

Safety engineered injection devices for intravenous use in healthcare delivery settings.

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Executive Summary

Background

Europe, the United Kingdom and the United States have mandated the compulsory use of needle safety devices. However, mandatory regulations have not been introduced in Australia and it is evident that some of the resources used to support organisation-wide decision making may be out of date. As a result, it is necessary to understand recent evidence exists and what the current state of play is. Hence, the rationale for this review.

Objective

The objective of this review is to determine if the use of safety devices on needles or syringes used intravenously or for phlebotomy has an impact on the rate of sharps injuries or subsequent needlestick injury infection.

Search Strategy

Pubmed Clinical Queries and Cochrane Library were searched to add to the evidence of a recent review on the topic known to the authors. The previous review searched CINAHL, OVID, and MEDLINE. To also ensure that important grey literature was captured, Google was searched. In addition, reference lists and citation searches were also performed to ensure any further relevant resources were included. Any review that investigated safety devices and needlestick injuries and/or infections was included in this review. All other study types were excluded. Reviews that included only Intramuscular, subcutaneous, or intradermal needles were also excluded.

Results

Database searches revealed 225 results and Google searches identified 285 results. Applying the inclusion/exclusion criteria and secondary searched found 6 relevant reviews included in this review. One review focused strictly on intravenous and phlebotomy needles. The other five reviews focused on all needlestick injuries during any procedure (e.g. intravenous, intramuscular, etc.). Only one review was high quality. One review was of moderate quality, and all others were low quality reviews.

Conclusions

For intravenous and phlebotomy procedures, there is low to moderate quality evidence that safety devices reduce the risk of needle stick injuries in healthcare workers. However, the cost, training, waste generated and safe management of the new device need to be considered as these all impact implementation. For safe blood collection systems, there is very low quality evidence that safety devices decrease needlestick injuries. It should be noted that safety devices alone can have a positive impact however, the introduction of safety devices in combination with training leads to a greater protection than training interventions alone.

Background

Healthcare workers who use sharp medical instruments are at risk of injury. Devices such as syringes and needles can penetrate the skin, and as a result, cause discomfort, bleeding and, in some cases, transmit infectious diseases. In addition to the immediate injury, anxiety can also impact the individual¹. In Australia, 11.2% of nurses over a 12 month period had at least one needlestick or sharps injury².

Currently, there are a number of devices, such as needle-less and retractable devices, that can be used to prevent needlestick injuries. The use of devices that have specially designed and engineered protective features has been mandated in the United States in 2000³. In the years after the US law went into effect, the number of NSIs has decreased⁴ (Hadaway). In addition, their mandated use has also been implemented in the UK and Europe⁵. However, there is no such mandate here in Australia.

Given overseas mandates regarding needle safety devices, a number of healthcare services have put organisation-side policies in place to make mandatory the use of needles with in-built safety features. However, it is evident that some of the resources used to support organisation-wide decision making may be out of date⁶. As a result, it is necessary to understand recent evidence exists and what the current state of play is. Hence, the rationale for this review.

Objectives

The objective of this review is to determine if the use of safety devices on needles or syringes used intravenously or for phlebotomy has an impact on the rate of sharps injuries or subsequent needlestick injury infection.

Search strategy

Inclusion/Exclusion Criteria

The following inclusion/exclusion criteria was applied to search results (Table 1).

Table 1. Inclusion/Exclusion criteria

Population	Include: Any healthcare worker using intravenous needles. Exclude: Intramuscular, subcutaneous, or intradermal injectable Medications.
Interventions	Include: Needle or syringe safety devices.
Outcomes	Include: Rate of sharps injuries, subsequent infections.
Control	Include: Devices without a safety feature.
Types of evidence	Include: Reviews only Exclude: Case studies, commentaries, editorials, descriptive studies, experimental studies, observational studies.
Limits	Date: 2012-current

Search strategy

A recent review on the topic⁷ was known to the authors and searched the following databases; CINAHL, OVID, and MEDLINE. Subsequently, a decision was made to further strengthen the previous search by including searches of the following databases in this review; Pubmed Clinical Queries and Cochrane Library. To also ensure that important grey literature was captured, Google was also searched. The results of Google were hand searched with the potentially relevant links being explored to determine if they were to be included. Searches performed in Pubmed Clinical Queries and Cochrane Library were exported into Endnote. Below is a table outlining the search terms used for each source (Table 2). In addition, reference lists and citation searches were also performed to ensure any further relevant resources were included.

Table 2. Database and search terms used.

Database/resource	Search terms	Results
Pubmed Clinical Queries	Systematic AND safety AND needle OR needlestick AND review	163
Cochrane Library	safety AND needle OR needlestick	62
Google (from 2012)	safety AND needle OR needlestick AND review	Cropped to 285

Study Selection

Titles and abstracts identified in Pubmed Clinical Queries and Cochrane Library were exported to EndNote X7 (Thompson, Reuters, Carlsbad, California, USA). Links found in Google were explored. Relevant items identified were screened using inclusion and exclusion criteria established *a priori* by one author (CJ) (Table 2).

