneous venepuncture practice in a large urban teaching hospital. Clin Med 7 (3): 243-249
Evidence Level: 3	
Study Type: Prospective cohort study (uncontrolled).	
Source of Funding: No funding support information is given.	
A	Questionnaire responses from 53 HCW were central to the study (representing a 76% response rate for questionnaires sent out). Of the 53 staff responding to the survey questionnaire: 34 were doctors, 2 HCA and 17 nurses
B	The responders were all HCW who regularly carried out an exposure prone procedure (venepuncture) at a 660-bed central London hospital. All staff were based in either A&E or an acute admissions unit.
C	Central intervention: Use of Vacutainer as opposed to syringe and needle. The study was based on a questionnaire survey - predominantly concerned with the number of sharps injuries (Sis) suffered by HCW staff and how this related to their training completion date, place of work, frequency of performing venepuncture technique and use of gloves (all irrelevant for this PICO 1 question. However, data on the uptake and use of a safer venepuncture device (BD Vacutainer) was also collated, and this was only one component of the study but was relevant.
D	Comparisons were drawn between injury rates and different levels of experience; also in relation to injuries related to occupation type.
E	Not strictly applicable. The questionnaire was sent out in Jan. 2006 and SI data received then allowed the calculation of an 'annualised' SI rate from the number of injuries reported and the length of time the individual had been routinely involved in taking blood.' All follow up data analysis were completed within the one month.
F	The frequency and percentage of staff using the Vacutainer device was recorded and the associated injury rate (annualized) compared with those staff using standard needle and syringe devices. The number of reported sharps injuries per year was calculated from number of sharps reported and length of time that the individual had been routinely involved in taking blood.
G	Main conclusions – Vacutainer use does not make any difference to NSI: The overall mean SI rate was 0.37 episodes per year (95% confidence interval, 0.2 to 0.5). Whether the respondent was a doctor or a non-doctor, or whether or not they used a Vacutainer, had 'no effect' on reported SI rate. There was no correlation between the use of evacuation blood collection (Vacutainer) and the rate of SI sustained by HCW. However, in this study 80% of doctors and 37% of nurses and healthcare assistants performing routine venepuncture admitted to not exclusively using the Vacutainer device, even though it was freely available to all staff. 92% of responders reported using the Vacutainer device at least some of the time.

 S I G N	Evidence Table PICO Question One 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?
Reference 6	Little MA, Hussein T, Lambert M, Dickson SJ. (2007) Percutaneous venepuncture practice in a large urban teaching hospital. Clin Med 7 (3): 243-249
H	<p>The main thrust of the study was to look at the general level of injuries and which occupation type this was linked with; also associated information such as glove use and training/experience. More than 5 years experience resulted in minimal NSI – about one every 5 years.</p> <p>Useful information did come to light, such as the fact that SI rate overall fell with increased experience (>5 yrs since qualification).</p> <p>Negative aspects of the study included:</p> <p>The fact that the study group (cohort) was small.</p> <p>It proved difficult in some cases for the authors to encourage questionnaire recipients to respond and complete the questionnaire, although final response rate was good (76%).</p> <p>The ‘annualised data’ was effectively an extrapolation of reported injury (or a mean value calculation) depending on whether the responder had worked in their role for less than or more than one year, so some inaccuracies would be likely.</p> <p>The authors acknowledged that recall bias (remembering incidents) or the fact that junior staff perform a far greater number of clinical procedures than their senior colleagues, could explain the apparent increased risk of SI in those qualified <5yrs.</p> <p>The authors indicated that they would not expect their study to have the power to demonstrate any association between evacuation blood collection and needlestick injury rate.</p>

 SIGN	Evidence Table PICO Question One: 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?
Reference:7	Lamontagne F, Abiteboul D, Lolom I, Pellissier G, Tarantola A, Descamps JM, Bouvet E. (2007) Role of safety-engineered devices in preventing needlestick injuries in 32 French hospitals. <i>Infection Control and Hospital Epidemiology</i> 28 (1): 18-23
Evidence Level: 2-	
Study Type: Multi-centre prospective survey	
Source of Funding: The research Group (GERES) is supported by the French Ministry of Health. Also co-funded by la Mutuelle Nationale des Hospitaliers; Becton-Dickinson; Bristol-Myers-Sqibb, Glaxo-Wellcome; Johnson & Johnson Medical, Kendall Sherwood David & Geck, MAPA Hutchinson, Merck Sharp & Dohme Chibret, Sanofi Winthrop, SIMS France and Terumo.	
A	The study focused on 1,506 HCWs spread across 102 medical units within 32 French hospitals; this involved 2000 beds and 600,000 patient hospital days
B	All participants were HCWs based in either medical or intensive care units.
C	The study used a self-reporting system and anonymised questionnaire to record the impact on needlestick injury of introducing three main types of safety engineered device (SED) within the participant hospitals.
D	A direct comparison was made between near-identical surveys conducted in 1990 (no safety-engineered devices available) and 2000 (safety engineered devices available).
E	This was a prospective study, where HCW data were prospectively collected during a 12-month prospective follow up period from April 1999 to March 2000.
F	The key measured outcomes were the number of needlestick injuries recorded vs. device used (SEDs or conventional non-SED devices), using the annual number of devices purchased as the denominator. The unit of measurement was the number of NSIs per 100,000 SEDs or number of NSIs per 100,000 non-SEDs purchased. The context in which any injury was sustained was also recorded.



Evidence Table PICO Question One: 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?

Reference:7

Lamontagne F, Abiteboul D, Lolom I, Pellissier G, Tarantola A, Descamps JM, Bouvet E. (2007) Role of safety-engineered devices in preventing needlestick injuries in 32 French hospitals. *Infection Control and Hospital Epidemiology* 28 (1): 18-23

G

2000 study of NSIs

130 NSIs in 1506 nurses during one year study in 2000

Rate of NSI: SED 2.9 NSI / 100K purchased; Non SED 11 NSI / 100k purchased

NSI during phlebotomy per 100k purchased	Non SED	SED	RR
IV catheter ¹	15.8	3.6	0.23 (0.03-1.70)
Winged steel needle ²	13.2	4.8	0.36 (0.15-0.98)
Vacuum tube ³	4.9	1.4	0.30 (0.07-1.19)
Overall ⁴	11.2	2.9	0.32 (0.16-0.65)

P values

- 1 p= 0.15
- 2 p= 0,02
- 3 p= 0.09
- 4 p= 0,001

Comparing the above data with earlier 1990 data it was concluded that there was a strong correlation between use of SEDs and reduction in NSIs $r=0.88$ $p=0.02$. Attributable fraction 77% of variation explained by variation rate in SED use.

H

The study concludes that SEDs appear to be a major factor in the prevention of NSI. The strongest decrease in NSIs - from both the current 2000 survey and an earlier 1990 survey - was observed for finger-stick based collection of capillary blood and for blood collection for culture

From the most recent (2000) survey the two most risk-prone procedures remained implantable port manipulation and arterial blood sampling (as documented in 1990; though overall numbers of injuries were lower. SEDs were seldom used for such procedures.

The authors acknowledge that findings from attributable fraction calculations could be challenged, but that the benefits of SEDs plays an important role in reducing NSIs.

The authors acknowledge other possible limitations to study design; namely the categorization of devices as SED or non-SED, since the notion of safety is relative.

The underreporting of NSI is also acknowledged as a potential problem but was addressed by using a proactive monitoring approach, and by indirectly calculating the annual numbers of procedures performed to avoid bias caused weeks when atypically low numbers of nurses were participating in a particular observation week.

The comparison between the two (1990 and 2000) studies might be 'an issue' because the two studies were similar but not strictly identical.

The authors acknowledge that the analyses lacked statistical power given the low number of NSIs reported, thus the SED impact could not be assessed for every device.

 SIGN	Evidence Table PICO Question One 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?
Reference:8	Azar-Cavanagh M, Burdt P, Green-McKenzie J. (2007) Effect of the introduction of an engineered sharps injury prevention device on the percutaneous injury rate in Healthcare workers. Infection Control and Hospital Epidemiology 28 (2): 165-170.
Evidence Level: 2-	
Study Type: Controlled, retrospective, interventional, before-after study	
Source of Funding: Funded “in part” by grants from National Institute for Occupational Safety and health Education, Research Centre for Occupational Safety and Health at the Johns Hopkins University Bloomberg School of Public health, and the Occupational Health and Safety Service Training Grant.	
A	3,720 HCW employees during the pre-interventional period; 4,284 HCW employees within the post-interventional period
B	Participants were all HCW at risk of blood borne pathogen exposure – all based within the affiliated clinics and hospitals of an urban medical centre (USA). This included house staff, physicians, medical students and nurses based in these locations during a 3-year period.
C	Introduction of an engineered sharps injury prevention device (ESIPD) – an intravenous catheter stylet
D	The numbers of percutaneous injuries (PIs) both pre- and post-intervention were measured for the IV catheter safety device. Suture needles – which did not undergo similar replacement by intervention – were used as a point of comparison (a control of sorts)
E	The HCW group was studied for 18 months pre-intervention and 18 months post-intervention
F	Percutaneous injury (PI) rates arising from use of intravenous catheters are recorded for 3x6 month (i.e. 18 months in total) periods before and then after “overnight” introduction of the ESIPD (i.e. a total of 3 years). Results are expressed both in terms of total number of PIs and the rate of PIs per 1000 HCWs. In addition, analogous data from use of suture needles, the design of which did not change over the period of study, are also provided.
G	IV-catheter related PIs – pre ESIPD 27, post ESIPD 13. Corresponding rates were 7.3 and 3.0 PIs per 1000 HCWs (p<0.01) Suture needle related PIs – pre-ESIPD 20, post ESIPD 46. Corresponding rates were 5.3 and 10.7 PIs per 1000 HCWs (P<0.008). I.e. injuries from suture needles rose over the same period, where no intervention with a safer sharps device took place.
H	A useful study that demonstrated, for a specific type of safer sharps device (the IV catheter stylet) significant reductions in sharps injuries over a large HCW population based on a before and after assessment of the intervention. The study has a simple design and the data is easy to interpret. Also on the plus side (i) only injuries relating to the specific device were assessed, and (ii) a control device, which did not alter during the course of the study, was included as a control. The data look convincing, i.e. that this specific safety device reduces percutaneous injuries in comparison to the conventional device. However, the authors acknowledge that some gaps in knowledge were not addressed. E.g. the context of the sharps injuries were not considered and failures of any of the safety devices were not logged; the study did not allow for comparison of injury rates with a comparable IV catheter safety device from another supplier.

