Effectiveness of measures to prevent needlestick injuries among employees in health professions

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Prepared for:

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Abstract

The pathogens of greatest concern that may be transmitted by a needlestick injury (NSI) are hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV). The objective of the study was to critically review and summarize the published literature on NSI, with the main focus on studies evaluating the effectiveness and cost aspects of the implementation of safer devices and other preventive measures in hospitals.

A comprehensive literature search on MEDLINE identified more than 2,300 publications. A multi-stage selection process was used to identify those studies appropriate for inclusion in the Quality Based Critical Review (QBCR), which finally included 61 publications on intervention studies. These studies were evaluated and rated according to quality indicators. Additionally, papers discussing the costs and benefits of the introduction of safer device have been analyzed.

Those with the most patient contact, nurses and physicians, were the most likely to report NSI, and NSI were most likely to occur in patient and operating rooms. However, underreporting presents a serious problem for the development of accurate risk estimates. The majority of the intervention programs, despite large differences in methodological quality, showed in general that engineering controls, especially the introduction of safety-designed devices, were effective in reducing the number of reported NSI. There are only few studies investigating the cost-effectiveness of this introduction and their results are suggesting that a complete substitution currently might not be cost neutral for a hospital. However, these studies showed little methodological consistency and therefore do not allow to draw firm conclusions. Societal as well as intangible costs and benefits should be considered in an overall assessment.

Wirksamkeit und Wirtschaftlichkeit präventiver Maßnahmen zur Vermeidung von Nadelstichverletzungen bei Beschäftigten in Gesundheitsberufen

Kurzfassung

Die Krankheitserreger, deren Übertragung durch Nadelstichverletzungen (NSV) die größte Bedeutung haben, sind Hepatitis B (HBV), Hepatitis C (HCV) und das Human-Immundefizienz-Virus (HIV). Zielsetzung dieser Studie war es, die bezüglich der Nadelstichverletzungen veröffentlichte Literatur kritisch zu bewerten und zusammenzufassen. Dabei lag der Schwerpunkt auf Studien, die Effektivität und Kostenaspekte der Einführung sicherer Geräte und anderer präventiver Maßnahmen in Krankenhäusern evaluiert haben.

Eine umfassende Literatursuche über MEDLINE ergab mehr als 2 300 Publikationen. Ein mehrstufiger Auswahlprozess wurde durchgeführt, um solche Studien zu identifizieren, die für die Einbeziehung in den Quality Based Critical Review (Qualitätsbasierter kritischer Review QBCR) geeignet erschienen. Hieraus resultierten letztlich 61 Publikationen zu Interventionsstudien. Diese Studien wurden evaluiert und aufgrund von Qualitätsindikatoren bewertet. Ergänzend wurden Publikationen, die sich mit Kosten und Nutzen der Einführung sicherer Geräte auseinander setzten, analysiert.

Krankenschwestern und Ärzte mit dem meisten Kontakt zu Patienten meldeten am häufigsten NSV. Diese Art von Verletzungen trat meistens in Krankenzimmern und Operationssälen auf. Allerdings stellt unzureichendes Meldeverhalten ein ernstzunehmendes Problem bei der Erstellung präziser Risikoschätzungen dar. Die Mehrheit der Interventionsprogramme zeigte im Allgemeinen – trotz großer Unterschiede in der methodischen Qualität –, dass technische Steuerungsmaßnahmen, insbesondere die Einführung von Instrumenten mit Sicherheitstechnik, die Zahl der gemeldeten NSV deutlich reduzieren. Nur wenige Studien untersuchten die Einführung der sicheren Systeme unter dem Aspekt der Wirtschaftlichkeit und ihre Ergebnisse deuten an, dass ein kompletter Ersatz für ein Krankenhaus momentan nicht kostenneutral wäre. Diese Studien zeigten allerdings eine geringe methodische Konsistenz und erlauben es daher nicht, daraus sichere Rückschlüsse zu ziehen. Gesellschaftliche sowie immaterielle Kosten und Nutzen sollten bei einer Gesamtbewertung berücksichtigt werden.

Efficacité et rentabilité des mesures de prévention pour éviter les blessures par piqûres d'aiguilles dans les professions médicales

Résumé

Les agents pathogènes les plus importants pouvant être transmis par blessure d'aiguilles (BPA) sont l'hépatite B (VHB), l'hépatite C (VHC) et le virus de l'immuno-déficience humaine (VIH). L'objectif de cette étude était d'évaluer de façon critique et de résumer les ouvrages publiés concernant les blessures par piqûres d'aiguilles, en se concentrant surtout sur les études évaluant l'efficacité et la rentabilité de l'introduction d'instruments sûrs et d'autres mesures de prévention dans les hôpitaux.

Une recherche détaillée d'ouvrages, via MEDLINE, a donné plus de 2300 publications. Un processus de sélection à plusieurs niveaux a été réalisé afin d'identifier les études propres à l'inclusion dans le Quality Based Critical Review (QBCR). Ce processus de sélection a donné 61 publications sur des études d'intervention. Ces études ont été évaluées et classifiées selon des indicateurs de qualité. De plus, des publications concernant les coûts et utilités de l'introduction d'instruments plus sûrs ont été analysées.

Les personnes déclarant le plus grand nombre de BPA sont les infirmières et médecins ayant le plus de contact avec les patients. Ce genre de blessures parvient le plus souvent dans les chambres d'hôpitaux et les salles d'opération. Toutefois, le fait que de nombreux cas ne sont pas déclarés pose un grave problème dans l'établissement d'évaluations précises des risques. La majorité des programmes d'intervention, malgré une grande différence au niveau de la qualité des méthodologies, montrait en général que des mesures de contrôles techniques permettaient de diminuer sensiblement le nombre de BPA déclarées, en particulier l'introduction d'instruments avec une technique de sécurité. Seules quelques études ont analysé l'aspect rentabilité de l'introduction des systèmes sûrs et elles ont montré que, pour un hôpital, un remplacement complet ne serait pas sans avoir des répercussions financières. Toutefois, ces études faisaient preuve d'un manque de cohérence méthodique et ne permettaient ainsi pas de tirer des conclusions certaines. Les coûts et bénéfices sociaux et immatériels doivent aussi être pris en compte dans une évaluation générale.

Eficacia y rentabilidad de medidas preventivas para evitar pinchazos accidentales en el trabajo del personal sanitario

Resumen

Los patógenos transmisibles a través de heridas resultantes de pinchazos accidentales (NSI = needle stick injury) que presentan el mayor riesgo son hepatitis B (HBV), hepatitis C (HCV) y el virus de la inmunodeficiencia humana (HIV). El objetivo del presente estudio es evaluar de forma crítica y resumir la literatura publicada sobre los pinchazos accidentales. En el centro del interés estuvieron estudios que evaluaron la eficacia y los aspectos de costes relativos a la implementación de equipos seguros y otras medidas preventivas en hospitales.

Una extensa búsqueda bibliográfica a través de MEDLINE dio por resultado más de 2300 publicaciones. Se realizó un proceso de selección de varias etapas para identificar aquellos estudios que parecían adecuados para ser incluidos en el Quality Based Critical Review (revisión crítica basada en la calidad, QBCR). Al final se incluyeron 61 publicaciones sobre estudios de intervención. Estos estudios se evaluaron y valoraron a base de indicadores de calidad. Adicionalmente, se analizaron publicaciones que tratan de los costes y beneficios de la implementación de equipos seguros.

El personal de enfermería y el personal médico, que tienen el mayor contacto con los pacientes, acusaron la mayor incidencia de pinchazos accidentales (NSI). Este tipo de lesiones ocurre, en la mayoría de los casos, en las habitaciones hospitalarias y quirófanos. Un serio problema para la elaboración de estimaciones precisas de los riesgos es la notificación insuficiente por parte de las entidades afectadas. La mayoría de los programas de intervención mostró en general – no obstante las grandes diferencias en la calidad metodológica – que las medidas técnicas de control, especialmente la introducción de instrumentos con técnica de seguridad, redujeron nítidamente el número de los pinchazos accidentales notificados. Sólo pocos estudios analizaron la implementación de sistemas seguros bajo el aspecto de la rentabilidad y sus resultados indican que una sustitución completa actualmente no sería de coste neutro para un hospital. Estos estudios, sin embargo, mostraron poca consistencia metodológica y, por tanto, no permiten sacar deducciones seguras de los mismos. También se deberían tomar en cuenta los costes y beneficios tanto sociales como inmateriales en una apreciación global.

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Preface

It has long been recognized that needlestick and other injuries from sharp objects place healthcare workers at risk of infection. The most common pathogens carried in body fluids are hepatitis B virus (HBV), hepatitis C virus (HCV), and the human immunodeficiency virus (HIV).

Infections caused by occupational exposures are costly in terms of human suffering, the social-economic impact, and the financial responsibilities borne by accident insurance institutions. In recognition of these burdens, prevention measures have been the focus of hazard reduction for health care professionals. For example, German employers have been obligated to provide free HBV immunization for as long as an effective vaccination has been available, since 1982. The legislation mandating free HBV immunization was originally part of accident prevention regulation 103 "Health and Welfare", and in 1999 was incorporated into the "Biological Agents Ordinance" (Biostoffverordnung). Not all eligible employees agree to be vaccinated. Unfortunately, there are no effective vaccines currently available to protect against HCV and HIV. Therefore, additional preventive measures that focus on technical changes to equipment must also be implemented.