Quality Appraisal

One author (CJ) appraised the quality of each review using a quality appraisal tool specifically designed for review articles⁸.

Results

Database and Google searches identified 6 relevant studies^{4,7,9-12} (Figure 1).

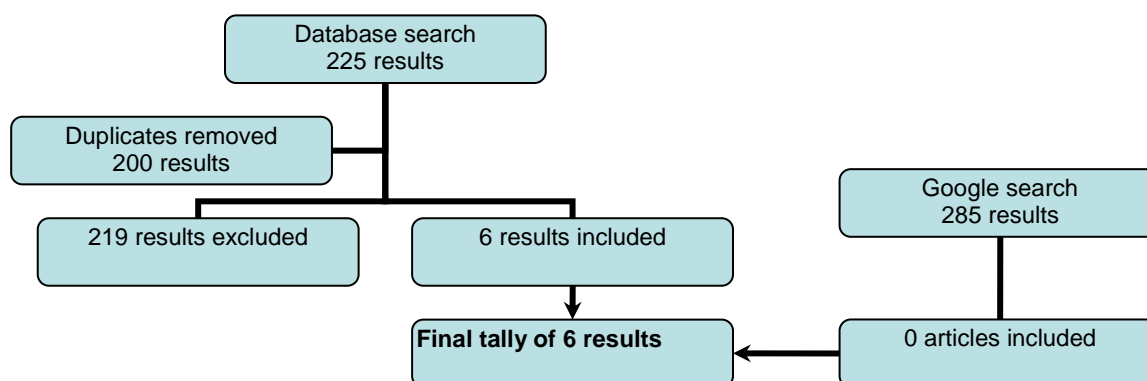


Figure 1. Flowchart of search results and final tally

Summary of Findings

Of the reviews included, one study focused specifically on safety devices used for intravenous and/or phlebotomy procedures⁷, the others included needlestick safety devices used in all procedures including non-intravenous procedures (e.g. intramuscular injections, etc.)^{4,9-12}. Study quality appraisal can be found in Appendix table 3. A summary of each study can be found in the Appendix Table 4.

Intravenous and/or phlebotomy procedures⁷

There is moderate quality evidence that intravenous and phlebotomy safety devices reduce the risk of needle stick injuries in healthcare workers. However, the cost, training, waste generated through added consumables and safe management of the new device need to be considered as these all impact implementation. There is no evidence regarding the impact of safety devices and infection rates in healthcare workers.

Moderate quality evidence shows intravenous safety devices reduce the risk of needle stick injuries in healthcare workers (Figure 2). Low quality evidence shows safety devices reduce needle stick injuries per procedure performed (Figure 3). Moderate quality evidence shows safety devices reduce needle stick injury rates per year (Figure 4). Moderate quality evidence shows needlestick injuries per healthcare worker using phlebotomy safety devices were reduced compared to control (Figure 5). Moderate quality evidence shows rates of needlestick injury per device or procedure performed were reduced using phlebotomy safety devices compared to control (Figure 6).

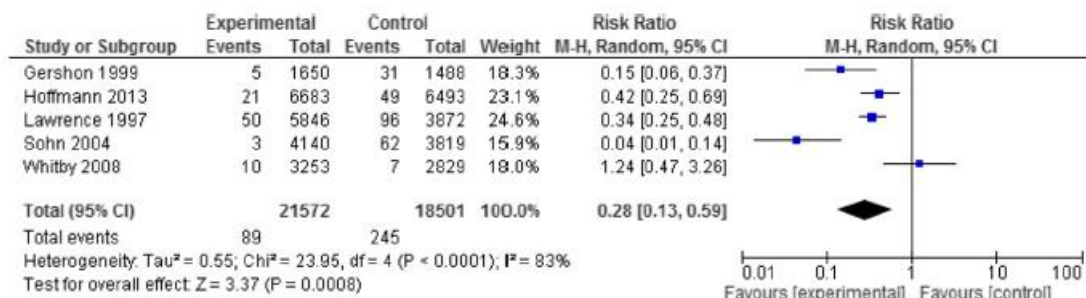


Figure 2. Needle stick injury data of the studies assessing IV safety devices reported as rates of injuries per number of healthcare workers

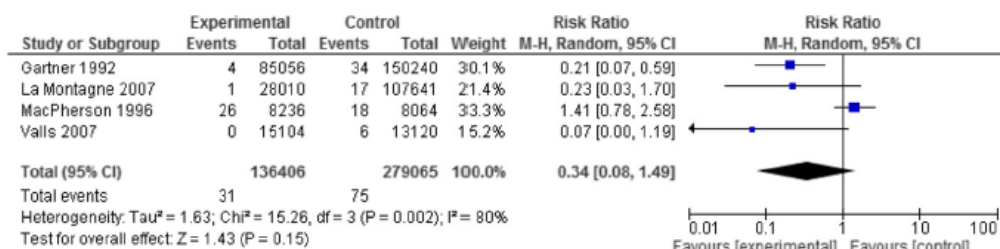


Figure 3. Needle stick injury data of the studies assessing IV safety devices reported as rates of injuries per number of devices or procedures performed