 SIGN	Evidence Table PICO Question One 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?
Reference:9	Elder A, Paterson C. (2006) Sharps injuries in UK health care: a review of injury rates, viral transmission and potential efficacy of safety devices. Occupational Medicine-Oxford 56 (8): 566-574
Evidence Level: 4	
Study Type: Structured but non-systematic literature review	
Source of Funding: By the Occupational Health & Safety Strategy Implementation Group of the Scottish Executive	
A	This paper is not a HCW or patient study. It is a literature review that identifies 24 publications where UK sharps injuries are reported and 31 papers related to injury prevention (mainly US-sourced but includes other international papers).
B	Not applicable. However, the focus of the review is on UK sharps injury rates.
C	No specific intervention described. This is a non-systematic review article.
D	Not applicable.
E	Not applicable.
F	Published sharps injury rates per 100 person years are presented for many of the papers discussed (other injury rates are also presented). Under-reporting rates are also described in 3 cases.
G	This depends on which study is being considered within the review. However, the review concludes that various safer sharps studied cite partial injury reduction potential, e.g. potential for up to 29% injury reduction (US); 21% to 61% (Scotland); Up to a 78% reduction in injury following the introduction of safer needle devices are reported (Scotland); 70% to 80% for safer IV lines and 70% to 80% for blunt-ended suture needles.
H	Although this is not a systematic literature review it does provide compelling evidence – in the form of 31 cited papers from various sources – that safer sharps devices can reduce the incidence of sharps injury. However, two of the mentioned studies are previously unpublished and not all the data from the cited papers seems to have undergone full statistical analysis. At least 12 of the studies present both % injury reductions alongside either P values and/or confidence intervals. As a review, this paper does not present the original data that would allow conclusions to be drawn. It comes to the conclusion that “safety-engineered sharps devices, dependent on type, are likely to be successful in preventing injury”. The best quality evidence is for blunt suture needles.

 SIGN	Evidence Table PICO Question One: 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?
Reference:10	Cullen BL, Genasi F, Symington I, Bagg J, McCreaddie M, Taylor A, Henry M, Hutchinson SJ, Goldberg DJ. (2006) Potential for reported needlestick injury prevention among healthcare workers through safety device usage and improvement of guideline adherence: expert panel assessment. J Hosp Infect 63 (4): 445-451
Evidence Level: 4	
Study Type: A Prospective survey of HCW in Scotland (prospective cohort?). NB. This is a “virtual” study.	
Source of Funding: The study was supported by the Chief Scientists Office, Scottish Executive Health Dept. (Grant no. CZH/4/26).	
A	1497 injuries reported, of which data were available for analysis from 952.
B	All those included in the study were HCW in Scotland who had actually sustained a needlestick injury.
C	None. An expert panel assessed whether “in their opinion” the injury was preventable or not, and if so, by what means (safety devices, following protocol, revising protocol)
D	Not applicable. The study attempted to assess which sharps injuries were avoidable, but did not make any formal comparison (e.g. as a before and after study would).
E	Not applicable; there was no ‘follow up’ – HCW suffering needlestick injury between June and December 2002 were all administered with a proforma to complete and return to Health Protection Scotland (HPS).
F	Based on criteria that included details of the needlestick injury, occupational group, circumstances surrounding the incident and contributing factors, a panel of experts at Health Protection Scotland then sat and decided which of the injuries would probably/definitely been preventable.
G	56% of all injuries and 80% of venepuncture/injection administration injuries would probably/definitely have been prevented through use of a safety device. 52% of all injuries and 56% of venepuncture/injection admin’ injuries would probably/definitely have been prevented through guideline adherence 72% of all injuries and 88% of venepuncture/injection admin’ injuries would probably/definitely have been prevented through either intervention injuries sustained through venepuncture/injection admin’ were significantly more likely to be prevented through safety device usage (adjusted odds ratio (OR) 5.09, 95% confidence interval (CI) 3.11-8.31 and adjusted OR 2.70, 95% CI 1.64-4.45, respectively).
H	The paper is entirely opinion-based. There are no actual data on which to base any conclusion about the potential of the 3 interventions (use of safety devices, adherence to guidelines, revision of guidelines) to reduce the number of needlestick injuries. This does make the useful point (although in a theoretical way without any data) that even though safety devices may improve injury rates, so might simple adherence to existing guidelines! Also, the corollary is likely to be true i.e. that some injuries (28% in this paper) may not be preventable by either approach. The paper does contain some information about the frequency and type of injuries sustained by HCWs in Scotland.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 11	Wolf BL, Marks A, Fahrenholz JM. (2006) Accidental needle sticks, the Occupational Safety and Health Administration, and the fallacy of public policy. <i>Ann Allergy Asthma Immunol</i> 97 (1): 52-54
Evidence Level: 3	
Study Type: The paper reports findings from a simple questionnaire study. This constitutes (i) Retrospective cohort for some respondents and, (ii) Before and after study for those practices that had switched to the safety devices.	
Source of Funding: No funding details are provided.	
A	The study considered questionnaire responses from 70 US outpatient clinics (i.e. 28% of the 252 originally contacted via email).
B	Allergists were the main targets of the questionnaire.
C	The authors wished to ascertain whether responding clinics had introduced safety needles in to their practices. The number of monthly injections given and number of related accidental needlestick injuries were also sought.
D	The use of “new” safety needles versus the use of old style needles.
E	Not applicable. The authors do not state a start or end date, or the years covered by their study. They appear to have simply asked for the number of injections per year, with or without the intervention of safer needles.
F	The accidental needlestick injury rates for clinics using older needles & for clinics that have introduces newer, safer needle devices are presented. Intra-dermal and allergy needle rates are considered. The rate of accidental needlestick injury are measured, expressed per total number of needle-based injections per year
G	Practices using safety needles reported a rate of NSI (32 needlesticks, 806,784 injections, rate 0.00396) more than twice that in practices using old needles for allergy shots (27.5 needlesticks, 1.54 million injections, rate 0.00178, p<0.01). Rates of NSI with old (23 needlesticks, 1.08 million injections, rate 0.00212) and new (11 needlesticks, 293,508 injections, rate 0.00374) needles for intra-dermal injection were not significantly different. In practices that switched from old to new, rate of NSI for allergy shots increased from 0.00211 (19.75 needlesticks, 935,988 injections) to 0.00396 (32 needlesticks, 806,784 injections, p<0.05). Rates for intra-dermal injections did not change (old – 17 needlesticks, 535,776 injections, rate 0.00317; New – 11 needlesticks, 293,508 injections, rate 0.00374, p>0.05).
H	The findings question the wisdom of a blanket approach to introducing safer sharps devices and question their use in outpatient allergy clinics (practices). The study concludes that twice as many accidental needlestick injuries occurred in practices giving immunotherapy when using new (safer?) needle devices vs. old needles (P<0.01). The rate of accidental needlestick injury was roughly the same for intra-dermal procedures when using old or new needle devices. The authors question whether US (OSHA) guidelines for safe needle use in outpatient departments need revision, as their use is not supported by these findings. They suggest that an ‘opt-out’ for allergy clinics may be appropriate, but recommend that a multi-centre prospective trial would be needed to examine the large-scale impact of safer needles in these practices. Although these data are collected by retrospective questionnaire, the conclusions are convincing.

 SIGN	Evidence Table PICO Question One 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?
Reference:12	Tuma S, Sepkowitz KA. (2006) Efficacy of safety-engineered device implementation in the prevention of percutaneous injuries: A review of published studies. <i>Clinical Infectious Diseases</i> 42 (8): 1159-1170
Evidence Level: 3	
Study Type: A form of semi-systematic literature review – with stated paper selection / exclusion criteria ('other design').	
Source of Funding: Funded by the National Institute of Allergy and Infectious Diseases, CDC, National Surveillance System for Hospital Healthcare Workers, NaSH to Reduce percutaneous Injuries and the CDC Prevention Epicenters Program.	
A	17 studies that met the authors' inclusion criteria were included in this review (refs 3 – 19). These covered needleless iv systems, safety syringes, re-sheathable winged steel needles, vacuum-tube blood collection devices, retractable lancets and guarded av fistula needles.
B	Varied according to setting, device studied, study design. However, all papers considered by this review related to safer sharps use in the clinical setting.
C	The review focuses on papers that report the interventional use of needless systems or systems with some other form of sharps injury protection.
D	Some level of comparison is drawn between different frequencies of injury reported by various studies.
E	Not applicable.
F	The authors assessed the outcome measures of other studies, and this primarily focused on reductions of percutaneous injury (PI). Some form of assessment of frequency of injury was made in each case. Denominators and units varied between studies. However, the paper did not in itself have outcome measures. Its primary purpose was to determine whether the available evidence base could confirm improved efficacy in minimizing PIs
G	This is a review, not a single study. "All studies reported decreases in device-associated or overall PI rates after implementation of safety-engineered devices. As a breakdown: All 17 studies assessed by the author reported a reduction in percutaneous injury (PI) ranging from 22% to 100% reduction. These data included: <ul style="list-style-type: none"> ➤ Reductions in PIs from hollow bore needles – 70.6% (P<0.01). ➤ Reductions in PIs associated with suture needles and other sharp objects (30.8% and 13.8% respectively; P = Not significant for both). ➤ Reduction in PIs for needless IV systems at two hospitals; adjusted final values 54.5% and 57.2% (P< .005): Syringe related PI reduction up to 100%.
H	This systematic review provides secondary reported data (i.e. not itself a primary study), which contribute to the evidence base on safer sharps leading to measurable PI reduction: 'In all studies reviewed, the introduction of safety-engineered devices was followed by considerable reductions in PI rates (range, 22% to 100%)'. However, the authors acknowledge that most of the reviewed reports (n = 12) were uncontrolled before and after trials with inherent limitations to control for confounding factors. The authors also make an important observation in terms of the types of papers that are often recovered within searches/reviews of this kind: they note that 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.