Safety engineered sharp devices have been available in the US since the late 1990s, and their use was formalized into law by the "Needlestick Safety and Prevention Act" of 2000. Similarly, the use of safety engineered sharps was mandated in Germany by the Technical Rule 250, "Biological Agents in Health Care and Welfare Facilities" (TRBA 250). The TRBA 250 was developed by the Committee on Biological Agents (Ausschuss für Biologische Arbeitsstoffe, ABAS) of the German Federal Ministry of Economics and Labour, in cooperation with the expert committee on Health Care and Welfare of the Federation of Institutions for Statutory Accident Insurance and Prevention (HVBG). In paragraph 4.2.4 it is demanded that spike, sharp or breakable devices should be replaced by suitable devices or methods which have no or low risk of needlestick injuries. The TRBA 250 further stipulates that model or evaluation projects demonstrating equipment effectiveness must be considered when devices are to be introduced into a workplace.

Some reluctance on the part of employers has been evident in the implementation of the TRBA 250. Barriers to the introduction of safety engineered sharp equipment include a significant investment in staff training, as well as high procurement costs: the unit cost for new, safer technologies is still higher than the costs of traditional sharp equipment. On the other hand there is no doubt about the effectiveness of new safety-engineered devices which are preventing human suffering and reducing costs of the insurance companies, costs due to sick leave and recruitment of new personnel etc. These advantages were perceived only restrictedly in practice until now due to the lack of information and data.

In order to reduce uncertainties and to obtain information on the effectiveness of safety-engineered devices and training programs the following institutions have funded the meta-analysis „Effectiveness of measures to prevent needlestick injuries among employees in health professions": The German Federal Ministry of Labour and Social Affairs[1], the Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Service, the BG Institute for Occupational Safety and Health – BGIA, and the Central Office for Safety and Health at Work (BGZ). The meta-analysis was supported by a working group of experts from the funding and other institutions. In this report, the results of the study are presented to the public.

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[1] The project was initiated by the former Ministry for Economics and Labour, since the end of 2005 Ministry for Labour and Social Affairs.

1   Introduction

Although the extent of tissue damage to health care workers injured while using sharp medical equipment, especially needles and intravenous (IV) equipment, is generally minor, a more serious problem, and the impetus behind the development of needle-stick injury (NSI) prevention programs, arises from the risk of infection by blood-borne pathogens subsequent to NSI. The pathogens of greatest concern that may be transmitted by NSI are hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV). While other blood borne pathogens (BBP), including, for example, Hepatitis G; Herpes Simplex 1; Group A Streptococcus; and Human Parvovirus B19 may also be transmitted by NSI, they are less common [1 to 7]. Because of these potentially serious consequences of NSI, ongoing surveillance and tracking of injuries and any subsequent infections are crucial for identifying high-risk groups or activities, and for planning health care services for health care workers (HCW) who may become infected.

In the United States of America (USA), the growth of NSI prevention programs correlated with the growth of awareness of the HIV epidemic in the mid-1980s [8]. The United States Centers for Disease Control and Prevention (CDC) issued its first set of guidelines on needlestick safety in 1983; the revised version, issued in 1987, became the so-called "Universal Precautions" in which health care and emergency services providers were instructed to treat all body fluids as if they were infective [8; 9]. The Occupational Safety and Health Administration (OSHA) lagged several years behind CDC in recognizing the risks associated with NSI, issuing the first blood borne pathogens (BBP) standard in 1991. These regulations were designed to protect health care workers from risks of occupational exposure to BBP by investing employers with the responsibility of evaluating the effectiveness of existing risk control measures, and of identifying and evaluating new technologies that might prove to be more effective at reducing the risk of NSI occurrence [10]. The 1999 version of the OSHA BBP standard reiterated and emphasized employers' responsibility to review the efficacy of their infection control plans annually, to keep informed about newly developed engineering controls, and to use the most advanced system that could be feasibly adopted by their institution [10]. In parallel with the implementation of increasingly specific regulatory

controls pertaining to protective technology, the US Congress passed legislation in 1998 that required reporting occupational NSI to OSHA, using the same mechanisms as were in place for other types of occupational injuries.

Federal attention has remained focused on NSI prevention. The CDC teamed with the National Institute of Occupational Safety and Health (NIOSH) to issue a report in 2000 stating that sharps should be eliminated from use whenever possible. In situations where sharps were necessary, engineered safety precautions such as shielding should be used. The report addressed other features of safety programs, as well, including the need for regular evaluation of the efficacy of standing safety programs and the devices in current use [10]. Later in 2000, the Needlestick Safety and Prevention Act was passed into law by Congress. For the first time, this law authorized OSHA to require employers to replace traditional equipment with safety-engineered sharp devices [10]. The 2001 version of the OSHA BBP standard additionally emphasized the need for accurate and complete recording of occupational NSI [10], recognizing that analyses of the descriptive epidemiology of NSI can be used to identify subpopulations of health care workers at highest risk of NSI and subsequent infection and, therefore, most likely to benefit from NSI preventive measures.

1.1   Legal situation in Germany

In Germany, the use of safer devices is not mandatory and their introduction in hospitals is rare. The "Directive on the Protection of Workers from Risks related to Exposure to Biological Agents at Work" (2000/54/EU) [11] of the European Parliament and the Council of the European Union was transposed into German law with the "Ordinance on safety and health protection at work involving biological agents (Biological agents ordinance - BioStoffV)" [12] in January 1999. The purpose of this ordinance is to protect workers against health and safety risks, including the prevention of such risks, arising or likely to arise from occupational exposure to biological agents.

Activities with biological agents are defined by the ordinance as targeted and non-targeted activities. Targeted activities are intentional activities in which the identity and character of the microorganisms is well-known. Examples are operations with specific microorganisms encountered in food production, or handling of specific pathogens in

scientific laboratories. Non-targeted activities are not primarily focused on biological substances but exposure may occur. Examples are activities in the field of health services, waste management or agriculture.

Both the labor protection laws [13] and the Biological Agents Ordinance require risk assessments and subsequent actions (e.g. hygienic measures, individual protective measures, information and instruction of employees, health monitoring) to be carried out by the employer. Appropriate assessment of risks associated with biological substances and establishment of adequate measures require identification of the type, extent and duration of exposure for each task. The reduction of risks must be specified by the ranking of actions (technical, organisational and personal protective measures). In addition, hygienic measures, labelling of dangerous substances and application areas, personal protective measures, safe waste management and safe transport have to be considered. These rules also apply to non-targeted activities with potential exposure to biological agents. Exceptions are allowed, if the result of the risk assessment shows no detectable health risk.

In Germany, the Technical Rules for Biological Agents (TRBA) specify protective measures. The Technical Rule 250 "Biological Agents in Health Care and Welfare Facilities" (TRBA 250) [14] was developed by the "Committee on Biological Agents" (ABAS) in cooperation with the expert committee "Health Care and Welfare" of the Federation of Institutions for Statutory Accident Insurance and Prevention (HVBG) (see cooperation instructions, Bundesarbeitsblatt No. 5, 2001, p. 61) and became effective by publication through the Federal Ministry of Economics and Labour on December, 1st 2003. TRBA 250 corresponds to the Regulation of the Institutions for Statutory Accident Insurance and Prevention (BGR 250). Both the TRBA and BGR apply to activities in health care and welfare facilities, in which humans or animals are medically examined, treated or nursed.

The TRBA 250 defines for the first time concrete protective measures designed to avoid needle stick injuries. In paragraph 4.2.4, the use of devices is demanded, which have no or low risk of needlestick injuries: *"Spike, sharp or breakable devices should be replaced by suitable devices or methods which have no or low risk of needlestick injuries. These devices should be given priority if special risks are anticipated. Results of*

model- or evaluation projects have to be considered in the selection of adequate devices or methods. The treatment of sick people, who are infected with risk group 3** organisms (e.g. HIV) or working in emergency medical services… can be a special risk. A procedure also is appropriate for example if safe recapping of a needle in its protective cover with one hand is possible."

1.2   Objectives and format of the report

This report addresses three major aims. The first is to provide an overview of the descriptive epidemiology of needlestick injuries to health care workers, including the estimated frequency of injuries, risk of NSI by location and device, and a description of populations at high risk of NSI.

The second major aim is to assess and discuss results of NSI prevention programs, especially those implementing new safety devices, on the basis of published evaluation studies. For this report, needlestick injury is defined as any percutaneous (passing through the skin) injury with sharp equipment used in the delivery of medical care. Such equipment may include hollow-bore needles, suture needles, scalpels, IV equipment, etc. Several types of safety-engineered devices are described in table 1 (see page 87).

An overview about currently available safety-engineered devices in Germany can be found in a recent brochure of the BGW[2]: Risiko Virusinfektionen[3], in the "Merkblätter Biologische Arbeitsstoffe"[4] and in a work by Beisel[5]. Further safety equipment or engineering controls include e.g. assistive devices for recapping used syringes, double gloving and changes to disposal boxes. The different measures for NSI prevention in general are also summarized in table 1.

The third major aim of the report is to provide a summary of published analyses comparing the costs and benefits of use of safety equipment.

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[2]   BGW = Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Service)
[3]   Available at: http://www.bgw-online.de/internet/preview?id=926 (2006-01-17)
[4]   *Hofmann, F.; Jäckel, R.*: Merkblätter Biologische Arbeitsstoffe. Ecomed, Landsberg am Lech – Losebl.-Ausg.
[5]   Available at: http://www.nadelstichverletzung.de (2006-01-17), see section "Downloads"

To complete each of the major aims for this project, extensive searches of the medical literature were necessary. After identifying relevant publications, however, the methods used to address each aim diverged. Therefore, the following section (Literature search: Methods and general results) describes the procedure used to identify and screen literature potentially relevant to the project overall. The remainder of the report is divided into three parts, presenting methods, results and discussion specific to each major aim. The final section of the report provides a synthesis and a series of recommendations.

2   Literature search: Methods and general results

A comprehensive search of the National Library of Medicine (NLM) literature indexing database (MEDLINE) was completed using the PubMed system. MEDLINE includes articles indexed since 1966, and currently includes over 4,800 journals published in 70 countries. The database includes journals in the fields of medicine, nursing, dentistry, veterinary medicine, health care administration and policy, as well as life, behavioral, and chemical sciences, and bioengineering [16].