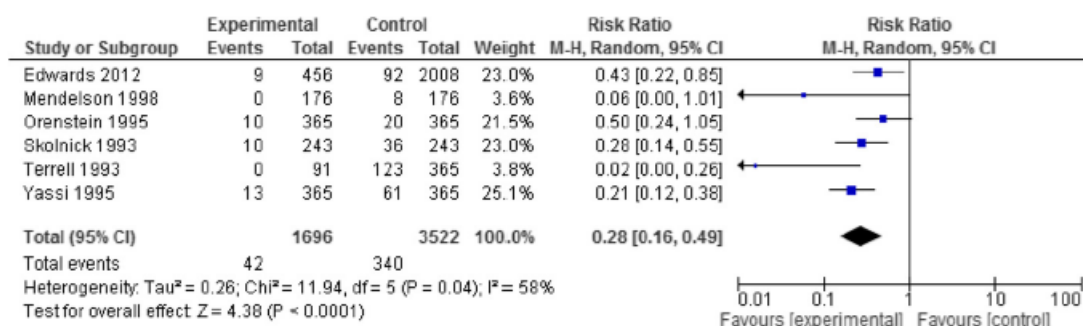


Figure 4. Needle stick injury data of the studies assessing IV safety devices reported as rates of injuries per year



Figure 5. Needle stick injury data of the studies assessing phlebotomy safety devices reported as rates of injuries per number of healthcare workers

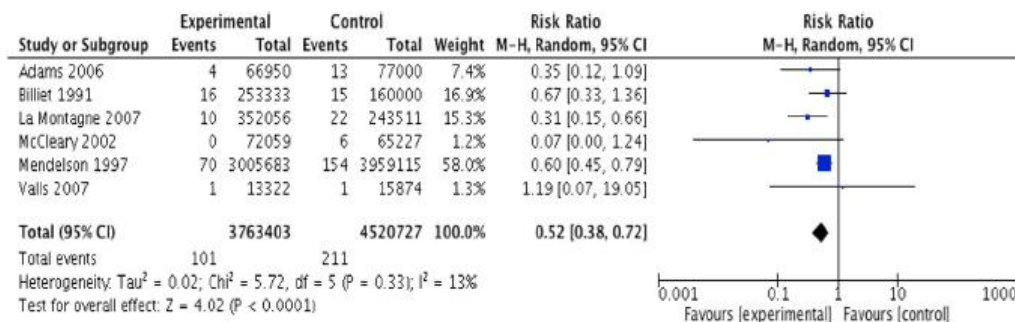


Figure 6. Needle stick injury data of the studies assessing phlebotomy safety devices reported as rates of injuries per number of devices or procedures performed

All sharps, needles or syringes

In general, the use of safer sharps devices improves safety and reduces needle stick injury incidence^{9,10,12}. Safety devices should not be regarded as an infallible solution as most of the devices need to be activated to protect users and preventative injury (e.g. reliant on user input)¹².

This review identified a 2012 Cochrane review investigating the evidence of safety devices, sharps injuries and blood contamination¹⁰. Safety features on intravenous access systems (needles) can lower needlestick injuries, when compared to systems without safety devices however, this is very low quality evidence. Safety features on intravenous devices that have to be actively set in motion increase the risk of blood contamination. There is no evidence showing a decrease in needlestick injuries due to safe injection needles. The lack of evidence of a benefit may be due to confounding factors and bias across the different studies.¹⁰

There is a non-significant decrease in needlestick injuries when using a safe blood collection systems such as shielded needle caps (Figure 7). Further, there is a decrease when using a needle sheath compared to regular systems. The quality of this evidence is very low.¹⁰

Analysis 1.1. Comparison 1 Safe blood collection systems versus regular systems ITS, Outcome 1 Number of reported sharps injuries, level.

Review: Devices for preventing percutaneous exposure injuries caused by needles in healthcare personnel