 SIGN	Evidence Table PICO Question One: 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?
Reference:13	Lee JM, Botteman MF, Nicklasson L, Cobden D, Pashos CL. (2005) Needlestick injury in acute care nurses caring for patients with diabetes mellitus: a retrospective study. <i>Curr Med Res Opin</i> 21 (5): 741-747.
Evidence Level: 4	
Study Type: Survey.	
Source of Funding: Sponsored by Novo Nordisk Inc.	
A	400 Registered Nurses.
B	Nurses caring for patients with diabetes mellitus in a hospital setting.
C	Incidence of needlestick injury (NI). The type of injury device used.
D	None.
E	No follow up, web based survey, one off data collection opportunity.
F	Of those that experienced NI in last 12 months: Characteristics of NI, device involved purpose of needle use, when did injury occur and did the NI draw blood.
G	400 respondents. 313 (78.3%) reported at least 1 NI. 110 (27.5%) reporting injury in last 12 months. 66 (60%) had 1 NI, 28 (25.5%) had 2 NI; 8 (7.3%) 3 NI; 7 (6.4%) 4 NI; 1 (0.9%) had 5 NI. NI in last 12 months (n = 110). 73 (66.4%) punctures that drew blood. 21 (19.1%) no blood, the rest were scratches or did not break the skin. 106 (96.4%) occurred in registered nurses (the rest advanced nursing practitioners). 68 (61.8%) female and 74 (67.3%) <45 years old. 33 (30%) occurred giving insulin, 26 (23.6%) occurred non-insulin intramuscular injection, 15 (13.6%) non insulin IV injection. 81 (73.6%) went unreported despite knowing the reporting procedure. 1 case (0.9%) of Hepatitis C.88 (80%) involved disposable syringes, 55 the device had a safety feature but in 40/55 (72.7%) it was not activated and in 7/55 (12.7%) only partially activated. In cases where safety feature was fully nor partially activated, 2 (13.3%) reports of safety malfunction, 3 (20%) reported not knowing if the safety feature malfunctioned. 81 (73.6%) injury occurred prior to injection.

 SIGN	Evidence Table PICO Question One: 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?
Reference:13	Lee JM, Botteman MF, Nicklasson L, Cobden D, Pashos CL. (2005) Needlestick injury in acute care nurses caring for patients with diabetes mellitus: a retrospective study. <i>Curr Med Res Opin</i> 21 (5): 741-747.
H	<p>In part the study answers the key question.</p> <p>A one off survey of nurses caring for patients with the condition diabetes was surveyed. In particular those that had suffered a NI in the last 12 months. The study team were particularly interested in the nurses experience of the NI (characteristics, device used, when NI occurred, did the NI draw blood).</p> <p>The study mentions safety-engineered devices as an element, but it was not the whole focus of the study and therefore does not specifically address whether there is a reduction in the incidence of NI because of their use.</p> <p>It is clear though that even when a safety-engineered device is used the safety feature is not always activated or may malfunction.</p>

 SIGN	Evidence Table PICO Question One: 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?
Reference:14	Waclawski ER. (2004) Evaluation of potential reduction in blood and body fluid exposures by use of alternative instruments. <i>Occup Med (Lond)</i> 54 (8): 567-569.
Evidence Level: 4	
Study Type: Retrospective Review.	
Source of Funding: No evidence of external funding.	
A	161 HCWs.
B	HCWs in a hospital setting, all had reported a needle stick, sharps injury or blood body fluids splash to OHS.
C	A theoretical use of a safety-engineering device.
D	N/A.
E	2-year period.
F	Potential avoidance of injury.
G	<p>Average injury rate was 7.8 per 1000 employees per annum (95%CI, 6.8 - 9.4 per 1000). Highest rate pre reg house officers 164 per 1000 (95% CI 64-264 per 1000), phlebotomists 154 per 1000 (95% CI 15-291 per 1000), senior house officers 45 per 1000 (95% CI 13-77 per 1000). Theatre sterile staff 33/1000 and Radiographers 30/1000, no CI, as not significant due to small groups of workers and small number of incidents Most common injury was needlestick 63%. Other sharps 27% of injuries.</p> <p>Instrument associated with injury was hollow bore injection needle in 76 cases (50%). Butterfly, subcutaneous needle 18 cases (12%). Stylet blood glucose 10 cases (7%). Venflon 7 cases (4%). Scalpel blade 11 cases (7%). Other instruments included suture needles, dental equipment, guide wires and staple gun blade. Blood was the most common material associated with injury (77%). Other high-risk body fluids were present in 8 incidents (5%). Other factors included: patient movement 11 (8%), staff error 22 (14%), overfilled sharps box 9. In 101 cases no external problem was noted on the audit form. Assumed the injury was associated with injured persons error.</p>
H	<p>Assuming a safety instrument was identified and used correctly in 101 cases reported without external problem then 80 could have been avoided (65%). Use of such instruments would additionally have prevented 17 other staff and 8 overfilled sharps injuries.</p> <p>An estimate of 105 incidents (65%; 95% CI=58-72%) would have been preventable with a change to a alternative device.</p> <p>Concludes that more effort should be made to introduce safer instrumentation. Strategic change for Occupational Health is necessary.</p> <p>No costs included of either new devices or training required.</p> <p>Clearly safety devices will reduce injuries but as seen from this study they will not prevent all injuries.</p> <p>Limitations: This is an evaluation of the potential to reduce NSIs based on use of retrospective data. There are large confidence intervals rates reported by for junior house officers and phlebotomists.</p>

 SIGN	Evidence Table PICO Question One 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?
Reference: 15	Sohn S, Eagan J, Sepkowitz KA. (2004) Safety-engineered device implementation: does it introduce bias in percutaneous injury reporting? Infect Control Hosp Epidemiol 25 (7): 543-547
Evidence Level: 2-	
Study Type: Before & After Intervention	
Source of Funding: Funding from MIH, CDC (2 grants) and Prevention Epicentre Programme.	
General Comments: Same study as paper P.1.33.	
A	1,132 pre intervention and 821 post intervention surveys.
B	HCWs (including building staff) in a 427-bed cancer hospital.
C	Safer needle systems including 7 manufacturers to assist in IV delivery, blood collection, IV insertion, IM and subcutaneous insertion.
D	3 years pre and 2 years post intervention.
E	As D.
F	<i>Self reported injuries via anonymous survey compared with official reports.</i>
G	Pre intervention 1132 of 1423 anonymous surveys returned (79.6% rate), annual rate of percutaneous injury (PI), self reported 36.5 per 100, compared with 8.3 per 100 formally reported. Post intervention 821 of 1094 anonymous surveys returned (75%), self reported rate of PI 13.9 per 100 (61.9% reduction p<.01), compared with formal reports 3.1 per 100 (62.7% reduction, p 010). Differences in reports seen across all occupational groups except 'other staff'. Reductions in all groups except non-surgical medical staff. Occupational differences in report rates still evident post intervention, but, less discordant than before. Reason for not reporting: injury considered low risk; source patient low risk; no time to report (same as pre intervention though 1 st and 2 nd reason have reversed).
H	To some extent resolves the issue of how to depend on official reports. This may be an under report of the true picture but the differences pre and post were significant.

 SIGN	Evidence Table PICO Question One 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?
Reference: 16	Sohn S, Eagan J, Sepkowitz KA, Zuccotti G. (2004) Effect of implementing safety-engineered devices on percutaneous injury epidemiology. Infection Control and Hospital Epidemiology 25 (7): 536-542
Evidence Level: 2-	
Study Type: Before & After Intervention.	
Source of Funding: Funding from MIH, CDC (2 grants) and Prevention Epicentre Programme.	
General Comments: Same study as reference 15.	
A	529 blood exposure events for the entire period of the study. 449 of which were percutaneous injury (PI). 390 pre and 59-post intervention.
B	HCWs (clinical and ancillary staff) in a 427-bed cancer hospital.
C	Survey.
D	Safer needle systems including 7 manufacturers to assist in IV delivery, blood collection, IV insertion, IM and subcutaneous insertion.
E	3 years pre and 1 year post intervention.
F	Incidence of percutaneous injury by occupational group, activity, procedure, timing and device.



Evidence Table PICO Question One 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?

Reference: 16

Sohn S, Eagan J, Sepkowitz KA, Zuccotti G. (2004) Effect of implementing safety-engineered devices on percutaneous injury epidemiology. Infection Control and Hospital Epidemiology 25 (7): 536-542

G Incidence -
 529 blood exposure events during study period.
 Of these 449 (84.9%) percutaneous.
 390 of these were pre-intervention (average 10.83 per month; 34.0 per 1000 FTE) 59 post intervention (average 4.92 per month 14.25 per 1000 FTE) SD +/-8.61
 p <.001.
Occupational Group -
 Nurses greatest proportion reporting injury 54.1%, ancillary 14.4%. Post intervention rates < by 74.5% p <.0001 and 61.5% p=.03 respectively.
Activity -
 Manipulating patient or sharp 83.5% reduction p<.001, collisions or contact with sharp 73% reduction p=0.1.
 Disposal related injury 21.41% reduction p=.001.
 Greatest reduction catheter insertion (88.2% reduction p<.0001).
 All others non significant.
Timing -
 100% reduction before use p=.02.
 66.9% after use but before disposal p <.001.
 60.45 during or after disposal p<.001.
 50.9% no one holding the sharp p =.01.
Device -
 70.06% decrease in percutaneous injuries involving hollow bore needles p<.001.
 Pre intervention all 390 conventional devices.
 Post 16 (27.1% associated with safety engineering devices).
 Info only available on 7 all required activation by HCW.