Because of our interest in identifying the maximum pool of articles potentially relevant to each major aim, we completed several PubMed searches and reviewed the bibliographies of key review articles. Initial PubMed searches were completed on November 4, 2004, and updated on April 26, 2005. There was a substantial degree of overlap among results of all searches (Table 2, see page 88); after removal of duplicates, 1,069 unique references were identified.

3   Descriptive epidemiology of NSI

The descriptive epidemiology of NSI is presented in two different forms, a literature review and a summary of publicly available surveillance data.

3.1   Methods

3.1.1 Literature review

The initial literature pool contained 525 articles published in English and German (none were published in French) that discussed some aspects of the descriptive epidemiology of NSI. Because of the large amount of research completed in the last decade and a half, and because many aspects of the epidemiology of needlestick injuries have already been well-documented, this literature review focused mainly on published summary papers. This review of the literature on the epidemiology of NSI is meant to describe overall trends in NSI, as well as factors modifying the risk of NSI among HCW, such as occupational group; medical specialty; and activity leading to NSI.

3.1.2 International NSI surveillance

Reports from NSI surveillance systems in several European Union (EU) countries and the United States (US) were publicly available via the internet (Table 3, see page 89). Many of these reports were based on data collected using the Exposure Prevention Information Network (EPINet), a software package developed and maintained at the University of Virginia (US) specifically for tracking and reporting NSI. Because many reports tended to be similarly formatted, we were able to compare the results of NSI surveillance internationally. Not all data elements were reported or defined identically by all users, however, and tracking periods varied by country, in some cases by several years. It is also likely that some data elements and categories were defined differently by the various user organizations, but documentation was inadequate to be certain. We attempted to standardize definitions through the use of logical groupings for the summary tables included here.

Two sources of NSI surveillance data were available for the US, also via the internet. EPINet data have been compiled and summarized approximately annually since 1992, and the National Surveillance System for Hospital Health Care Workers (NaSH) has been operated by CDC since approximately 2000. There are several differences between the two surveillance systems. Hospitals participating in NaSH tend to be larger than EPINet user hospitals, averaging 592 vs. 315 beds. NaSH hospitals tend to cluster in northeastern US, while EPINet user hospitals are generally located in southeast and northwest regions of the country. Characteristics of patients treated by larger versus smaller hospitals, as well as regional cultural differences and differences in the workplace culture of larger compared to smaller hospitals could influence actual numbers of NSI, within-institution completeness of reporting and actual patterns of NSI within occupational groups. In addition, NaSH and EPINet employed different methods for estimating the overall rate of NSI, and for estimating average rates of underreporting (dependent upon occupational subgroup). For example, EPINet assumes an overall average of 39 % underreporting per year, while the NaSH assumes an average of 50 % underreporting [17]. Consequently, NaSH rates are higher than those from EPINet, and data from the two sources are reported separately.

3.2   Results of literature review

Results of several summary papers and selected studies are summarized by subtopics of interest, including overall estimates of NSI risk to HCW, modifiers of risk, underreporting, and risk of infection by pathogen.

3.2.1 Risk of NSI

According to a CDC study reported in several of the reviews [5; 6; 18; 19], approximately 384,000 NSI are estimated to occur annually to hospital workers in the US, and more than 800,000 to all HCW combined (hospital and non-hospital settings). Based on pooled data from several institutions, *Trim* and *Elliot* calculated the NSI rate in the United States to be 1 % to 6 % per year (113 per 10,000 HCW to 623 per 10,000 HCW), with a mean of 4 % [4]. Similarly, *Hofmann* et al. estimated a national

average of 500,000 NSI annually for Germany based on a survey in two hospitals [20].

3.2.2 Modifiers of NSI risk

The risk of NSI for any individual HCW depends on a number of factors, including frequency of potential contact, i.e., the number of procedures or needle manipulations performed [2; 4; 7; 21]; the type and duration of procedure; manual vs. instrumented tissue retraction during suturing and cutting; and the emergent status of the case [3; 7; 21]. Some types of devices also seem to confer higher risks of NSI than others, potentially due to the underlying frequency of use. For example, risk of NSI increases up to five fold when manipulation is required after use compared to single use devices [2; 7]. In particular, recapping used hypodermic needles has been noted as a major risk factor for injury, leading to the US Occupational Safety and Health Administration prohibiting the practice in most circumstances. In a study of one hospital conducted during the mid-1980s, recapping was reported to be the single most common cause of injury (reported in [2]). The habit of recapping persists, however, and interviews with HCW suggest that their rationale for recapping has been management of competing risks. For example, the risk to the individual posed by recapping single hypodermics is perceived to be lower than the risk to the individual posed by collecting several uncapped devices for disposal, or the risk to coworkers due to their potential exposure to uncapped needles left at the care delivery site prior to disposal [2; 4; 7; 19].

The overall risk of NSI also seems to depend on medical specialty area. For example, 6 % to 50 % of operating room (OR) and delivery room personnel report at least one blood contact per procedure, and 1 % to 15 % of their procedures include at least one NSI [2]. In contrast, needle sticks to anesthesiologists are relatively rare, occurring at a rate of about 1.4 injuries per 100 procedures [2]. Among physician specialties, injury rates appear to be highest for surgeons, with 2.6 NSI per 100 procedures for residents and 2.3 per 100 procedures for attending surgeons [21]. Among all occupational groups, nurses are the most likely to experience NSI, reporting 50 % to 75 % of all injuries within a given institution. Physicians generally rank second among hospital staff, with the rankings of other groups (phlebotomists, housekeeping staff, laboratory

personnel) varying by institution; individual groups of non-nursing, non-physician hospital staff typically account for no more than 5 % of all reported NSI [3 to 7; 19]. Within occupational groups, risk of NSI further varies by procedure: venipuncture or intramuscular injection present higher risks of injury and/or subsequent infection than other types of procedures [3; 21].

3.2.3 Underreporting

Most authors identified underreporting of NSI events as a serious threat to the development of accurate estimates of incidence rates or comparisons of incidence across categories of occupation, procedure, device type, etc. By comparing responses to anonymous questionnaires with aggregate data from institutional injury reports, the rate of underreporting has been estimated as ranging from 26 % to 90 %, with the extent of underreporting varying by occupational category [4 to 7; 18; 19]. Several possible reasons for underreporting have been described, e.g. the perception of low risk of infection associated with certain types of injuries, patients or both; lack of knowledge of the appropriate procedures after injury; fear of punitive employer response; time constraints and judgments of sufficient HBV vaccination [20; 22]. The ability to develop accurate estimates of risk and to compare estimates from different institutions is additionally hampered by the use of non-comparable denominators and varying requirements for injury reporting [4; 7; 18; 19].

3.2.4 Infection risk by pathogen

The overall rate of transmission of HBV among susceptible HCW without post-exposure prophylaxis or up to date vaccination has been estimated as ranging from 6 % to 30 % [4 to 7], although estimated rates of HBV infection among HCW have declined since the 1980s in the US by around 95 % [23]. Potential reasons for the declining infection rate include the licensing and increasingly common use of an effective vaccine, and changes in work practices, such as the adoption of universal precautions [2; 4].

Surveillance for HCV is not as well developed as surveillance for HBV, but a lower risk may be inferred from population (rather than occupational) studies. In four sentinel

counties in the US, HCV infection was about 0.14 case per 100,000 population in a 7 year period, and 2 % of those with acute HCV were HCW with reported "frequent" blood contact. Among staff of a single dialysis unit, the HCV transmission rate was 0.8 % over 3 years [2]. The transmission rate for HCV after percutaneous exposure is generally estimated to be about 3 % [4 to 6], but other estimates are as high as 10 % [7].

Fear of HIV transmission was the impetus driving the development of the so-called Universal Precautions against infection, and many of the preventive interventions discussed in this report. The transmission rate of HIV to HCW is estimated at less than 0.5 % [2 to 6; 19] but may be as high as 2 % [7]. Using either estimate, the risk of HIV infection is generally lower than the risk of infection by either HBV or HCV.

3.3   International NSI surveillance

Table 4 (see page 90) shows rates of NSI to HCW in several countries that reported surveillance data in a reasonably comparable format. Rates ranged from 6/100 occupied hospital beds in Australia (1995 to 1998) to 30/100 beds in the US (June 1995 to December 2001, NaSH system). While these data may reflect true differences in the rate of NSI in different countries, they may also reflect secular trends, differences in the likelihood of reporting or underreporting NSI; completeness of surveillance coverage; definitions of NSI; prevalence of use of safer devices; and differences in methods or assumptions underlying adjustment for underreporting.

Table 5 (see page 91) shows the distribution of NSI by HCW occupational group. Consistent with patterns reported in the literature, HCW most likely to be in direct patient contact were at the highest risk of NSI. Nurses and physicians, in that order, consistently reported the largest proportions of events. It has been suggested, however, that physicians are less likely to report NSI than members of other occupational groups [24 to 29] and therefore their risk might be underestimated by surveillance data.

Among NSI, syringes were more likely than other types of sharps to cause injury (Table 6, see page 92), but the proportions as captured by EPINet did not account for frequency of use of various types of equipment. The relative distribution of devices

involved in NSI might be altered if calculations accounted for frequency of use each type of equipment.

NSI are most likely to occur during use, with the second highest rate associated with recapping used needles and disposing of used sharps (Table 7, see page 93). These activities are all amenable to engineering controls and/or safety training aimed at reducing the NSI rate. Of note, the US Occupational Safety and Health Administration (OSHA) disallowed recapping beginning in 1992, with 29 CFR 1910.1030.

Bearing in mind that surveillance data are only available for hospitals, Table 8 (see page 94) shows that NSI were most likely to occur in patient rooms and operating rooms, locations where sharps were most likely to be used. Not included in these data were estimates for HCW employed in outpatient settings or nursing homes; home health care providers; emergency first responders; dentists and dental technicians; or others employed in non-hospital settings.