Comparison: 1 Safe blood collection systems versus regular systems ITS

Outcome: 1 Number of reported sharps injuries, level

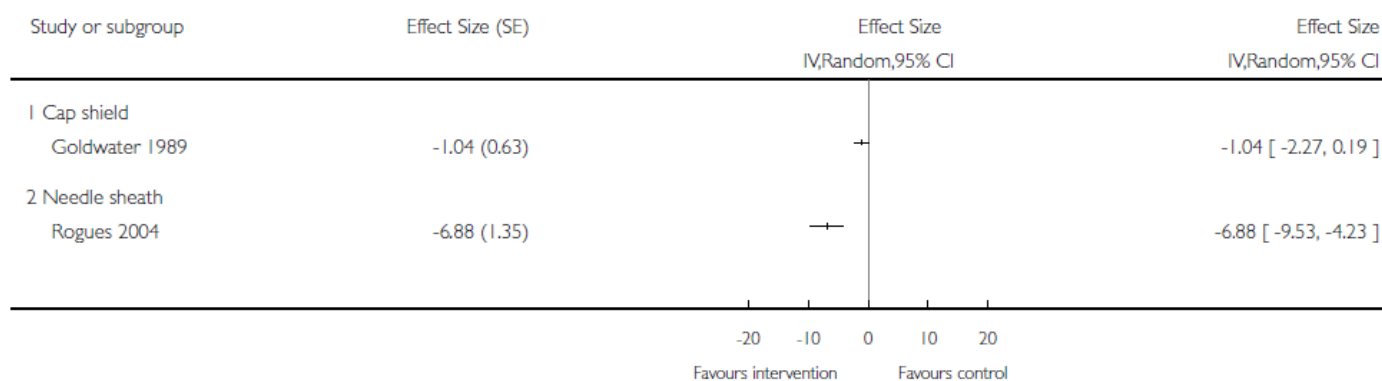


Figure 7. Comparison of cap shield versus needle sheath for reported sharps injuries.

Very low quality evidence shows that safe intravenous systems non-significantly decrease needle stick injury rates (Figure 8). Moderate quality evidence shows that the safe intravenous systems lead to a non-significant increase in the incidence of blood contamination, and active systems lead to an increase in blood splashes (Figure 9).¹⁰

Analysis 2.1. Comparison 2 Safe intravenous systems versus regular systems RCT, Outcome 1 Needlestick injuries.

Review: Devices for preventing percutaneous exposure injuries caused by needles in healthcare personnel

Comparison: 2 Safe intravenous systems versus regular systems RCT

Outcome: 1 Needlestick injuries

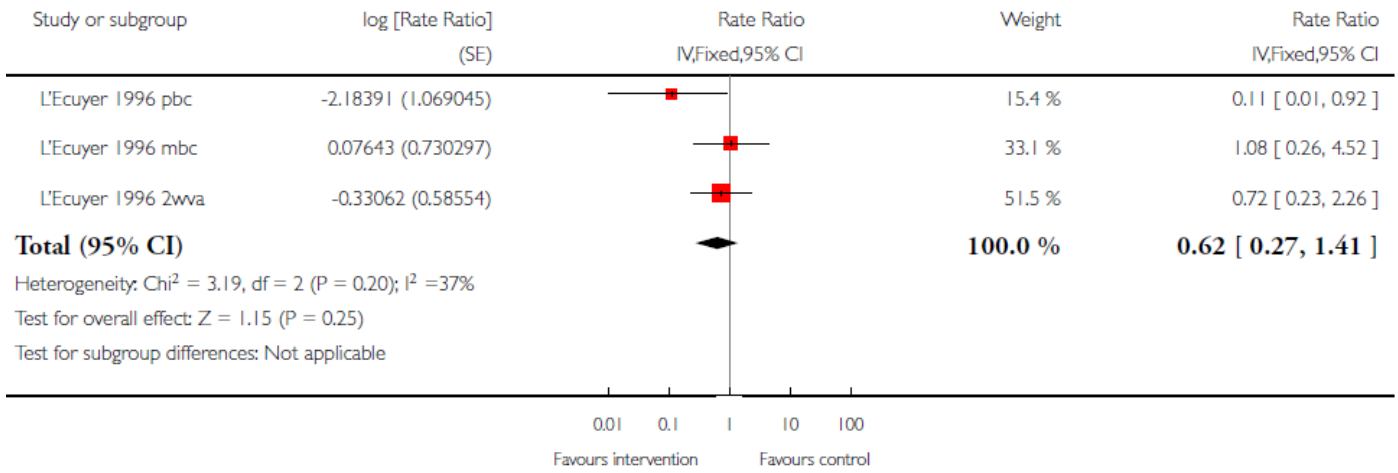


Figure 8. Comparison of needle stick injuries between safe intravenous systems and regular systems.

Analysis 2.2. Comparison 2 Safe intravenous systems versus regular systems RCT, Outcome 2 Incidences of blood contamination.

Review: Devices for preventing percutaneous exposure injuries caused by needles in healthcare personnel