H Demonstrates a clear and statistical significant reduction in percutaneous injuries after the intervention. This is a well conducted study but the results may be:

- Dependant on injuries being reported ie., there may have been significant under reporting (see other paper 1.32).
- There was limited information 'post-intervention' on devices causing injury.
- It was not stated which devices were used and so it is difficult to make recommendations.
- There was no cost analysis.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 17	Mendelson MH, Lin-Chen BY, Solomon R, Bailey E, Kogan G, Goldbold J. (2003) Evaluation of a safety resheathable winged steel needle for prevention of percutaneous injuries associated with intravascular-access procedures among healthcare workers. <i>Infect Control Hosp Epidemiol</i> 24 (2): 105-112.
Evidence Level: 2+	
Study Type: Before and after study.	
Source of Funding: Part funded by CDC through two grants and by Becton Dickinson Inc. (the safety device manufacturer)	
A	All healthcare workers performing intravascular-access procedures with winged steel needles in a 1,190-bed hospital. The number of healthcare workers is not specified. Period 1: 86 conventional winged steel needle injuries, with 641,282 devices used. Period 2: 28 safety winged steel needle injuries, with 436,180 devices used. Post study: 103 safety winged steel needle injuries, with 1,411,960 devices used.536 product evaluations completed
B	Set in 1,190-bed hospital. All healthcare workers performing intravascular-access procedures with winged steel needles. Study evaluated; nurses, patient care associates (nursing assistants), house staff, physician assistants, and phlebotomists during the training period as well as for new staff during orientation.
C	Introduction of a new safety resheathable butterfly needle (Safety-Lok, Becton Dickinson Inc.) accompanied by a standardised training programme and an instructional mailing (content unspecified).
D	Comparison between the percutaneous injury rate associated with a standard versus a safety resheathable winged steel (butterfly) needle.
E	Total study period 64 months; Period 1:19 month baseline period prior to introduction of safety device (1/9/95-31/3/97). Training period – 3 months (1/4/97-30/6/97). Period 11: 11 month study period (1/7/97-31/5/98). Post-study period: 31-month follow-up period (1/6/98-31/12/2000).
F	Injury rate by device type and procedure.
G	13.41 injuries per 100,000 conventional devices in period I declining to 6.41 injuries per 100,000 safety devices (RR 0.48, 95%CI 0.31-0.73) in period II. In the post-study period this rose to 7.29 injuries per 100,00 devices. The difference between the study and follow up period injury rates was not significant.
H	Main conclusion; “Implementation of a safety re-sheathable winged steel needle substantially reduced injuries among healthcare workers performing vascular-access procedures” (this contributes directly to Pico 1). Study is extensive and also adds value to questions regarding usability and touches on aspects of the need for compliance and training; “The residual risk of injury associated with this device can be reduced further with increased compliance with proper activation procedures”. Limitations: Only one type of device (re-sheathable winged steel needle) used in study. Results maybe only specific to the study population, environment and point in time. Completeness of implementation, perceived risk of injuries and transmission of blood-borne pathogens, and training and motivation of healthcare workers to use the device may not reflect the situation in other hospitals/regions.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 18	McCleary J, Caldero K, Adams T. (2002) Guarded fistula needle reduces needlestick injuries in hemodialysis. Nephrol News Issues 16 (6): 66-70.
Evidence Level: 2-	
Study Type: Retrospective single cohort study.	
Source of Funding: Not stated.	
A	Retrospective = 107 staff and 273-331 patients. Prospective = 128 staff and 331-370 patients.
B	Dialysis HCWs and patients in 5 HD clinics in the Pacific Northwest, USA either using or being treated with unguarded (retrospective) or guarded (prospective) fistula needles.
C	Introduction of guarded fistula needles to the clinics (Specifically, the Medisystems Guarded AVFN), and associated training.
D	Needlestick injury rates before and after introduction of safer device.
E	Retrospective NSI data gathered from 1st January 1999 for 15 months. Prospective data gathered from 1st April 2000 for 9 months.
F	Number of AVFN devices used, number of needlesticks and rate of needlesticks by conventional and guarded devices.
G	Needlestick injury rate for conventional device was 8.58 per 100,000 devices used (81,534 devices and 7 needlesticks) and 0 in the safety needle (54,044 devices and 0 injuries)
H	<p>Use of a guarded AV fistula needle reduced sharps injuries when compared with a conventional device in a small before and after evaluation of a single cohort of workers in four dialysis units in Washington state, USA.</p> <p>To what extent the educational intervention accompanying the introduction of the safety device influenced study results is unclear. Although the use of retrospectively gathered data for the 'before' element of the study and prospectively collected data for the 'after' element of the study is open to criticism, and given the significant under-reporting of sharps injuries shown in many studies, this may have attenuated any benefit seen if additional education increased healthcare worker awareness and so reporting rates of such injuries.</p> <p>The study offers relevant information specific to one particular device (Medisystems AVFN) used in one particular setting (Haemodialysis clinics), and that the use of that device significantly reduces NSI in that setting, compared to unguarded devices.</p>

 SIGN	Evidence Table PICO Question One: 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?
Reference: 19	Zakrzewska JM, Greenwood I, Jackson J. (2001) Introducing safety syringes into a UK dental school--a controlled study. Br Dent J 190 (2): 88-92.
Evidence Level: 2-	
Study Type: Case Controlled study.	
Source of Funding: Septodont (manufacturers of devices) assisted in the training initiatives and supply of equipment.	
A	300 staff within one UK Dental school. The control group was a similar sized surgical unit who did not implement the safer devices.
B	Undergraduate, postgraduate students, qualified dentists, dental nurses, hygienists and therapists. For analysis, “qualified” and “trainee” staff were identified as discrete populations.
C	Introduction of safety (disposable) syringes and training in their use.
D	NSI Rates pre and post introduction of safety devices and training.
E	3 years pre intervention and 2 years post interventions (intervention being the introduction and training in the use of the disposable safety syringes). Question over the cohort being the same over the 5-year period.
F	Reduction in the number of avoidable needle stick injuries in staff through the introduction of safety syringes (results quoted in absolute events per 100,000 hours worked by staff across the groups).
G	In the dental school, the frequency of avoidable needle stick injuries fell from a pre-change average of 11.8 to 0 per 1,000,000 hours worked per year in the second year of use of the safety syringes.
H	<p>A small single ‘before and after’ case study which demonstrated a reduction in sharps related injuries: However, whilst a controlled study, it does have limitations and the control group also showed a reduction in injuries, presumed to be a result of an awareness campaign. This suggests that safer devices alone may lead to a reduction but other factors (education, training and awareness/risk perception) are also key attributes for any change to be a success.</p> <p>Note: Due to the small numbers of injuries, the changeover to safer syringes has not resulted in a statistically significant change but there is a definite trend. In the dental school there is an estimated 1640 needle contacts a week whereas in the surgical unit it is 270 per week.</p>