Limited NSI surveillance or survey data for individual or small groups of hospitals were available for several other European countries (Denmark, Greece, Sweden, and Switzerland) but are not shown in the tables because they do not represent national data. The patterns of NSI occurrence, including the relative distribution by occupational group, location, type of equipment and activity during NSI, were generally similar to the national patterns noted in the surveillance data described in tables 4 to 8: Nurses and physicians uniformly reported the most injuries, and the nurses' generally exceeded physicians' reports by at least a factor of two [25; 26; 28; 30]. NSI tended to occur most frequently in patient rooms [26; 28; 30], and needles were the most frequently involved type of equipment [25; 26; 28; 30]. The high rate of NSI due to recapping or improper disposal of used needles suggests that a large proportion of reported events were avoidable [25; 26; 28; 30].

Additional data were available based on a survey of hospital-employed physicians in Denmark by *Nelsing* et al. [31]. About 30 % of respondents practiced surgical specialties, and this subgroup reported higher rates of NSI compared to their colleagues in non-surgical specialties: There were 6 to 8 NSI per person-year at risk among general surgeons, orthopedic surgeons and neurosurgeons, versus 3.1 and 1.3 NSI per person-year among internists and anesthesiologists, respectively. Overall, the surgical

specialties accounted for 71 % of NSI reported by hospital physicians. Reflecting the composition of the study population, the most common devices causing NSI were surgical instruments and suture needles, and NSI were most likely to occur in the operating room (63.9 %). Among respondents practicing non-surgical specialties, IV stylets, injection needles and blood collection devices were the most likely types of equipment to be involved in NSI [31].

Work practices accounted for a substantial proportion of NSI in the study population of *Nelsing* et al. Respondents identified use of hands rather than instruments during surgical procedures (e.g., manual tissue retraction during surgery) and/or inattentiveness as the cause of 29 % of 689 NSI due to surgical instruments, and recapping used needles was the identified cause of 19 % of NSI among internists. Similarly, 35 to 50 % of NSI caused by IV stylets, injection needles and blood collection devices were attributed to poor work practices, suggesting both a high level of self-awareness of risky behaviors among Danish physicians and the possibility that training might afford an effective preventive measure [31].

3.4   Summary

Data from countries reporting NSI surveillance activities show consistent patterns of risk of NSI, and the patterns noted here are substantially similar to patterns noted by authors of literature reviews published over the last decade:

❑   As expected by simple probability, the largest categories of HCW and those with the most patient contact, nurses and physicians, were the most likely to report NSI.

❑   NSI were most likely to occur in patient rooms and operating rooms, locations where sharps were most likely to be used.

❑   Risk of injury varied by the type of sharp equipment in use. These patterns should be interpreted with caution, as they do not account for differences in the underlying frequency of use of various types of equipment.

❑   Two common activities leading to NSI were inappropriate use or disposal of equipment. It is likely that injuries resulting from these activities can be prevented

by taking greater care during use and disposal of sharps, improved design of

sharp equipment, and placement of disposal units in closer proximity to work

areas.

Comparison of international rates of NSI is facilitated by the use of similarly formatted

reports, but methodological differences persist. For example, the data elements in-

cluded in each country's reports were not identical, and the documentation accompa-

nying the reports was inadequate, e.g. failing to provide definitions or to specify

underlying assumptions. It is clear that different time frames were reported for various

countries participating in NSI surveillance and that the respective health systems are

not identical, but the data may lack comparability in other, less obvious ways. Factors

likely to differ internationally include the completeness and overall quality of the sur-

veillance systems. Within individual hospitals, there is likely to be underreporting of

NSI events, and the degree of underreporting could be differential by both occupation

and country. None of the surveillance data identified for this report included quality

audits. In addition, surveillance data describing NSI among HCW employed in non-

hospital settings (outpatient care, in-home care, emergency care, etc.) are currently

not tracked, so any national estimate of overall risk to HCW must be multiplied by an

unknown, but possibly large, factor.

As shown in the tables summarizing international data, surveillance systems typically

describe rates of NSI per 100 occupied hospital beds, as proportions of employees by

occupational category, and as proportions of events attributable to various types of

devices or procedures. These calculations might not provide the most accurate risk es-

timates. Because many hospitals employ contract workers, and part-time employment

or significant overtime (e. g. among medical interns) are also common, the use of

actual duty hours would account for work load and more accurately reflect time at risk.

Number of full-time equivalent employees (FTE) overall and in each occupational

category would offer a better approximation of risk compared to either occupied

hospital beds or total numbers of employees, and might result in a re-ordering of

the apparent risks among occupational groups. For example, data from *Luhti* et al.

showed a similar number of NSI among nurses and physicians overall (78 and 76 per

month, respectively). When the annualized rate of NSI by occupation was calculated,

however, the use of FTE as a denominator showed physicians to be at five times higher risk compared to nurses (11.05 per FTE per year versus 2.23 per FTE per year, respectively) [25].

By the same reasoning, risks of NSI associated with particular types of devices would be more accurately estimated as a proportion of the number of devices of a particular type used, rather than as the proportion of injuries caused by each type of device. Since the number of devices used may be nearly impossible to track, the numbers of devices ordered or stocked (by category) in a specific time period would be useful surrogates. Likewise, NSI risk according to procedure should be calculated as a proportion of each type of procedure performed, not as a proportion of all procedures.

Some of the available surveillance reports included data describing trends: These indicated that the rate of NSI has tended to increase over time. At least some of this increase may reflect the higher likelihood of reporting injuries that is expected to accompany enhanced awareness of risks.

In spite of the trend toward increases in reported NSI rates, underreporting continues to present a problem for the development of accurate risk estimates. The rate of underreporting is likely to depend on occupational category. Some data suggest that physicians and surgeons are least likely to report NSI compared to other occupational groups [5 to 7; 18; 32]. Anecdotal evidence and data from surveys suggest that self-assessment of low risk and likelihood of self-care for injuries influences underreporting by physicians [24; 25; 27 to 29].

Actual risk of infection to an individual experiencing NSI depends on many factors, including infection status of the patient, the patient's viral load; the immune status of the HCW; the depth of injury and duration of contact; the time interval between injury and wound cleansing; and the availability and use of prophylactic treatments. None of these factors are typically taken into account when estimating risks of patient to HCW transmission of blood-borne pathogens due to NSI.

Because the prevalence of blood borne pathogens in patient populations is not usually known, general population prevalence estimates may be used as approximations. However, this substitution is likely to introduce error into the estimated prevalence of

infection among patients, further invalidating the estimated risk of infection due to NSI. Inaccurate estimates of disease transmission risks reduce the ability to effectively plan for infection control measures and delivery of health care to HCW who may become infected due to NSI.

4   Intervention program evaluation

4.1   Methods

4.1.1 Screening the literature

More than 1,000 references from the searches which we conducted had to be screened individually due to the lack of specific key words in the PubMed system. The preliminary screening was based on the title, abstract and key words of each article, and aimed to identify a subset of literature for more detailed review. It also resulted in the identification of articles that required further screening (e.g. due to lack of an abstract) to determine usefulness. Reasons for exclusion after the preliminary screening were:

❑   publication language not English, German or French;

❑   inappropriate inclusion (e.g. author's name was "Sharps" and no relation to study issue);

❑   non-occupational setting, and/or targeted population was not HCW

❑   data were collected in a developing country (thought to have much different risks and resources than developed nations);

❑   focus was on product development rather than evaluation of a specific product or intervention program;

❑   commentary/editorial; call for/suggested changes in safety standards or regulations; practice guidelines; call for information; recommendation for increased surveillance for occupational sharps injuries;

❑   case report/case series;

❑   discussed only institutional liability or other legal issues;

❑   focus was on post exposure prophylaxis (PEP), seroconversion, and/or treatment;

❑   focus was on specific diseases such as HBV, HCV, HIV transmission, not restricted to transmission via NSI.

Based on this initial screening, 161 articles were identified as containing potentially useful descriptions of NSI prevention programs, and 117 articles were of uncertain utility due to the lack of detail in their abstracts, titles and/or keywords. Thus, 278 unique papers were obtained for individual, preliminary review. Several additional articles were added from the bibliographies of key review papers, and from the updated PubMed search. After preliminary review using the criteria shown in Table 9 (see page 95), there were 98 articles retained for possible inclusion in the Quality Based Critical Review (QBCR). These 98 studies were subjected to more detailed review to make a final determination regarding inclusion in or exclusion from the QBCR. The distribution of reasons for exclusion for the articles dropped from the QBCR based on the preliminary review is shown in Table 10 (see page 96). Finally 61 papers were included in the QBCR.

4.1.2 Detailed review

The final QBCR, comprising the remainder of this report, was organized according to category of intervention (equipment, training in safety procedures, or both). Within each of these categories, interventions were evaluated according to quality indicators as summarized in Table 11 (see page 97). The quality indicators address such characteristics as clarity of writing, degree of planning apparent in the development of the intervention, intervention design characteristics (such as use of an appropriate comparison group, random allocation to intervention vs. comparison group, likelihood of bias resulting from data collection procedures), statistical rigor and reasonableness of the authors' interpretation of the results, including a critical consideration of alternative explanations for the results. The form used to abstract data for the QBCR as well as the instructions for the reviewers are provided in the Annex (see page 104).

4.1.3 Ranking

Within each category of intervention, papers were ranked according to their quality. The most important characteristics considered were: clarity of study design and methods, study design and methods appropriately minimized bias and maximized information, allowances were made for pre-testing and training on replacement equipment,

use of appropriate statistical analysis, adequate statistical power, and consideration of potential bias and confounding in the authors' interpretation of results. The studies judged to be of intermediate quality had some, but lacked others, of these critical characteristics. Common shortcomings included unclear descriptions of training and/ or data collection methods, cursory discussion of results and minimal assessment and/ or discussion of potential of bias, confounding, and effect modification. The weakest studies, rated "poor", had one or more serious flaws in design or execution, unclear descriptions of methods and/or results, inadequate statistical analysis, and/or inadequate discussion of bias, confounding, and effect modification.