Comparison: 2 Safe intravenous systems versus regular systems RCT

Outcome: 2 Incidences of blood contamination

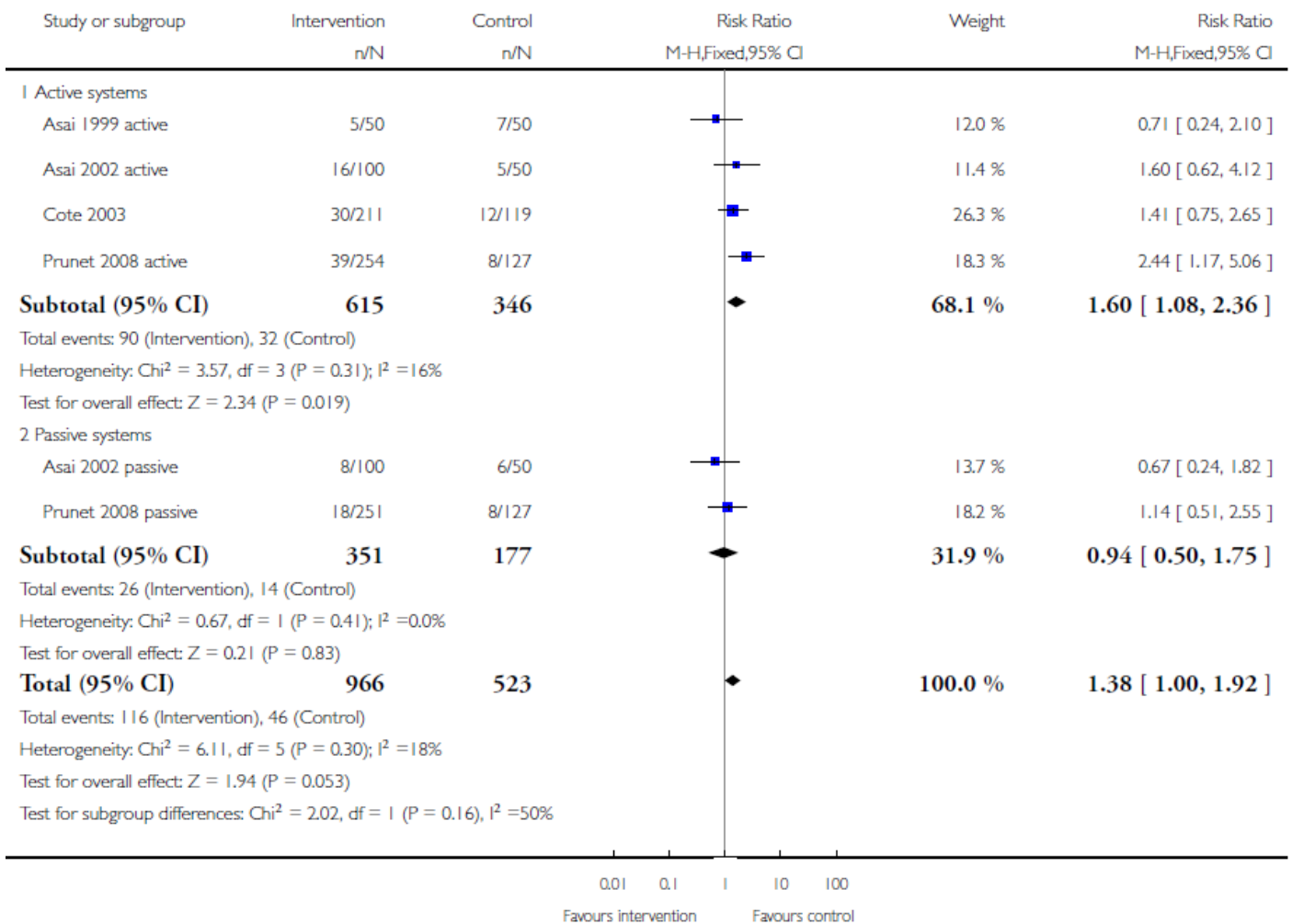


Figure 9. Comparison of the incidence of blood contamination between safe intravenous systems and regular systems.

Safety devices in combination with education

Evidence shows that safety interventions have a protective effect however, the introduction of safety devices in combination with training leads to a greater protection than training interventions alone (Figure 10)^{9,11,12}. Safety devices reduce the rate of needlestick infections by 49%⁹. Training reduces the rate of needlestick infection by 34%, but the combination of safety devices and education reduces the rate of needlestick infection by 62%⁹. However, this evidence for safety devices and education contains a large amount of heterogeneity between studies, and a possibility of confounding bias and therefore, these results should be interpreted with caution⁹.

High quality evidence with a low risk of confounding or bias has recommended that healthcare workers should also be involved in evaluating the products before they are introduced¹².