 SIGN	Evidence Table PICO Question One: 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?
Reference: 20	Cuny E, Fredekind RE, Budenz AW. (2000) Dental safety needles' effectiveness: results of a one-year evaluation. J Am Dent Assoc 131 (10): 1443-1448.
Evidence Level: 3	
Study Type: Before and after study.	
Source of Funding: Not stated.	
A	273 dental students from the University of the Pacific School of Dentistry. Note: for blood exposure incident reporting, the population from which these data are derived includes 273 clinical students, 50 clinical faculty members and 24 clinical staff members.
B	Dental practitioners and dental students.
C	Needlestick injuries before and after introduction of safety devices. Originally, 4 devices were selected for the evaluation, but 2 were removed from the study on the grounds of poor clinical usability. Results are based on evaluation of the remaining 2 devices.
D	NS I rates before and after introduction of safety devices, and the user acceptability of certain devices are compared.
E	Respondents completed were required to complete an evaluation (statement based) questionnaire at one, two, four, five, six, eight and 52 weeks after initiation of use to gauge the change in usability, if any, over time. For blood exposure incident reporting, 4 years pre intervention and one year post intervention results from reporting systems were analysed (in 6 month blocks). Note: It is unclear whether the same cohort was used in these previous 4 years.
F	User satisfaction of the devices and incident rates of blood exposures to staff from incident report logs.
G	Response rates to the surveys ranged from 14 to 39 percent. However, the Author states "the small sample size created a barrier to applying a statistical model to evaluate the safety of needles and syringes".
H	Results overall showed no significant change in injury rates following intervention, (but its unclear whether the cohort is the same for the previous 4 years as the 6 months post intervention). Coupled with poor user acceptance, the authors suggest that the move to safer devices may not be warranted. The author fails to recognize that the reporting levels may remain static due to increased awareness following training and publicity around use of safe mate device, however, the article suggests a need for a robust evaluation criteria to be devised for the future.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 21	Rogers B, Goodno L. (2000) Evaluation of interventions to prevent needlestick injuries in health care occupations. Am J Prev Med 18 (4 Suppl): 90-98.
Evidence Level: 1-	
Study Type: Systematic Review article.	
Source of Funding: Not stated.	
A	11 separate studies (in the published literature searched) were included.
B	Of the 11 studies evaluated, 3 evaluated the effectiveness of specialized needles in reducing needlestick injuries during wound closure. A further 3 evaluated other protective devices. All are Randomised Controlled Trials and included various healthcare workers (Nursing personnel, Surgeons, scrub nurses, assistants, doctors, medical students).
C	Reduction of needlestick injuries through the introduction of safety devices and or procedures (double gloves, no touch techniques, surgical assist devices and safety devices - protected point/blunt needles/needleless IV systems).
D	Review of 11 studies.
E	Not detailed.
F	Number of glove perforations and number of skin perforations and percutaneous injuries.
G	Some studies referred to absolute numbers of injuries reported for the intervention group vs the control group. In each case demonstrating that there were lower reported rates in the intervention (safer device) groups. Of the 11 studies, 8 quoted odds ratio and variable confidence intervals.
H	The review focuses only on RCT studies reported in peer reviewed published literature according to the author's criteria for selection. Whilst not all papers reviewed referred to safer devices (some looking at effectiveness of double gloving for example), each of the studies where device interventions existed demonstrated a decrease in needlestick events. The author's systematic review of studies show that engineering control interventions give significant reproducible reductions in NSI's. However, this is a systematic review with no meta-analysis carried out. Most studies were in the hospital theatre environment, where it was easier to carry out observational studies. The authors report of bias when there is reliance on self-reporting of injuries.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 22	Seemann S, Soukup SM, Adams P. (2000) Hospital-wide intravenous initiative. Nurs Clin North Am. 35(2): 361-373.
Evidence Level: 4	
Study Type: Descriptive.	
Source of Funding: Funding source is not stated, but an organization called Abbott Laboratories is mentioned in association with “project liaison”.	
A	Not applicable - patient numbers are not mentioned.
B	The study is focussed on IV device safety, rather than the patients receiving them. At study onset, there was no “needle protection” in their iv infusion system, with minimal safety measures to reduce needlesticks. No other information is provided.
C	Assessment, design, implementation and evaluation standardisation of iv infusion delivery system within a 6 month period Review of published literature to identify best practice, including that related to needlestick injuries. This resulted in introduction of pre-pierced reseal blunt cannula system for the iv tubing lines and the needless Clave system for the insertion sites. Educational and training programme implemented involving 800 clinicians in 2 weeks
D	The study compares injury rates and their financial costs for approx. one year before and one year after intervention and also comments on staff satisfaction with the devices used across this period.
E	The study was not patient-based but does cite needlestick injury data for one year prior to intervention and one year afterwards. Staff ‘satisfaction’ over this period, which includes general acceptability of the new system, is claimed
F	Staff and patient ‘satisfaction’ are described, though no real data are presented. A reduction in IV related injury is described over the course of device introduction and for a year after.
G	The study claims that the cost of needlestick injuries prior to intervention = \$7600 in 14 months prior to intervention; In 18 months post implementation costs = \$2000. The study claims that needlestick in jury numbers fall from 13 in the year prior to intervention, to 3 in the year after intervention. It also claims that 2 of the 3 incidents were preventable if equipment instructions had been followed.
H	No firm data on user acceptability of safer sharps are mentioned, only general comments on positive acceptance of the new device. Data are mentioned in relation to a reduction in sharps injury that is perceived as related to intervention, but this is more observational than substantiated. In no way could this be used as a source of firm evidence either in favour of, or against the introduction of “safe needle devices”.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 23	Reddy SG, Emery RJ (2001) Assessing the effect of long-term availability of engineering controls on needlestick injuries among health care workers: a 3-year pre-implementation and post-implementation comparison. Am J Infect Control. 29 (6): 425-427.
Evidence Level: 2-	
Study Type: Retrospective Study.	
Source of Funding:	
A	800 bed metropolitan hospital in the USA.
B	Retrospective analysis of a database of 550 entries related to sharps injuries during a six-year period (1994 to 1999). Entries were excluded for physicians and those who did not record occupation. This left a total of 533 injuries. Only included HCWs who had direct patient contactor ancillary workers working in areas where medical procedures had taken place.
C	Safety syringes and needless intravenous systems were introduced in all departments. The transition occurred in 1997 over a six-month period.
D	No comparison.
E	Data from three years pre implementation and 3 years post implementation of safety devices was analysed.
F	Annual incidence rates before and after implementation. Incidence rates per 100 full time equivalent (FTE). Statistical significance and trends. Injuries classified according to those resulting from needles, glass, medical devices and unidentifiable sources.
G	Incidence rate per 100 FTE fell from 10.6% in 1994 to 4.2% in 1999. Pre implementation $\chi^2 = 40.5$, $df = 1$, $P < .0001$. Post implementation $\chi^2 = 63.1$, $df = 5$, $P < .0001$.
H	Whilst that was a reduction in the injury rates there were a number of confounders within the study that need to be highlighted: <u>Confounders</u> Retrospective analysis so limitations in quality and consistency of information available. Physicians not included. Availability of traditional needled devices during post intervention phase, allowing workers a choice. Began an in-service education programme about needlestick safety and blood borne pathogens during 1995, so a decline in the number of injuries was apparent during the pre implementation phase. Not apparent which device caused injury (not asked on injury report form) – traditional versus safety. There was therefore an assumption that the implementation of the safety devices was responsible for fewer injuries. Occupation and department specific rates could not be calculated as only FTE data were available.

 SIGN	Evidence Table PICO Question One: 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?
Reference: 24	Rogues AM, Verdun-Esquer C, Buisson-Valles I, Laville MF, Lasheras A, Sarrat A, Beaudelle H, Brochard P, Gachie JP. (2004) Impact of safety devices for preventing percutaneous injuries related to phlebotomy procedures in health care workers. American Journal of Infection Control 32 (8): 441-444
Evidence Level: 2-	
Study Type: Before and after study.	
Source of Funding: No evidence of external funding.	
A	8,500 full time equivalent staff working in one hospital of which, 2,900 nurses who are responsible for phlebotomy.
B	Number of needlestick injuries sustained during phlebotomy, pre and post introduction of two safety devices.
C	2 safety devices: re-sheathable winged steel needles (SafetyLok) and Vacutainer blood-collecting tubes with re-capping sheaths introduced 1996.
D	N/A.
E	3 years pre and post intervention.
F	Sharps Injuries.
G	Total sharps injuries – 4624. Phlebotomy accounted for 19.4% (n=244) pre intervention and 12% (n=127) post (RR 0.62; 95% CI, 0.51-0.72: p<.001). Post intervention 117 involved vacuum-tube blood collecting needles compared with 191 pre (38.7% reduction) and 10 winged steel needles compared with 53 pre (81% reduction). Overall 48% reduction in percutaneous injuries per 100,000 and no sero conversions to HIV, Hep B or C throughout survey period. No statistically significant decrease in other needle related injuries.
H	Yes it demonstrates the effectiveness of safety devices in reducing percutaneous injuries. Data collected over 3 years pre and post. However there are weaknesses: No data on device compliance. Effectiveness measured on reported injury, therefore possible bias over/ under. Number of phlebotomies performed estimated using number of devices purchased. No cost comparisons. Incidence rates remain high despite devices.

 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: 25	Sossai D, Puro V, Chiappatoli L, Dagnino G, Odone B, Polimeri A, Ruzza L, Palombo P, Fuscoe MS, Scognamiglio P. (2010) Using an intravenous catheter system to prevent needlestick injury. Nurs Stand 24 (29): 42-46. ALSO USED TO ADDRESS PICO 1 QUESTION
Evidence Level: 3	
Study Type: Before & After study: Case series (non-analytical) with a longitudinal follow up period of 3 years after the introduction of a Safety IV Catheter system (Introcan) and with comparison to data on needle stick injuries for the two years preceding the intervention when standard catheter needles were used.	
Source of Funding: Training sessions were carried out by manufacturers of the safety catheter and by members of the hospitals.	
A	The paper does not focus on patients but on the number of reported needle stick injuries occurring amongst hospital staff when a safe design of catheter was introduced. The following numbers of catheter needles were used during this period: Conventional catheter (2 year period): 295,000 Safety needle catheter (3 year period): 512,000
B	Patients groups not included but the study involved hospital employees in 90 departments (outpatient clinics, operating theatres, intensive care units, day hospitals and surgery). The number of hospital employees suffering needle stick injuries was monitored and the total numbers of staff reported in employment during the study varied from 4,447 to 4,636 (between 2003 to 2007)
C	Safety catheter: The key intervention was the introduction (in 2005) of a safety catheter (Introcan Safety IV Catheter system manufactured by B. Braun) after an educational intervention to raise awareness (i.e. awareness campaign) of needle stick injuries (started in 2003). The safety catheter had a self-activating safety clip that automatically shields the needle's sharp bevel during retraction after cannula insertion. This safety catheter was described as identical to the conventional catheter used up until the introduction of the safety catheter. Note this paper also contains information relevant to Pico 2 The education intervention continued between 2005 and 2007. This involved practical training and courses (for long-term employed healthcare staff) on the biological risk of needlestick injuries. A monthly compulsory training course on the need for prevention and safety precautions related to needlestick injuries, and the correct practical application of safety devices was also introduced for all new employees. During this period, 596 of 3,392(18%) long-term employed physicians, nurses and technicians and 882 (100%) new employees received safety training.
D	Comparison of use of safety device versus non safety catheters by healthcare staff
E	<ul style="list-style-type: none"> ➤ The entire study lasted 5 years (2003 – 2007) ➤ After the introduction of the safety catheter hospital employees were followed for two years ➤ 4 years for awareness campaign