4.2   Results

The types of interventions described by the articles included in the QBCR can be grouped into equipment or engineering controls (n = 59) or training programs (n = 8), with the note that these categories are not mutually exclusive: some interventions introduced both equipment and training. Among the intervention studies involving equipment, 12 introduced safety devices to replace hollow-bore needles for injection or blood drawing, 26 introduced replacements for other types of sharps (e.g. catheters, suture needles, scalpels); and 21 introduced new assistive devices, modified disposal containers or double gloving protocols. Again, these categories are not mutually exclusive because some interventions introduced two or more types of equipment as part of the same program. The majority of intervention programs were implemented in the United States (62 %) or United Kingdom (12 % – Table 3).

4.2.1 Replacement of hollow-bore needles for injection or blood drawing

Fourteen of the papers identified described evaluations of devices designed to replace traditional hollow-bore needles. Three interventions, described in four papers, were rated "good" and will be described in detail [33 to 36]. The remaining intermediate [37 to 41] and poor quality papers [42 to 46] will be summarized briefly.

☐   Good quality

Based on a previous review of causes of percutaneous injuries within their institution, a 900-bed urban hospital (US), *Orenstein* et al.[33] completed a twelve-month prospective evaluation of the Becton-Dickinson 3 milliliter (ml) Safety-Lok syringe with a 23 gauge needle and protective sheath (Becton Dickinson Corp.). The evaluation was completed between 1992 and 1993. Five medical and surgical units were randomly selected to test the new devices, and data were concurrently collected from an additionnal unit that served as a comparison series. A total of 262 nurses were included in the trial. Outcome data were obtained in three ways:

1. standardized incident reporting forms were collected weekly by infection control practitioners and a physician investigator;

2. employee health records were reviewed daily for evidence of NSI; and

3. lab records were reviewed to identify staff seeking serology during the study period.

The NSI rate was calculated as the number of injuries per HCW days, defined as the number of staff assigned to study units multiplied by the number of days worked during the intervention interval. In addition to number of work days, the authors considered the following covariates: degree of illness among the patients, reporting methods, season, and staffing.

A total of 14 NSI were reported following the introduction of the safety devices. Overall, nurses in the intervention units experienced 61 % fewer NSI (0.303/1,000 HCW days) compared to nurses in the comparison unit (0.785 NSI/1,000 HCW days, $p = 0.046$). Subcategories of NSI associated with IV line manipulation, use of 3 ml syringes, and sharps disposal were also reduced, by about 50 % each. Reductions in these subcategories were not statistically significant, possibly due to the small number of events within categories, and the resulting lack of statistical power.

This well-designed intervention evaluation benefited from the use of active surveillance for injuries, which helped to decrease the likelihood of confounding due to underreporting. The inclusion of a comparison ward and consideration of a number of potential confounders also added to the quality of this evaluation. The investigators additionally allowed time for training staff in the use of the replacement devices, but

did not specify whether or not the training interval was excluded from the analyses. In spite of training, staff reported difficulties using the Safety-Lok syringe, and compliance with use of this device was notably low.

Sohn et al. [34; 35] used NaSH data to compare self-reported NSI for three years preceeding (1998 to 2001) and two years following (2001 to 2002) institution-wide introduction of various replacement devices (product names and manufacturers not specified) in a 427 bed tertiary-care hospital (US). The equipment included needle-safe intravenous (IV) delivery, blood collection, IV insertion, and intramuscular and subcutaneous injection devices. The specific devices were selected for broad introduction and evaluation after a year of short-term piloting on various hospital units with evaluation by both nursing and medical staff.

NaSH data allowed for calculation of NSI rates per full-time equivalent employee (FTE). Of the 529 blood exposure events reported during the entire study period, 449 (84.9 %) were percutaneous injuries. During the 36-months preceding the intervention, 390 NSI were reported, for a monthly average of 10.83 (standard deviation, SD $\pm$ 3.02) and an annual average incidence rate of 34.08 NSI /1,000 FTE (SD $\pm$ 9.49). Following introduction of the safety-engineered devices, 59 percutaneous injuries were reported, yielding a monthly average of 4.92 NSI/1,000 FTE (SD $\pm$ 2.97) and a decrease to 14.25/1,000 FTE annually (SD $\pm$ 8.61, $p < 0.001$ for both comparisons).

Within occupational groups, nurses experienced the greatest reduction in injury rate (74.5 %, $p < 0.001$), followed by ancillary staff (61.5 %, $p = 0.03$). Statistically significant reductions were also observed for the specific activities: manipulating patients or sharps (83.5 %, $p < 0.001$), collisions or contact with sharps (73.0 %, $p = 0.01$), disposal-related injuries (21.41 %, $p = 0.001$), and catheter insertions (88.2 %, $p < 0.001$). Analyses by device type indicated a 71 % reduction in NSI involving hollow-bore needles ($p < 0.001$). The authors reported evidence of contamination of the intervention period, with 390 NSI reported due to conventional devices during the intervention period, when only new equipment should have been in use.

The major strengths of this program included the pre-testing of candidate replacement equipment by staff, the exclusion of the pilot-testing period from the analysis, and the consideration of secular, policy, and procedural changes during the study period that

might have influenced the number of procedures performed by particular categories of HCW over the four year observation period. The major weaknesses were reliance on passive surveillance and the lack of information regarding the specific devices used.

Mendelson et al. completed a similarly designed evaluation of the Safety-Lok re-sheathable winged steel needle (Becton Dickinson Corp.) [36]. The evaluation was conducted in a 1,190 bed acute care hospital in New York City (US). An 11-month intervention period was followed by a 31-month post-intervention observation period, and risk of NSI was quantified as relative risk (RR) and 95 % confidence interval (CI) comparing the two. Overall, NSI associated with winged steel needles declined from 13.41 to 6.41 per 100,000 devices ordered (RR 0.48; 95 % CI 0.31-0.73) following implementation of the safety device. Injuries occurring during or after disposal were reduced most substantially (RR 0.15; 95 % CI 0.06-0.43). Because injuries were reported directly to the area supervisor, underreporting could have inflated these esti-mates of benefit. Overall, however, this intervention was well-planned, and included both objective outcome measures and consideration of potential confounding by such covariates as type of procedure, occupation, work location, timing and mechanism of injury.

The remaining interventions employing replacement hollow-bore needles were rated as intermediate [37 to 41] or poor quality [42 to 46]. Most employed weak study designs, e.g. employing ecological (group-level) measurements. Other common problems included lack of description of data collection methods, or the methods were clearly subject to bias; information on statistical methods was lacking; and/or potential biases were not acknowledged by the author(s). In several cases, the authors over-interpreted the results, generalizing to populations or health care settings beyond the scope of the paper. While the results all showed reductions in NSI with the introduction of safety engineered hollow-bore needles, weaknesses in study design and/or analysis did not allow for a causal interpretation of the changes in NSI rates.

❑   Intermediate quality

Alvarado-Ramy et al. combined NSI data from 1993 to 1995 from 10 hospitals to evaluate the efficacy of the Safety-Lok resheathable winged steel needle (Becton Dickinson Corp.), the Punctur-Guard bluntable vacuum tube blood-collection needle

(Bioplexus, Inc.), and Venipuncture Needle Pro resheathable vacuum tube blood-collection needles (Protex Inc.) for phlebotomy [37; 38]. The ten participating hospitals did not use standardized reporting methods: some relied on institutional injury surveillance policies and data collection, while others surveyed their employees specifically for this evaluation. In spite of documented differences in data collection methods and associated differences in likelihood of completeness, and therefore, potential for bias, the authors combined data from all ten hospitals for their efficacy analysis.

Completeness of reporting, assessed by comparing interview (recall) results for a sample of participants with the number of phlebotomy-related NSI reported at the institution level, was about 90 %. Although the authors concluded that the three selected replacement devices reduced NSI rates when compared with conventional devices, they were not able to verify that conventional equipment had, in fact, been replaced.

Trape-Cardoso et al. [39] used passive surveillance data available from the NaSH system for an ecological evaluation of the effectiveness of multiple interventions introduced between 1997 and 2002. In addition to safety piggyback (interlink) systems, safety butterfly needles, retractable lancets, and, eventually, replacements for all needles attached to syringes, administrative and educational interventions were also implemented. Specific product names or manufacturers were not specified.

From unadjusted analyses, the authors concluded that NSI to medical and dental students and nursing staff declined over a five-year period. Reported incidence rates decreased from 7.9 % in 2000 to 2001 to 2.6 % in 2001 to 2002 for students, and from 9.2 % in 1997 to 1998 to 2.7 % in 2001 to 2002 for nursing staff. There was also a small decrease in NSI among residents, but the effect was temporary. The reversal of the trend in NSI among residents argues against a causal effect of the interventions, and suggests the possibility of differential completeness of reporting by HCW category. If the devices were effective at reducing NSI, the effect should have been seen among all potential users and should not have been transient.

Younger et al. [40] evaluated the Monoject Safety Syringe (Sherwood Medical), a shielded 3 cc safety syringe. Three participating medical centers reported the number of NSI among staff relative to the number of inventory units ordered per year. *Younger*

et al. did not provide a clear description of their data collection methods, but did indicate that participating centers may have had different reporting policies and procedures. Systematic biases are thus possible, but were not addressed by the authors. Unadjusted analyses indicated an overall increase in the total number of NSI, from 134 during the baseline period to 140 after introduction of the Monoject; this suggests an increase in completeness of reporting, possibly stemming from increased awareness of NSI and safety among participating staff. When analyses were restricted to 3 cc syringes, reported NSI decreased from 14/100,000 inventory units to 2/100,000, with similar declines at each of the participating medical centers.