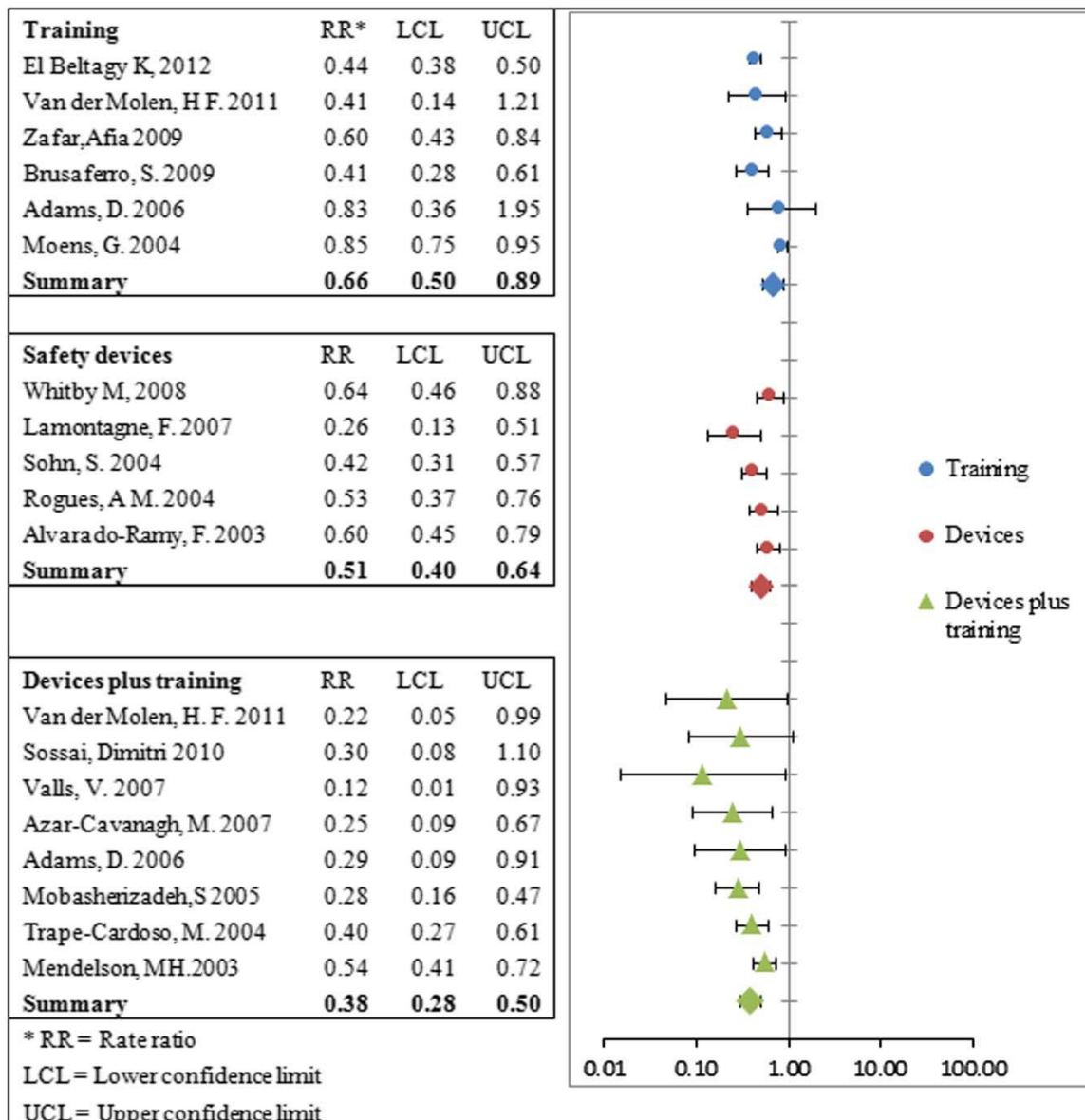


Figure 10. Forrest plot of studies evaluating the effects of 3 different interventions on the rate of needlestick injuries.

Risk factors for needlestick injury

The highest needlestick injury rate occurred during emergency care to the finger tips, hands, and eyes/face¹¹. Instrument preparation resulted in the highest rates of needlestick injury, followed by injections and recapping of used needles¹¹. Needlestick injuries are more likely to happen in understaffed departments, and in nurses who work mixed shifts¹¹. The most significant risk factors for needlestick injuries were being senior or nursing officer, having <10 years work experience, working long hours, and not wearing gloves^{4,11}.

The main reasons for occupational exposure to blood and body fluids were: a sudden movement of the patient during blood sampling or during the intramuscular or venous injection of drugs; during childbirth; during the handling of specimens; during the recapping of specimens; during the handling and collection of waste; or due to a lack of personal protective equipment¹¹.

The evidence for risk factors associated with needlestick injury is based on cross-sectional or retrospective studies and therefore, caution should be exercised given the absence of randomised trials¹¹. Many issues still remain to be addressed with research, such as data on mucocutaneous exposure is very limited⁴. The occurrence of mucocutaneous exposure during venipuncture has not been documented⁴. The need for face protection during all venipuncture attempts has not been suggested⁴. More data are needed about which safety designs on short peripheral IV catheters produce blood splashes, along with the distance and direction of those splashes⁴.

Review Quality

Only one review was of high quality, scoring the total points¹⁰. All other studies scored a range of 1-6 out of a possible 11^{4,7,9,11,12}. All other reviews did not register their protocol, did not search grey literature, did not provide an excluded study list, and did not examine publication bias.

Conclusions

For intravenous and phlebotomy procedures, there is low to moderate quality evidence that safety devices reduce the risk of needle stick injuries in healthcare workers. However, the cost, training, waste generated and safe management of the new device need to be considered as these all impact implementation. For safe blood collection systems, there is very low quality evidence that safety devices decrease needlestick injuries. Safety devices alone can have a positive impact however, the introduction of safety devices in combination with training leads to a greater protection than training interventions alone.

References

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Appendix 1.