 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: 25	Sossai D, Puro V, Chiappatoli L, Dagnino G, Odone B, Polimeri A, Ruzza L, Palombo P, Fuscoe MS, Scognamiglio P. (2010) Using an intravenous catheter system to prevent needlestick injury. <i>Nurs Stand</i> 24 (29): 42-46. ALSO USED TO ADDRESS PICO 1 QUESTION
	<p>The outcome of the study included</p> <p>Injuries data: Rate of occupational accidents, including sharps injuries involving catheters. Over the whole duration of the study, occupational injury data was collected from incident reporting data and analysed retrospectively. This data included all occupational incidents and percutaneous injuries caused by catheter needles and sharps. Needlestick injuries caused by catheters were investigated and the type of catheter, and occupation of the affected staff member were recorded. The total number of catheters used annually was used as the denominator. All hospital employees were included in the study.</p> <p>Other supporting data included</p> <ul style="list-style-type: none"> ➤ The time, location and accurate description of an accident: ➤ The profession, department, ward or operating unit of where the incident occurred ➤ The type of device responsible for the sharps injury The use of any safety measures during the incident
G	<ul style="list-style-type: none"> ➤ The authors do not carry out a statistical analysis of the results (probably because of the low number of needle stick injuries) and instead summarise the annual data as an incidence rate for injuries with either conventional or safety catheters. ➤ The number of needle and sharp injuries entailing biological risk reduced from 163 to 86 from the beginning (2003) to the end of the study (2007). The rate of needlestick injuries was 24.1 per 100,000 cases for use of conventional catheters and 0.4 per 100,000 for use of safety catheters. The incidents of sharps injuries involving catheters fell from 19 in 2004 to two in 2007. No cases were reported for use of safety catheters. ➤ The results indicate that for healthcare staff the risk of injury when using a conventional device was more than 25 times higher than the risk associated with the use of the safety catheter. From 2005 to 2007 (after their introduction) the total number of reported needle stick injuries decreased from n=10 (2005); n=3 (2006), and n=2 (2007). ➤ During the study period, the authors indicate that nurses were affected more often by needlestick injuries than physicians but they do not report on the total number of needle stick procedures carried out by both groups during this period. ➤ Additional data reported that sought to measure the other aspects of the study included: ➤ Educational/ training intervention: The number of injuries caused by catheters increased from n=10 (in 2003) to n=19 (in 2004), and the authors suggest this is because of the introduction of the sharps safety awareness campaign in 2003, resulting in a increased reporting of needle stick injuries. ➤ Use of safety devices: The number of needlestick prevention devices used by the hospital was 130,000 in 2005 and increased to 165,000 in 2006 but decreased to 163,000 in 2007.

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H	<p>There caveats in this study which need to be considered:</p> <ul style="list-style-type: none"> ➤ Only needle sharp incidents were reported and given the low prevalence pre intervention the overall results do not allow a robust statistical analysis of trends. ➤ The study does not report on the numbers and variety of staff that were involved in using the needles. How experienced were the staff in using the catheters and how were the numbers of staff carrying out most catheter insertions similar throughout the study? ➤ No evaluation of staff experience of using the safety devices was undertaken and this might have helped resolve the influence of the educational programme and that of the safety design. ➤ The period of study following the introduction of the safety device was only two years, which is insufficient to anticipate long-term trends. <p>The study involved a large educational intervention before during and after the introduction of the safety catheter. This is understandable but at the same time the impact of the education versus the impact of the safety needle mechanism in reducing the incident of needle stick injuries is difficult to separate. The authors report an increased reporting of needle stick injuries after the start of the education and awareness raising. It is possible that the reduced injury rate after this period was due both to the design and a greater awareness of the problem. However, the authors note that only 18% of long-term staff received the safety needle training and all of the new employees from 2005 (but by 2007 they still only represented 25% of all employees).</p>

 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: 26	Brusaferrero 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
Evidence Level: 2-	
Study Type: Single cohort study design	
Source of Funding:	
A	708-768 HCWs and ancillary operators in a hospital.
B	<p>HCWs: Nurses, physicians, technical personnel, nursing personnel in a 350 bed hospital (~13,000 patients per year). Of this population the breakdown was Nursing staff: 39% Physicians: 6% Technical staff: 13% Ancillary operators: 39%</p>
C	<p>The introduction of a training programme (8 hour training session on biological risks) over a nine year period (1998 – 2006) to raise awareness about biological risk control, which included: the importance and availability of safer sharps protection devices, biological hazards; and how to prevent unsafe working practices. Not all of the participants received the training so that by 2006 only 69% of the relevant staff had received this training. Comparisons were made between the reported needle stick injuries amongst the trained versus non-trained HCWs. During this period the authors report “<i>Since this time, there have not been any significant changes in hospital layout, organization and quantity and quality of devices and tools for correct disposal (e.g. vacutainer system for venepuncture, gloves, masks, specific sharps waste bins)</i>”.</p>
D	Comparison before and after the introduction of a educational intervention to raise awareness about biological risk control and safer sharps and the subsequent incidence of reported NSI
E	Following the start of the educational intervention over a period of nine years.
F	<p>The study recorded every sharps injury but classified them as follows:</p> <ul style="list-style-type: none"> ➤ Accidents in operating rooms ➤ Accidents during routine assistance to patients, ➤ Syringe disposal and laboratory procedures. <p>The data was recorded as Density Index (DI) = total no. of sharps injuries reported per year/total number of actual hours worked by HCWs per year x 1,000,000.</p>

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G	<ul style="list-style-type: none"> ➤ Incidence of sharps injuries in this study was reduced from 85 venepunctures per year (11%) in 1998 to 32 venepunctures per year (4%) in 2006 (p<0.01) ➤ The rate of sharps injuries reduced from 77/ 1,000,000 to 32/1,000,000 worked hours (p<0.01) over the 9 years of the intervention. ➤ The reduction of sharps injuries reached significant levels (p<0.01) amongst nurses but not physicians, laboratory technicians or ancillary operators, different ➤ The relative risk of sharps injuries amongst trained HCWs compared to non-trained staff was 0.06 in 2006 compared to 0.8 in 1998. ➤ The reduced sharps injury rate was mainly attributable to a risk reduction for syringe disposal (p<0.01). ➤ Procedures on patient was another activity where injuries decreased significantly (p<0.05) but operating room procedures and laboratory procedures did not show a significant reduction following training
H	<p>Yes: The study demonstrates a significant reduction in the rate of sharps injuries amongst one group of HCWs (nurses) over an nine year period during which each year a certain percentage of the staff received training about sharps injuries and the risk to health. These reductions were related to disposal of syringes and procedures on patients.</p> <ul style="list-style-type: none"> ➤ However, the educational intervention took place over a very long period and so it is difficult to assess how much of this change was due to the gradual education of staff or attributable to other changes. The authors note that during this period no new safety devices were introduced and there were no major changes to existing protocols or guidelines for preventing ➤ If this is the case then this study provides a much clearer indication of the impact of educational training on reducing sharp injuries. It is possible that changes to the frequency of self reporting of injuries could have contributed to this change but the authors note that the reporting general accidents did not decline during the same period. <p>The study concluded that an educational intervention in a single university hospital with ~67% uptake across all healthcare workers reduced reported sharps injuries from 85 injuries in 1998 to 32 in 2006.</p> <p>The drop in numbers of all injuries occurred as the percentage of trained staff rose from 26% to 69%, while injuries to trained staff dropped from 19 to 4 in the same period (79% drop). So, put another way the trained staff (26% of all HCWs) suffered ~22% of sharps injuries in 1998 and this fell to ~13% of all injuries in 2006 when 69% of staff had been trained. The RR is reported to have fallen from RR=0.8 in 1998 to RR=0.06 in 2006.</p> <p>This is an interesting observational study limited by small sample size and inadequate reporting, in particular limited reporting of the educational intervention. The main impact seems to have been around improved sharps disposal but which aspect of disposal is unclear.</p>

 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: 27	Valls V, Lozano MS, Yanez R, Martinez MJ, Pascual F, Lloret J, Ruiz JA (2007) Use of safety devices and the prevention of percutaneous injuries among healthcare workers. <i>Infect Control Hosp Epidemiol</i> 28 (12): 1352-1360 ALSO USED TO ADDRESS PICO 1 QUESTION
Evidence Level: 2+	
Study Type: Before and after study: Intervention study with a control group in which new safer sharps devices were evaluated at 4 wards comparing the incidence of percutaneous sharp injuries before and after an educational intervention alongside the introduction of new 'safe' sharps devices.	
<i>Note: This study also provides an estimate of the economic costs of introducing safe sharp devices</i>	
Source of Funding: Direccion General de Salud Publica de la Generalitat Valenciana.	
A	The intervention involved 75 nurses. The study does not report the total numbers of medical interventions requiring use of a sharp device but measured the impact of the intervention in terms of the incidence of reported percutaneous injuries.
B	The intervention population were all nurses but the study population included physicians; attending or staff physicians, intern, resident, or fellows, nurses, nursing students and housekeeping staff. The investigation was carried out in 2 surgical wards (general surgery and gynaecology) and 2 medical wards (internal medicine and medical specialties).
C	Nurses (n=75) in the wards where the intervention was implemented received education about the safety devices (IV catheters (peripheral ?), sheathed needles, blunt medication transfer needles) to be tested and about ways to improve compliance in using these devices and reporting of injuries. This consisted of a 3-hour slide presentation of the risk factors and health consequences for blood borne infections, a 2-hour "hands on" training exercise and an additional 15 minutes of 'on-site' training each time a new safety device was introduced. Posters showing how to use the devices were also put up in the nurse stations.
D	Comparison (before and after) between non safe and safety catheters, sheathed needles and blunt needles on the reported incidence of NSI.
E	The pre-intervention period lasted 6 months and the post intervention period lasted 6 months.
F	The number of percutaneous injuries and the number of devices (safe and non safe) used as percutaneous injuries per 100,000 patient days or per 100,000 patients depending on location. Also recorded number of devices used for the economic analyses.