The Septodont Safety Plus disposable syringe (Deproco UK Ltd.), evaluated by *Zakrzewska* et al. [41], apparently reduced the number of "avoidable" NSI from an average of 11.8/1,000,000 work hours per year to none among staff of a dental school in the United Kingdom, including students, dentists, dental nurses, hygienists and therapists. An additional hospital unit was monitored for NSI concurrently with the intervention units; the comparison group experienced an NSI reduction from 26 to 20 NSI/1,000,000 work hours. Although the results reported by *Zakrzewska* et al. appear dramatic, the analysis was based on a small number of reported NSI and data collection methods were not well-specified in their paper. It was, therefore, impossible to evaluate the possibility of bias or errors as alternative explanations for their results.

☐   **Poor quality**

The evaluations described by *Dale* et al. [42] and *Rogues* et al. [45] each used an ecological design to evaluate the effectiveness of several concurrent changes to the phlebotomy service in their institutions. These results of their studies could not be used to separately assess the effectiveness of safety engineered equipment (recapping blocks, single use evacuated tube holders, re-sheathable needles, retractable lancets, and retractable capillary puncture devices) from secular changes arising from policy or training modifications, changes in awareness or compliance with universal precautions. *Dale* et al. noted increases in the number of and improved locations for needle disposal containers and discontinuation of the practice of changing needles before inoculation of blood culture bottles that were concurrent with introduction of new equipment. In addition, NSI reporting policies were changed. Initially, NSI were

counted proportionate to all needles used (clean or used); subsequently, NSI were counted proportionate to used needles, only.

Neither *Dale* et al. nor *Rogues* et al. conducted statistical analyses, but both reported reductions in NSI to phlebotomists, from 1.5/10,000 venipunctures to 0.2/10,000 venipunctures in the *Dale* et al. study, and from 18.8/100,000 devices purchased to 7.4/100,000 devices purchased in the *Rogues* et al. study. The authors asserted a causal link between the changes implemented and the reduced risk of NSI, without addressing the methodological weakness of the ecological study design or other complications, such as concurrent changes in NSI reporting, as described above.

D'Arco et al. [43] also used an ecological design in their evaluation of a venous arterial blood management protection (VAMP) needleless blood drawing system (Baxter HealthCare). Needleless IV equipment and changes to needle disposal container locations were introduced at the same time as the VAMP. The authors suggested a causal relationship between the observed decrease in NSI and changes in equipment and staff education, although there were no adjusted analyses presented to support their conclusion. Because of the lack of information on data collection procedures, it was impossible to assess the validity of the reported results.

McCleary et al. [44] evaluated the Medisystems Arteriovenous fistula needle (AVFN) with MasterGuard for use during hemodialysis in five affiliated dialysis clinics. In 81,534 cannulations, the unguarded AVFN injury rate was 8.58 NSI per 100,000 unguarded compared to no NSI using guarded AVFN in 54,044 cannulations (p < 0.029). The primary weakness of this report stemmed from the lack of information regarding data quality, completeness, and collection techniques. It was, therefore, not possible to adequately assess the quality of the intervention evaluation.

In another ecological evaluation, *Louis* et al. described a six-month intervention introducing a safety device to prevent against blood exposure accidents (no product information provided). Since the study article was missing critical elements, (no consideration of target population, no information on data collection, no information on training, did not assess confounders, no statistical analysis or methods described) the causal relationship in the reduction of monthly accidents (from 2 to 0.16 accidents per month), cannot be attributed to this new safety intervention [46].

4.2.2 Other sharps

Of the 26 interventions in which other (non-hollow bore) needles were replaced, 15 evaluated needleless IV systems, six introduced blunt suture needles, two introduced safer (not needleless) IV delivery devices and three evaluated the use of retractable lancets. Results will be discussed according to the general type of equipment evaluated.

4.2.2.1   Needleless IV systems

Of the 15 needleless IV evaluations, two studies were classified as good quality [33; 47], and the rest were considered poor [43; 48 to 59].

❐   **Good quality**

Both studies of *Orenstein* et al. and *Mendelson* et al. are described in the "replacement needles" section, above [33; 47]. *Orenstein* et al. [33] evaluated the effectiveness of the Baxter InterLink intravenous system (Baxter Healthcare Corp.), components of which were substituted for standard IV set-ups on five hospital wards. The rate of IV-related injuries to nurses in the intervention wards was compared to the IV-related injury rate among nurses employed in a comparison ward using standard IV equipment. Although the NSI rate associated with IV line manipulation declined among nurses in both the intervention and comparison unit, there was no statistically significant difference between groups at the end of the intervention interval. Additionally, the authors observed a decline in the rate of NSI under circumstances considered not preventable by the InterLink, suggesting an overall lack of benefit attributable to efficacy of the replacement equipment. However, the overall number of NSI during the study year was relatively low, and lack of statistical significance also reflects lack of statistical power. Additional injuries associated with use of the InterLink might have been avoided during the intervention period had the entire replacement device been used, rather than the mix-and-match setups introduced by the investigators.

Mendelson et al. [47] introduced a needleless IV system, the "Safsite", to 16 medical and surgical units at an acute-care teaching hospital. The six-month study employed a cross-over design with random assignment of wards to replacement sharps versus

traditional equipment. Wards were included in the intervention evaluation on the basis of their similarity with respect to staff-patient ratio, and types and degrees of illness of the patients. Twenty-seven of the 35 NSI reported during the study were not related to IV manipulation, and therefore were not preventable by the SafeSite. All of the remaining eight injuries were associated with use of traditional equipment. However, because staff were aware of the type of equipment they used and reporting NSI was voluntary, bias might have played a role in these results.

❑   Poor quality

The remaining 13 evaluations in this group all showed decreases in NSI with the introduction of safety engineered needleless IV devices [48 to 54]. The authors of three papers rated their own results as reliable, but failed to consider important limitations. Specifically, *Gershon* et al. [49] failed to consider reporting bias suggested by a steep decline in NSI immediately following implementation of the intervention (no product name provided). *Gartner* [48] and *Yassi* et al. [54] both evaluated the InterLink System (Baxter), and each failed to consider alternative explanations for their results, including potential biases and confounding. Both groups also used passive surveillance to detect NSI, which could introduce biases if differential underreporting occurred, as may be expected if participants were aware of the intervention, and/or if they were aware of an institutional interest in reducing NSI rates. *Yassi* et al. also failed to statistically test for between-group differences.

The authors of the other poor quality evaluations also reported decreases in NSI after introduction of a needleless IV system, but were more appropriately cautious in interpreting their results [50 to 53]. *Moens* et al. completed an ecological-level assessment by comparing institution-wide NSI rates before and after the introduction of a needleless IV system (no product information provided) [52]. *Lawrence* et al. [50] conducted a retrospective evaluation of the InterLink System. The authors attempted to adjust for secular trends in NSI rates or changes in institutional procedures or policies that might have influenced either the likelihood of injury or of injury reporting (a strength), and reported an adjusted RR of 0.46 (95 % CI 0.32-0.65) when the new devices were used. However, traditional IV devices remained in use during the so-called intervention period, biasing results toward the null. Similar contamination of study groups was

notable in the evaluations completed by *Reddy* et al. (no product information pro-
vided) [53] and by *L'Ecuyer* et al. (three products introduced concurrently) [51]. *Reddy*
et al. additionally relied on a poorly designed NSI report form that lacked an ade-
quate level of detail and standardization, and the analyses of *L'Ecuyer* et al. were
hampered by low statistical power due to a small number of reported injuries. Inter-
pretation of the *L'Ecuyer* et al. results was also problematic, because the investigators
introduced three different products as part of the same intervention. It is impossible to
attribute changes in NSI rates to any one replacement device [51].

Five papers evaluated the efficacy of the InterLink System [43; 55 to 58] and one
considered the Safsite [59]. In general, these authors failed to discuss possible bias,
confounding, or effect modification, and all but one failed to provide appropriate
statistical analysis. Five of the poor quality studies did not provide adequate descrip-
tion of data collection methods, rendering judgment about possible biases impossible
[43; 56 to 59]. The sixth paper in this group, *Beason* et al., was judged unreliable
because of its very short intervention period (one month), which did not allow for
collection of sufficient data for analysis and interpretation [55].

4.2.2.2   Blunt suture needles

Six papers described evaluations of blunt suture needles. One was rated "good qual-
ity" [60] and five were intermediate [61 to 65]. All authors reported large reductions in
the risk of NSI and/or glove perforations when blunt needles were used, but it was dif-
ficult to assess the validity of the results due to weaknesses in study design or insuffi-
cient detail in the reports.

❏   **Good quality**

Mingoli et al. evaluated the use of the Protect Point MT25 (Davis and Geck, Inc.) blunt
suture needle for closure of incisions to the abdominal fascia [60]. One hundred sur-
geries were randomly allocated to the intervention condition, and compared with 100
surgeries in which standard suture needles were used. Study personnel observed all
surgeries, and inspected the surgeons' hands for injury and/or skin contamination
prior to initiating closure, when fresh gloves were put on. Following each procedure,

all used gloves were tested for perforation, a surrogate measure of risk of NSI. In addition to reducing likelihood of confounding by random allocation to the blunt versus traditional needle groups, the authors evaluated potential confounding by time of day, operation length, and surgeon experience.

Overall, 14 NSI were observed, all due to sharp needles. Seventy-six perforations were detected in 69 pairs of gloves, and 58 of them (76 %) were from sharp needles. Glove perforations during abdominal fascia closure were found to be mostly related to use of sharp needles (50 % due to sharp needles versus 7 % due to blunt needles; $p < 0.0006$). Surgeon experience and duration of procedure were not associated with the likelihood of NSI or glove perforation, but skin contamination was more likely to occur during procedures carried out during the night shift.