Table 3. AMSTAR quality scores for each review

AMSTAR criteria	1	2	3	4	5	6	7	8	9	10	11	Score/11
Ballout et al. ⁷	No	Yes	Yes	No	No	Yes	Yes	No	Yes	No	Yes	6
Hadaway et al. ⁴	No	No	Yes	No	No	No	No	No	N/A	No	No	1
Beswick et al. ¹²	No	No	No	No	No	Yes	Yes	Yes	N/A	No	Yes	4
Lavoie et al. ¹⁰	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Motaarefi et al. ¹¹	No	No	No	No	No	Yes	No	No	N/A	No	No	1
Tarigan et al. ⁹	No	Yes	No	No	No	Yes	No	No	Yes	No	No	3

Table 4. Summary of review results, quality of studies included in each review, and quality of review score.

Author	Results	Quality of studies included	Quality of review
Intravenous and/or phlebotomy procedures			
Ballout et al. ⁷	We identified twenty-two eligible studies: Twelve assessed safety engineered devices for intravenous procedures, five for phlebotomy procedures, and five for both. Twenty-one of those studies were observational while one was a randomized trial. All studies assessed the reduction in needle stick injuries (NSIs) among healthcare workers (HCWs). For safety engineered intravenous devices, the pooled relative risk for NSI per HCW was 0.28 [0.13, 0.59] (moderate quality evidence). The pooled relative risk for NSI per device used or procedure performed was 0.34 [0.08,1.49] (low quality evidence). For safety engineered phlebotomy devices, the pooled relative risk for NSI per HCW was 0.57 [0.38, 0.84] (moderate quality evidence). The pooled relative risk for NSI per device used or procedure performed was 0.53 [0.43,0.65] (moderate quality evidence). We identified no studies assessing the outcome of blood borne infections among healthcare workers or patients.	Only 2 studies declared conflicts of interest. Moderate quality evidence.	Moderate
All sharps needles or syringes			

<p>Hadaway et al.⁴</p>	<p>Healthcare workers All studies focus on the HCW at the bedside performing patient-care tasks. A few studies also report downstream injuries to housekeeping staff and waste-management personnel. Most experts agree that these downstream NSIs can be eliminated and that workers can be protected by correct management of all sharp devices. The professional group with the greatest risk depends on the scope of practice for each group. In most countries, nurses have the greatest risk of NSI because they are the group using the majority of hollow-bore needles. The specific professional performing venipuncture procedures varies between countries. Whereas nurses have this responsibility in the United States, junior physicians in many countries perform this procedure. Studies that assessed risks only for surgeons in the operating theatre focused on suture needles and other types of blood splashes and were omitted from this analysis.</p> <p>Underreporting of exposures Severe and serious underreporting of PCE and MCE is included in all of these studies, with some reporting extremely high rates. This compromises the ability of the organization to provide post-exposure prophylaxis (PEP) and monitoring of the HCW's health status (data such as critical laboratory values or mental health). In countries where applicable, underreporting would have a negative impact on an employee's ability to claim worker's compensation if illness did occur. Reporting behaviour is strongly influenced by the HCW's personal assessment of the perceived risk for each event.</p> <p>Physicians have the worst rates of reporting exposure events, a common theme among numerous studies. Some of the same issues create barriers to reporting, including the time and paperwork required and the perception that, as physicians, they can do a self-evaluation of the risks from each event. MCE is reported to be significantly lower than PCE, which might cause a perception that this is less of a problem than it truly is. The low rates of reporting MCE could be related to the HCW's perception that the risks of disease transmission from MCE are extremely low. Data on occupationally acquired HIV infection included 51 PCEs (all from a hollow-bore needle) and 8 MCEs. In this report, 2 HCWs had concurrent PCE and events. Descriptions of the 8 MCE events did not include insertion of a short peripheral IV catheter.</p> <p>Risks Disease transmission Exposure to percutaneous exposure (PCE) from needles remains a problem, with rates of these injuries being much greater than mucocutaneous exposure (MCE). EPINet reported 951 PCE and 247 MCE events occurring in 2007, the most recent year for which data are available. The risk of infection from these exposures increases with injuries to deep tissue, from a device with the patient's visible blood, and from a procedure with a hollow-bore needle placed in a vein or artery.</p> <p>According to the published literature, disease transmission from MCE is a much smaller problem than PCE. The published data on MCE are limited to statistics on the type of HCW involved and the location within the organization where the event occurred. Studies from the operating room are much more detailed about MCE events, with data available for different types of surgeries. No reports have been found of MCE events resulting from any type of venipuncture procedure in any health care setting.</p> <p>Discussion There is a lack of enforceable mandates to use safety engineered devices except in the United States.</p>	<p>Not commented on.</p>	<p>Low</p>
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	<p>Hospitals in the United States have seen a rise in the number of OSHA citations and fines in the years after the enactment of the Needlestick Safety and Prevention Act of 2000, a serious concern that drives compliance with the law. Small alternative health care facilities (e.g. private doctors' offices, clinics, laboratories, etc.) in the United States remain slow to adopt safety-engineered devices, primarily because there is a lesser degree of enforcement in these organizations. The US experience demonstrates that enforceable mandates, rather than voluntary compliance, are what increase the use of safety devices. In the years after the US law went into effect, the number of NSIs has decreased. Whereas most data show a gradual decline across many years, data from Memorial Sloan Kettering Medical Center in New York showed a distinct and sharp decrease because there were no safety devices used in this facility until the law took effect. The number of injuries from hollow-bore needles dropped by 71% when safety-engineered devices were introduced.</p> <p>Many issues still remain to be addressed with research. The data on MCE are very limited. The occurrence of MCE during venipuncture has not been documented. The need for face protection during all venipuncture attempts has not been suggested. Because of the application of standard precautions, the decision about which PPE to employ for each procedure is generally left to the individual HCW, and it is assumed that all patients are managed as if they were potential sources of infection transmission. More data are needed about which safety designs on short peripheral IV catheters produce blood splashes, along with the distance and direction of those splashes. Armed with these data, HCWs can make more informed decisions about changing their practices associated with face protection.</p> <p>More data are needed about which safety designs on short peripheral IV catheters produce blood splashes, along with the distance and direction of those splashes. Armed with these data, HCWs can make more informed decisions about changing their practices associated with face protection.</p>		
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<p>Beswick et al.¹²</p>	<p>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.</p> <p>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).</p> <p>Evidence-based conclusions</p> <ul style="list-style-type: none"> • 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. 	<p>Grade C evidence – there is a body of evidence directly applicable to the target population and demonstrating overall consistency of results.</p>	<p>Low</p>
<p>Lavoie et al.¹⁰</p>	<p>We included four RCTs with 1136 participants, two cluster-RCTs with 795 participants and 73,454 patient days, four CBAs with approximately 22,000 participants and seven ITS with an average of seven data points. These studies evaluated safe modifications of blood collection systems, intravenous (IV) systems, injection systems, multiple devices and sharps containers. The needlestick injury (NSI) rate in the control groups was estimated at about one to five NSIs per 1000 person-years. There was only one study from a lower middle-income country. The risk of bias was high in most studies.</p> <p>In one ITS study that evaluated safe blood collection systems, NSIs decreased immediately after the introduction (effect size (ES) -6.9, 95% confidence interval (CI) -9.5 to -4.2) and there was no clear evidence of an additional benefit over time (ES -1.2, 95% CI -2.5 to 0.1). Another ITS study used an outdated recapping shield.</p> <p>There was very low quality evidence that NSIs were reduced with the introduction of safe IV devices in two out of four studies but the other two studies showed no clear evidence of a trend towards a reduction. However, there was moderate quality evidence in four other studies that these devices increased the number of blood splashes where the safety system had to be engaged actively (relative risk (RR) 1.6, 95% CI 1.08 to 2.36).</p> <p>There was no clear evidence that the introduction of safe injection devices changed the NSI rate in two studies.</p> <p>The introduction of multiple safety devices showed a decrease in NSI in one study but not in another. The introduction of safety containers showed a decrease in NSI in one study but inconsistent results in</p>	<p>The risk of bias was high in most studies.</p>	<p>High</p>