	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: 27	Valls V, Lozano MS, Yanez R, Martinez MJ, Pascual F, Lloret J, Ruiz JA (2007) Use of safety devices and the prevention of percutaneous injuries among healthcare workers. <i>Infect Control Hosp Epidemiol</i> 28 (12): 1352-1360 ALSO USED TO ADDRESS PICO 1 QUESTION
G	<ul style="list-style-type: none"> ➤ The rates of injuries dropped from 45.7/ 100,000 patient days (95%CI=, 16.7-99.5 injuries) before the intervention to 0 / 100,000 (95% CI, 0-24.3 injuries) after the intervention with respect to numbers of intra-vascular catheters used. This was a significant change (p<0.005) ➤ For unattached needle stick injuries the injury rates dropped from 5.9 /100,000 patient days (95%CI=1.9-13.7) to 0 / 100,000 (95%CI=0-5.8). This was a significant change (p<0.031). ➤ In the four hospital wards using the safety devices the average rate of percutaneous injury dropped from a baseline rate of 44.0/100,000 patient-days injuries before the intervention to a rate of 5.2/100,000 after the intervention. This was a significant reduction (p=0.007). ➤ The preventive fraction was estimated at 88.3%. ➤ In the emergency department, the rate of percutaneous injury dropped from 18.5/ 100,000 patients to 0.0/100,000. This was a significant reduction (p<0.002) with a preventive fraction estimated at 100%. ➤ The rate of percutaneous injuries in the non-intervention areas increased slightly from 40.7/ 100,000 patients days to 48.8/100,000 over the last six months of the study. This was a non-significant change (p=0.333). ➤ Over all a 93% reduction in relative risk.
H	<p>Yes: Although limited to a smaller population, this study has selected a more uniform population of nurses, limited the study to two different types of ward, and compared before and after the introduction of an educational intervention. Although not of long duration the educational intervention is clearly described and consisted of awareness raising and practical training.</p> <ul style="list-style-type: none"> ➤ The authors explain the greater impact of their intervention (compared to previously published interventions) on the basis of their use of a combined educational intervention alongside the introduction of the new safety devices. However, whilst this intervention had a significant impact in reducing injuries it is not possible to separate out the impact of the education from the introduction of the safety devices. ➤ The authors also acknowledge that the short follow up period after the intervention (6 months) did not give them a perspective on the long term impact of this intervention in reducing sharps injuries. <p>No: It is not possible to distinguish between the effect of training or the device introduction as the intervention is a combination of safety device introduction and enhanced training programme. This study is however a useful study for the question on whether safety devices can reduce NSIs when introduced in a comprehensive manner (replacement of all traditional devices plus comprehensive training). The authors also report that there was a 3-fold increase in budget necessary to replace the conventional devices with safety devices. Study limitations: Assumes similar patient staff ratio is maintained, although it is unlikely that the staff/pt ratio increased over the study period. No way to tease out the device effect from the training effect. Especially as the paper conclusion states: “education and training are the keys to achieving the greatest preventative effect” - but the paper provides no evidence for this from their own research. Straight Post/Pre study – no randomization. Possible Hawthorne effect. Post study data revealed 4 percutaneous injuries (no time period stated) – 3 in emergency dept, 1 on wards. However the text is not clear on whether the safety devices were still being used or not. The authors explained the rise as being partly due to hiring of HCWs with less experience.</p> <p>Note: Most useful of the papers, package of education that had a measurable effect.</p>

 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: 28	Adams D, Elliott TS. (2006) Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study. J Hosp Infect 64 (1): 50-55.
Evidence Level: 2+	
Study Type: A four-year prospective interrupted time series study.	
Source of Funding: Becton Dickinson, Oxford, UK.	
A	The study examined 51 staff.
B	The study involved healthcare workers in four clinical areas at the University Hospital Birmingham NHS Foundation Trust. Two surgical wards, one medical ward and one outpatient department.
C	<p>The study examined enhanced sharps awareness training and the introduction of safety needle devices.</p> <ul style="list-style-type: none"> ➤ From late 2001 to 2002, an enhanced sharps awareness-training programme was implemented in addition to a standard sharps awareness training programme for healthcare workers. The enhanced programme included road shows, inoculation injury information, a safety device open day, the introduction of sharps box trays to all clinical areas, and the development of new inoculation injury and sharps awareness posters. In 2003, the standard training programme (which included universal precautions and actions to undertake following an NSI) continued, but the additional educational programme was not continued. ➤ In 2003 safety needle devices (SafetyGlide) were introduced into four clinical areas. The healthcare was taught how to use, activate and dispose of the devices safely. Standard needles were removed except for the cardiac arrest trolley where staff had not received the appropriate training.
D	Comparison between an enhanced education intervention to raise awareness of sharps biohazards and standard awareness raising on the reported incidence of NSI.
E	The study followed the reported incidence of sharps injuries over a four-year period.
F	<ul style="list-style-type: none"> ➤ The study collected anonymised needle stick injuries captured from 2001 in occupational health and safety reports. These reports included information about site of injury, date, the procedure undertaken and level of exposure risk. The number of devices utilized throughout the study was also determined. ➤ Bed occupancy and staffing levels of the clinical areas were recorded from 2001 to 2005. ➤ To determine compliance activating the safety needle devices after use each clinical area was visited weekly and the contents of the sharps boxes inspected to assess device activation. ➤ To evaluate healthcare workers' acceptance of the safety needle devices, a user evaluation form was completed by 51 randomly selected staff at 1, 6, and 11 months after introduction of the safety devices. A Likert scale was used to assess the level of agreement about the perceived benefits. Questions were also about the clinical setting and procedures most likely to benefit from use of the safety devices.

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G	<ul style="list-style-type: none"> ➤ Following the enhanced sharps education programme, the NSIs reported in 2002 (13.9 NSIs/100,000) devices decreased by 18% compared with 2001 (16.9 NSIs/100,000). This was not a significant decrease (p= 0.813). ➤ In 2003, when training reverted to the standard education programme the number of NSIs increased to 20 NSIs/100,000 devices. ➤ The introduction of safety needle devices in 2004 was associated with a 70% reduction in the number of NSIs to 6 NSIs/100 000 devices (p=0.045). This reduction was not associated with a change in bed occupancy or staffing levels during this period. ➤ Thirty-eight NSIs were reported during this study the majority associated with the administration of drugs (40%) or needle disposal (37%). The remainder occurred during phlebotomy (18%) or unidentified procedures (5%). Only two occurred whilst using safety needles and prior to the advised activation of the safety mechanism. ➤ User evaluation of the safety devices showed that the staff considered that these devices as safe, usable and compatible with most clinical situations and should be used for procedure where a risk of exposure to blood and body fluids exists. ➤ Visual assessment of the safety needle devices following showed that ~85% of the needles had been activated prior to disposal.
H	<p>Yes: The study addressed a time limited ‘enhanced educational’ intervention as well as the introduction of safety needle devices. Overall the study is well designed and examines the reported incidence of needle stuck injuries before and after the withdrawal of the enhanced educational intervention. Whilst the study reports non significant changes the trends on NSI demonstrated a decreased incidence after the educational intervention and an increase once this programme was withdrawn.</p> <ul style="list-style-type: none"> ➤ The introduction of the safety needles resulted in a much larger and significant (70%) reduction in reported NSIs. ➤ The reporting of NSIs was undertaken systematically and the correct use (activation) of the safety needle devices was subject to additional checks. ➤ The study also included a user evaluation of the safety devices, which demonstrated that the perceived value of the use of these devices increased with time of use.

 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: 29	Zakrzewska JM, Greenwood I, Jackson J. (2001) Introducing safety syringes into a UK dental school--a controlled study. Br Dent J 190 (2): 88-92. ALSO USED TO ADDRESS PICO 1 QUESTION
Evidence Level: 2-	
Study Type: Before and after intervention.	
Source of Funding: No financial support acknowledged. Company provided syringes, training and support.	
A	300 dental staff, nurses, hygienists, therapists, across various grades.
B	Staff at a dental hospital, control group was a surgical ward.
C	Moved from using non-disposable syringes to disposable safety syringes.
D	Dental school versus surgical ward.
E	Used data on needle related injuries 3 years pre and 2 years post introduction of the disposable safety syringes.
F	Avoidable needle stick injuries.
G	<p>Frequency is defined as the frequency per 1,000,000 hours worked based on a 37.5 hour week, 46-week year.</p> <p>In the dental school there was an estimated 1640 needle contacts, compared to the surgical unit 270 per week.</p> <p>In the dental school the frequency of avoidable needlestick injuries fell from a pre change average of 11.8 to 0 per 1,000,000 hours worked per year in the second year of use of the safety syringes. Some reduction noted in the surgical unit but not as marked.</p> <p>Incidence of avoidable needle stick injuries per 1,000 employees also fell in the dental school from an average of 20.5 to 0 in the second year whereas the surgical ward stayed the same - 45.2 (pre) to 33.9 (post) per 1,000 employees (small numbers, not statistically significant).</p> <p>4 injuries occurred in the dental school post introduction in the first six months, 3 were avoidable and recorded as related to lack of training. The other recorded as patient movement during an injection.</p>
H	<p>It is debatable whether or not this paper helps to answer the key question. Clearly there was a reduction in injuries post introduction but the link to education is tenuous and difficult to single out. There are no details of what the training involved or if any evaluation took place. The 'success' could be in the instrument rather than the training though the fact that 3 of the 4 injuries occurring post introduction were related to training cannot be ignored. In the last 18 months no injuries were reported.</p> <p>The lack of success in the surgical unit is not discussed other than saying there is a downward trend. On this basis in terms of education, if there is a link has not made much impact.</p>

 SIGN	Evidence Table 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?
Reference: 30	Pratt RJ, Petlowe CM, Wilson JA, Loveday HP, Harper PJ, Jones S, McDougall C, Wilcox MH. (2007) Epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. Journal of Hospital Infection 65: S1-S64
Evidence Level: 2+	
Study type: Systematic review	
Source of Funding: The Department of Health (England).	
A	N/A.
B	Systematic review to revisit and update current guidance. The following topics were reviewed (n= number of papers reviewed in full for each topic). Hospital Hygiene = 5 Hand Hygiene = 25 PPE = 10 Sharps = 12 Urinary Catheter = 8 Central Venous access device = 20 Total papers = 80 (note, this is building on original review that formed guidelines).
C	Recommendations categorized into the following topics: 1. Hospital environmental hygiene; 2. Hand hygiene; 3. The use of personal protective equipment; and 4. The safe use and disposal of sharps.
D	N/A.
E	N/A.
F	Formed a comprehensive set of recommendations for preventing HCAI in hospitals and other acute care settings based on the best currently available evidence. A suggested research agenda is also provided where topics lack evidence. An audit approach is also recommended to help monitor effectiveness and implementation of the guidelines.
G	N/A.