◻   **Intermediate quality**

The remaining five evaluations of blunt suture needles were rated "intermediate" quality [61 to 65]. Three of these articles described evaluations of the Ethigard (Ethicon) blunt suture needle: *Hartley* et al. reported a decrease in the rate of glove perforation from 14/39 sharp needles used to 3/46 when the Ethigard was used, $p < 0.001$ [62]. *Wright* et al. noted 31 perforations in 16 out of 62 gloves worn while using a "cutting needle" and 18 perforations in ten out of 76 gloves worn while using a "taperpoint needle" ($p = 0.049$). In addition, three NSI were reported, two from cutting needles and one from a wound-drain introducer, but none from the Ethigard [64]. The final study in this group reported a reduction from 5.9 NSI/100 procedures prior to introduction of the Ethigard to 1.1 NSI/100 procedures after the Ethigard was adopted [61]. *Rice* et al. evaluated the Maxon Protec blunt suture needle (Davis and Geck, Inc.), and found that 16 % of outer and 6 % of inner gloves were perforated when traditional sharp needles were used, but there were no perforations among gloves worn by surgeons using the Maxon Protec ($p = 0.026$) [63]. *Meyer* et al. found that 39 % of surgical gloves were perforated when standard sharp needles were used, compared to 23 % of gloves perforated with use of the Protect Point (Maxon-Faden) blunt suture needle [65].

The evaluations by *Hartley* et al*., Rice* et al., *Wright* et al. and *Meyer* et al. each used a randomized design, but the reports were brief and lacked sufficient detail for a fair assessment of their quality and the validity of their results [62 to 65]. For the final report in this group the use of the intervention device was optional. Only 4 % surgeries were undertaken using a blunt suture needle alone while 24 % were performed using both the conventional and intervention devices and 74 % were performed using the conventional device alone. It is unclear how it was determined which device caused the injury when both devices were used. Therefore it is difficult to assess the effectiveness of the device in reducing injuries [61].

4.2.2.3   Safety-engineered IV systems (not needleless)

Re-engineered, but still sharp-containing IV systems were evaluated in two papers, which both were rated of intermediate quality [34; 66].

O'Connor et al. evaluated the use of a self-sheathing IV catheter in one emergency medical services system, with voluntary injury reports collected retrospectively from employee records [66]. Prior to the evaluation, employees received training in the use of the new devices and were encouraged to report all NSI. The estimated annual incidence of "contaminated" NSI dropped from 169/100,000 attempts at IV access (CI: 85, 253) to none (CI: 0, 46) following introduction of the safety IV. Overall, estimated annual incidence of NSI dropped from 231/100,000 attempts at IV access (CI: 132, 330) to 15/100,000 attempts (CI: 0, 40). Underreporting of NSI is likely to have played a role in the dramatic declines noted by *O'Connor* et al., because they noted similar decreases in NSI due to conventional catheters, from 176/1,000 employee-years prior to the intervention none during the study period.

The study by *Sohn* et al. is described in detail in the "replacement needles" section above [34]. While the results were presented separately for hollow-bore devices, the results for several other replacement devices were grouped together. The mean annual incidence of NSI decreased from 34.08 per 1,000 FTE employees before the intervention to 14.25 per 1,000 FTE employees after the intervention (p < 0.001). The concurrent introduction of multiple safety devices as part of the same program and the combined analysis does not allow for a valid assessment of the efficacy of any specific

device, including possible increases in safety awareness at the institutional level that could influence completeness of reporting or perceived disincentives to fully disclose NSI.

4.2.2.4   Retractable lancets

Three papers described the effectiveness of retractable lancets, but all were rated "poor" [42; 67; 68]. The evaluation by *Dale* et al. is described in the section on hollow-bore needles, above [42]. *Peate* employed an ecological study design, and lacked adequate statistical analysis to support his conclusions regarding efficacy [68]. *Roudot-Thoraval* et al. introduced several interventions to reduce NSI as part of the same program [67]. Apart from the resulting inability to separate the effects of the retractable lancets from other aspects of the program, the data collection methods were poorly described and appeared to be subjective, and statistical analyses in support of the authors' conclusions were not presented.

4.2.3 Other safety equipment

This section describes evaluations of other types of equipment designed to protect against NSI, rather than replacements for sharps. These include assistive devices for safely recapping used syringes, changes to disposal unit location or conformation, and double gloving protocols.

4.2.3.1   Assistive devices

Concerns pertaining to hazards of disposing of uncapped needles have motivated the creation of protective equipment that allows for safe recapping of used syringes. The recapping guard is a plastic shield with a central hole that receives the capped end of a needle. The guard can be used to remove and replace the cap or sheath of the needle while keeping the non-active hand protected. A recapping block supports needle covers in an upright position, allowing the user to recap the needle without holding the cover.

Two articles, both rated as poor quality, described evaluations of the efficacy of recapping guards [69; 70]; one, judged to be of intermediate quality, evaluated use of a

recapping block [71]. Also in the category of "assistive devices" is the Suture Mate, a small plastic device that contains an abrasive surface for cleaning needles, a sponge used to embed needles when not in use, and a cutting slot to assist in knot tying during surgery [72].

Goldwater et al. introduced voluntary use of a needle guard to a medical laboratory with approximately 70 employees [69]. On a typical day, between 1,000 and 1,100 venipunctures were carried out. NSI reports during 32 months following introduction of the guard were collected via a passive system, and comparisons were made between the NSI rates among users (n = 47) and non-users (23) of the needle guard. The average monthly NSI rate for needle guard users was 1/16,100 venipunctures (0.006 %), none due to recapping. Non-users were injured 1/3,739 venipunctures (0.03 %).

The major problem with this evaluation stems from voluntary use of the needle guard, and associated potential for bias due to differences in work practices between the user and non-user groups. Although no statistical analyses were presented by *Goldwater* et al., and no attempt was made to assess or control for potential confounding, the authors concluded that the needle guard was effective at preventing NSI among phlebotomists [69].

Based in part on the findings of *Goldwater* et al., *Whitby* et al. adopted the needle guard system at the Princess Alexandria Hospital of Australia. Contrary to the previous findings, *Whitby* et al. observed an increased risk of needle stick following adoption of the needle guard and associated training [70]. Injury reports were collected through a passive surveillance system, supplemented by questionnaires from approximately 25 % of the hospital staff that allowed for an assessment of underreporting rates. The authors determined that the baseline rate of reporting of NSI (i.e., prior to introduction of the needle guard) was approximately 36 %. After implementation of the intervention, which included safety training, reporting rates rose to nearly 75 %. This difference in reporting practices could have contributed to the observed increase in NSI risk associated with use of the needle guard. In addition to changes in underlying reporting rates, the *Whitby* et al. program included concurrent introduction of a new lancet that was not compatible with the needle guard. This new lancet could have minimized any protective effect the needle guard may have incurred, and the introduction of more

than one type of equipment makes it difficult to assess the effect on injury rates of either one.

Wright et al. tracked NSI during a ten-month interval following introduction of a needle recapping block [71]. There was a 60 % reduction in NSI that could have occurred after use, when a needle could have been recapped reported by nurses and housekeeping staff (OR 0.4; 95 % CI 0.18-0.82). The OR for cover-irrelevant injuries was 0.92 (95 % CI 0.40-2.03), indicating that major changes in underlying injury rates or reporting practices during the evaluation period were unlikely. However, two factors might have influenced the results, and they might have operated to either inflate or deflate the effect estimate. Specifically:

a) NSI reporting procedures were made easier during the intervention period. This would lead to an increase in the observed number of injuries, suggesting the effectiveness of the recapping block might be more protective than observed; and

b) A new sharps disposal system was implemented concurrently with the introduction of the recapping block.

The new system eliminated the occurrence of injuries resulting from needles protruding "through the rubbish bag", which is among the injury types use of a recapping block would also be expected to reduce (if the disposal system had remained the same).

Bebbington et al. conducted a good quality evaluation of use of the Suture Mate during obstetric surgery to repair vaginal tears [72]. Individuals performing the surgery included obstetricians, family physicians, residents, and medical students. Practitioners used the device for a three-week training period prior to the evaluation period, and the primary outcome measure was glove perforations as a surrogate for NSI risk. Perforations were detected through standard water manipulation, by study personnel blinded as to group assignment. The intervention group and the comparison group each contained 250 sets of gloves. Twenty gloves in the study group and 67 gloves in the control group were perforated. Based on stratified analyses, the authors concluded that the Suture Mate was statistically significantly protective in all groups except for medical students. The authors reported that 90 % of the practitioners reported satis-

faction with the Suture Mate, so compliance with the intervention may be assumed to be at least that high.

While generally employing a strong study design, there was one relatively serious problem with this trial stemming from potential selection for the complexity of surgical repair. Because the practitioners agreed to use the Suture Mate on a case by case basis, and after evaluating their patients, it is possible that more labor intensive repairs were not included in the trial. If participation in more difficult surgery is associated with a higher risk of NSI (or, in this case, glove perforation), then the observed results would have been artificially inflated in favor of the Suture Mate [72].

4.2.3.2   Disposal boxes

Various characteristics of needle disposal boxes were considered among the eleven papers in this group: Four assessed the effect of changing location, four assessed the effect of changing to a more rigid container with no change in location, and three assessed the effect of physical modifications to the box design. This section is subdivided according to these three primary manipulations (location, rigidity, modification).

☐   Location

Three studies in this subgroup, described in four papers, utilized a pre-post intervention comparison to assess the effectiveness of locating needle disposal boxes at the bedside or in patient rooms [73 to 76]. The hypothesized mechanism through which the relocation of needle disposal boxes may reduce the risk of injury is through minimizing the practice of recapping needles. Thus, the outcome of interest in these studies was the observed proportion of recapped needles found within the disposal boxes.