	<p>two other studies.</p> <p>There was no evidence in the included studies about which type of device was better, for example shielding or retraction of the needle.</p> <p>Authors' conclusions For safe blood collection systems, we found very low quality evidence in one study that these decrease needlestick injuries (NSIs).</p> <p>For intravenous systems, we found very low quality evidence that they result in a decrease of NSI compared with usual devices but moderate quality evidence that they increase contamination with blood. For other safe injection needles, the introduction of multiple safety devices or the introduction of sharps containers the evidence was inconsistent or there was no clear evidence of a benefit. All studies had a considerable risk of bias and the lack of evidence of a beneficial effect could be due both to confounding and bias. This does not mean that these devices are not effective.</p> <p>Cluster-randomised controlled studies are needed to compare the various types of safety engineered devices for their effectiveness and cost-effectiveness, especially in low- and middle-income countries.</p>		
Tarigan et al. ⁹	<p>From an initial pool of 250 potentially relevant studies, 17 studies met our inclusion criteria. Six eligible studies evaluated the effectiveness of training interventions, and the summary effect of the training intervention was 0.66 (95% CI, 0.50–0.89). The summary effect across the 5 studies that assessed the efficacy of SEDs was 0.51 (95% CI, 0.40–0.64). A total of 8 studies evaluated the effectiveness of training plus SEDs, with a summary effect of 0.38 (95% CI, 0.28–0.50).</p>	Quality appraisal not conducted.	Low
Motaarefi et al. ¹¹	<p>The data of the analysed articles indicated that the highest incidence of NSIs was seen in nurses and that the associated factors were age, level of education, number of shifts per month and history of related training. The highest rate of NSIs was related to instrument preparation followed by injection and recapping of used needles. Findings show that health care workers suffer a high rate of needlestick injuries.</p> <p>It was seen that device, location, or action cannot be separately considered as responsible for all types of the NSIs. Rather, each of them has a contribution to the NSIs. Nevertheless, factors with higher frequency should be given a higher priority.</p>	Quality appraisal not conducted.	Low