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Reference: 30	Pratt RJ, Petlowe CM, Wilson JA, Loveday HP, Harper PJ, Jones S, McDougall C, Wilcox MH. (2007) Epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. <i>Journal of Hospital Infection</i> 65: S1-S64
H	<p>7 key recommendations were formed from the review of the papers related specifically to the topic of the safe use and disposal of sharps. 6 out of 7 recommendations were deemed “Class D” (Evidence level 3 or 4, or Extrapolated evidence from studies rated as 2+, or Formal consensus). This constitutes lower levels of evidence and demonstrates that there is a need for higher quality studies relating to sharps work.</p> <ul style="list-style-type: none"> • Recommendation SP36 (Class D) states the importance of educating staff (clinical and non-clinical) in use and disposal of sharps. Also, other standard precautions e.g. safe handling and disposal, was a recommended measure from the guidelines. • The authors acknowledge that previous reviews failed to identify any convincing evidence that needlestick prevention devices were responsible for any significant impact on injury rates. However, more recent studies have shown significant reductions in injuries associated with the use of safety devices in cannulation, phlebotomy and injections. • The authors concluded that it is logical that where needle free or other protective devices are used there should be a resulting reduction in sharps injuries, but, recommend further research into the cost effectiveness, acceptability and efficacy of such devices.

 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. <i>J Occup Health</i> 49 (5): 424-429
Evidence Level: 2-	
Study Type: Before and after intervention.	
Source of Funding: Not stated.	
A	569 student nurses received an initial (pre-test) questionnaire before graduation - 527 valid questionnaires (drop out of 3) - only 524 graduated - 406 valid questionnaires - 299 excluded (2 reasons) leaving 107 valid questionnaires.
B	Pre-intervention third year undergraduate nurse trainees. Post-intervention group comprised the 107 post-intervention - working as licensed nurses, working with needles for more than 4 weeks.
C	Educational intervention consisted of a 30-minute lecture after internship rotation. Plus brochure developed and distributed before graduation.
D	No comparison/control group.
E	Pre-interventional test period was undertaken between July and December 1999. Post-interventional test period was from October 2000 to March 2001.
F	The % incidence of NSI was measured and compared between the pre and post intervention groups. The number of injury episodes/person/yr was calculated. Reporting rates were also compared between the groups.
G	After the training interventions the incidence of NSI fell significantly from pre test 50.5% (54/107) to post test 25.2% (27/107). The average frequency of injuries reduced from 8.1 to 2.7 times /person/year. No significant difference in the frequencies of NSI in different departments in the hospital. Post intervention % of participants in each department reporting NSI's was lower than pre test. Reporting rates increased by 1.5 times from 37.0% (20/54) to 55.6% (15/27) respectively.



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	Brusaferrero 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	<p>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).</p> <ul style="list-style-type: none"> ➤ 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. <p>The study collated all of the hospital recorded sharps injuries, which were then classified as:</p> <ul style="list-style-type: none"> ➤ 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. <i>Occupational Medicine-Oxford</i> 59 (7): 512-514. ALSO USED TO ADDRESS PICO 1 QUESTION
G	<ul style="list-style-type: none"> ➤ 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	<p>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.</p> <ul style="list-style-type: none"> ➤ 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 < 1 yr.

 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. <i>Anesth Analg</i> 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. <i>Anesth Analg</i> 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:					
	<i>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.</i>					
	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 <input type="checkbox"/>	Academic <input type="checkbox"/>	Institution <input type="checkbox"/>	Healthcare Industry <input type="checkbox"/>	Government <input type="checkbox"/>	NGO <input type="checkbox"/>
	Public funds <input type="checkbox"/>	Other <input type="checkbox"/>				
	One centre.					
	Scotland	UK	USA	Canada	Australia	New Zealand
	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. <i>Anesth Analg</i> 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.			
<i>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.</i>			
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 seen as programmed admissions and ~24% as emergency admissions. No significant differences between the three study groups. <i>Very similar patient characteristics between the three study groups: age, gender, weight and height (almost too similar).</i>			
<i>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.</i>			
	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.



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.

<p>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</p>	<p>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</p>	<p>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</p>	<p>Outcome 4:</p>
<p>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?</p>	<p>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?</p>	<p>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?</p>	
<p>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?</p>	<p>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?</p>	<p>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.</p>	



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

	<p>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?</p>	<p>Outcome 4: Difficulty of needle withdrawal (Arm 2) Value: 1.8 Measure: Visual analog scale P value: <0.05 <i>Vs outcomes 1 & 3</i> Upper CI not given Lower CI not given Primary outcome? Greater difficulty withdrawing this needle.</p>	<p>Outcome 4: Difficulty of needle withdrawal (Arm 3) Value: 1.3 Measure: Visual analog scale P value <0.05 <i>Vs outcome 1</i> Upper CI not given Lower CI not given Primary outcome? Greater difficulty withdrawing this needle.</p>	
	<p>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?</p>	<p>Outcome 5: Abnormal blood reflux in the catheter delivery system (Arm 2) Value: 7.2% Measure: P value: <0.05 <i>Vs outcome 1 & outcome 3</i> Upper CI not given Lower CI not given Primary outcome? More abnormal blood flow in the catheter delivery system</p>	<p>Outcome 5: Abnormal blood reflux in the catheter delivery system (Arm 3) Value: 16.1% Measure: P value <0.05 <i>Vs outcome 1</i> Upper CI not given Lower CI not given Primary outcome? More abnormal blood flow in the catheter delivery system.</p>	



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

	<p>Outcome 6: Staff exposure to blood (Arm 1) Value: 6.3% Measure: P value: Upper CI not given Lower CI not given Primary outcome?</p>	<p>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?</p>	<p>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</p>	
	<p>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?</p>	<p>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.</p>	<p>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.</p>	
	<p>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?</p>	<p>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</p>	<p>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</p>	

 S I G N	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. <i>Anesth Analg</i> 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.
	<p>Yes</p> <p>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.</p> <p>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.</p> <p>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.</p>

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	<p>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.</p>

 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 needleless 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 TM or the standard device) were preferred.
G	No statistics presented, just % (see section H).

H	<p>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.</p> <ul style="list-style-type: none"> ➤ 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 <u>usability</u> a positive response was given to each question of more than 85% for all questions. ➤ With regards to <u>acceptability</u> 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™ needless connectors.
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 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. <i>Infection Control and Hospital Epidemiology</i> 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.

 S I G N	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	<p>50 nurses completed user evaluation questionnaires.</p> <p>The users considered that the three devices met the <u>safety standard criterion</u>, mean score range 1.78 – 1.88.</p> <p>Ability to be aware that <u>safety device activation</u> - all nurses considered the devices allowed for you to see when activation had occurred, mean score range 1.30 – 1.58.</p> <p>Ability to <u>deactivate safety device</u> – the mean score range 1.60 – 1.74 demonstrated that even when reasonable force was applied none of the safety devices could be deactivated.</p> <p><u>Failure rate</u> - 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.</p> <p>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.</p> <p><u>Splashing</u> (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.</p> <p>Usability - easy to assemble, use, techniques should be similar to that of standard practice.</p> <p>The nurses concluded the devices were easy to activate, mean score range 1.58 – 1.78.</p> <p>Also that they did not hinder routine use, mean score range 1.70 – 1.80.</p> <p>Lastly that they did not require detailed training, mean score range 1.60 – 1.74.</p> <p>Compatibility - should be able to be used in all circumstances and be used with devices from other suppliers.</p> <p>The nurses concluded that the safety feature did not hinder the products’ use, mean score range 1.70 – 2.1.</p> <p>Only 3 out of 50 (6%) of the nurses considered whether the devices were suitable for phlebotomy.</p>
H	<p>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.</p> <p>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.</p> <p>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.</p>

 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 ' <i>A significant association between primary bloodstream infection and a needleless connector device was observed</i> '. 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. <i>Arthritis Rheum</i> 58 (7): 1907-1914
<i>Evidence Level: 2-</i>	
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. <i>Arthritis Rheum</i> 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	<p>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.</p> <p>Secondary measures:</p> <p>Use of the RPD resulted in a reduction in patient-assessed pain scores of 35.4% (p<0.001).</p> <p>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.</p> <p>In terms of immediate complications to the patients these were very infrequent (1.4%) and equivalent in both the RPD and conventional syringe groups.</p> <p>At 2 weeks, no major complications were observed with the use of either device, and outcomes were good.</p> <p>Physician acceptance of the RPD was improved compared with satisfaction with the conventional syringe (P< 0.001).</p> <p>The performance of attending physicians and resident physicians using the conventional syringe was almost identical (both pain scores and significant pain).</p> <p>Resident physicians and attending physicians performed significantly better with the RPD compared with the conventional syringe.</p> <p>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.</p>
H	<p>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.</p>

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.

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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