A major concern with the pre-post study design is the difficulty of controlling for secular changes related to the outcome occurring during the same time interval. For example, the relocation disposal boxes may also correspond with new training, policies, type of box being used, or other interventions. These studies were considered strongest if the authors considered the potential effects of simultaneous changes not directly related to the needle disposal box location. Additional factors that contributed

to the quality assessment of the studies included appropriate definition of outcome, reliability of outcome assessment, and appropriate time intervals.

The best of this subgroup was by *Makofsky* et al., judged to be of intermediate quality [76]. Hospital employees within a medical/surgical ward and an intensive care unit were part of the evaluation. Prior to the intervention, needle disposal boxes within the medical surgical ward were located in common restrooms; the intensive care unit already had bedside needle disposal boxes, and thus served as a comparison series. On the medical-surgical ward, the intervention consisted of relocating needle disposal boxes to patient bedsides and changing from round to letterbox style. Box type alone was changed for the intensive care unit, so post-intervention changes could be attributed to the change in the box type and not relocation. Prior to the intervention, 20 boxes in the medical-surgical ward and seven from the intensive care unit were collected and rates of needle recapping were determined. Six months later, boxes were again collected and recapping rates determined. The authors observed no differences in recapping rates in the intensive care unit (change of box type, only), but a statistically significant decrease from 30.2 % to 26.2 % recapped needles in the medical-surgical ward following the intervention (p = 0.0019). Although the outcome measure was not a direct measure of injury incidence, it was an objective, valid and reliable metric, given the study design and objective. A major strength of this evaluation was the authors' consideration of the potential effect of changing disposal type in addition to location.

Two other interventions (described in three papers) evaluated the effect of bedside placement of disposal boxes and risk of injury; both were rated "poor" quality. The two *Haiduven* et al. papers described a program in which needle disposal boxes were relocated to the area of use [74; 75]. The number of reported needle stick injuries decreased from 144 in 1986, the year preceding the intervention, to 104 in 1990 (p = 0.003). The number of reported injuries specifically resulting from recapping decreased from 32 in 1986 to six in 1990 (p = 0.005). The authors' selection of reported annual injury incidence failed to account for changes in number of personnel or number of procedures between intervention periods. No adjusted analyses were presented in either report, although the second paper describes a concurrently imple-

mented educational program. It was not possible, therefore, to conclude that changes in reported injury rates were the result of box relocation, increased safety awareness or changes in knowledge resulting from the educational program, or uncontrolled confounding.

Edmond et al. placed observers to record needle recapping by nurses before and after relocation of needle disposal boxes [73]. The observed rates of recapping both before and after relocation of the boxes held steady at higher than 90 %, suggesting either that this was a uniquely non-compliant population or that the presence of the observers affected the nurses' behavior more than placement of the disposal boxes.

❏   Rigid disposal containers

The pre-post intervention comparison was also used by all four of the studies within this subgroup assessing the effectiveness of transitioning from cardboard disposal boxes to impermeable plastic boxes [43; 77 to 79]. None of these evaluations adequately addressed the concern about concurrent changes in practice, policy or background risks (e. g. due to changes in staffing levels). All relied on self-reported injuries, potentially introducing bias if reporting practices changed during the observation period independent of the change to rigid disposal containers.

D'Arco et al. rated poor, implemented several interventions at the same time, including safety training and improvements to injury reporting systems, in addition to the transition to rigid disposal containers [43]. Though a decrease in the needle stick injury rate was observed, it was not possible to conclude that the decrease was attributable to the new disposal boxes.

Smith et al. judged to be of intermediate quality, reported no change in injury rates following introduction a plastic sharps disposal box [79]. However, they did note that the number of needle containing devices used increased 13.5 % over the observation period. Therefore, a constant incidence of needle stick injuries may actually be indicative of a decreased risk, since exposure had increased. The analyses presented by the authors were inadequate to reach a firm conclusion, however.

Ribner et al. and *Krasinski* et al. both of intermediate quality, provided slightly more evidence of the potential protective effect of rigid containers as compared to card-

board containers [77; 78]. In both programs, concurrently initiated educational programs complicate the interpretation of results. *Ribner* et al. reported a reduction in disposal-related needle stick injuries from 0.9 per FTE to 0.3 per FTE over the observation period [78], and *Krasinksi* et al. reported reductions in disposal-related injuries from 1.3 to 0.3 per month [77]. The rates of other needle stick injuries (e. g. occurring during procedures, due to recapping, or carrying sharps) remained the same or increased. The decrease in disposal-related injuries in either of these studies could be due to changes in needle disposal practices, such as avoidance of overfilling disposal units, more frequent emptying of units, or greater caution while disposing of sharps, or to changes in reporting practices following from the educational programs.

❒   **Other design features**

Three interventions focused on changes in box design, including open top, letterbox style units, units with hinged lids and units with clear tops [80 to 82]. The letterbox style disposal unit has a counterbalanced lid that allows sharps to enter but is otherwise closed. All employed weak methods, and were considered to be of intermediate quality.

Hatcher compared NSI rates with the use of a straight drop disposal box vs. use of a letter drop box [81]. During a 24-month baseline observation period with a straight drop container, 2.83 injuries/month were reported. During the 14-month period following introduction of the letterbox style unit, 1.17 NSI/month were reported. After adjusting for number of people at risk, the author noted a statistically significant change from 0.36 % of employees reporting injuries with old box to 0.13 % reporting injuries with the new box (p = 0.002). The main strengths of this evaluation were the inclusion of a pre-testing period to acquaint employees with the new equipment, and the adjustment for changes in the size of the population at risk. However, no other potential confounders or biases were considered, and the author failed to adequately describe or consider the impact of concurrent safety training. In addition, the outcome was poorly defined in this report.

In another study, *Sellick* et al. described three separate time periods [82]. Data were collected over a nine-month interval prior to the implementation of any interventions to

serve as a baseline period. The first intervention consisted of an educational program and moving disposal units to the bedside. Data were collected for six-months to assess the effectiveness of these changes. Finally, disposal units with clear lids replaced the hinged lid disposal boxes at bedside, and data were collected for an additional nine-month period.

Comparing the baseline interval with the first stage intervention, the authors reported a statistically significant increase in NSI due to needles protruding from the disposal boxes ($p = 0.002$). The investigators found that needles frequently fell into the boxes vertically (needle-tip up) rather than horizontally, and healthcare workers reported an inability to determine whether the disposal box was full. Replacement with clear-lidded boxes resulted in a decrease of injuries resulting from protruding needles or occurring during disposal (i. e. comparing periods two and three), but the NSI rates were not significantly different from those observed during the baseline interval [82].

Grimmond et al. investigated the effectiveness of the Sharpsmart disposal system in eight international acute care hospitals (Australia, 5; New Zealand, 2; and Scotland, 1) [80]. The Sharpsmart disposal system includes a puncture resistant container, location in patient rooms, and sterilization of used disposal containers. The containers also have passive overfill protection, hand entry prevention, and multiple brackets allowing for flexibility in placement. Reported sharps injuries were categorized using EPINet criteria with seven additional categories. Outcomes of interest for evaluation of the Sharpsmart system include injuries occurring while putting an item into disposal container; injuries due to sharps protruding from disposal container; and injuries due to sharps that pierced the side of disposal container.

The authors reported a total of 60 container-related injuries due to sharp equipment (CRSI) during a baseline observation period, compared to three CRSI during Sharpsmart use. The overall decrease was from 0.5 CRSI per FTE/year to 0.07 CRSI per FTE/year ($p = 0.011$). The main strength of this evaluation derived from its focus on a single intervention, which was completely adopted by seven of eight participating hospitals. Although the authors presented some stratified analyses, they did not adequately account for baseline differences between the participating hospitals [80].

4.2.3.3   Double gloving

Five authors evaluated the protective effect of double gloving against surgery-related NSI. Four were similar with respect to design, methods and findings, and were rated of intermediate quality [83 to 86]. These studies were randomized trials, and the outcome of interest was incidence of glove perforations as a proxy for injury. Study methods were similar with respect to use of latex gloves, detection of perforations through water manipulation, and assignment of single or double glove barrier through randomization. While all four studies concluded that perforations were less likely when double gloves were used compared to single gloves, only *Jenson* et al. and *Doyle* et al. conducted statistical comparisons of the study groups [84; 85]. *Jenson* et al. reported perforations in 4 % of double gloves and 20 % of single gloves (p < 0.001) [85], and *Doyle* et al. reported perforations in 4 % of double gloves and 35 % of single gloves (OR 13.8, 95 % CI 3.9-48) [84].

While the randomized trial is a strong design, the surgeons could not be blinded as to study group and thus may have been influenced to take more care during surgeries in which double gloves were used. Furthermore, if double gloving is associated with decreased sensitivity and dexterity, surgeons may move more cautiously to compensate. A longer observation interval would address at least the latter concern by providing some time after surgeons have adjusted to the use and feel of double glove barriers. There might additionally have been differences in compliance with the double glove protocol for simple vs. complex surgeries. For example, more intricate procedures that require greater dexterity might have deterred surgeons from experimenting with the double glove barrier. If these surgeries were associated with an increased risk of glove perforation, then some of the observed protective effect may be explained by differential non-compliance.

The risk of glove perforations with the use of double glove barriers was also assessed by *Greco* et al. [87; 88]. However, the lack of a comparison group renders any conclusion quite speculative. This was rated a poor quality study.

4.2.4 Training

Safety training was a focus of four identified NSI intervention evaluation programs [89 to 92], and was one part of multi-faceted interventions described in five additional papers [42; 43; 48; 73; 93].

The *Beekmann* et al., paper was considered reasonably good quality [89]. The authors compared NSI rates among employees of a clinical research center before (1985 to 1988) and after (1989 to 1991) implementation of training in universal precautions. By April of 1989, more than 95 % of employees had received training, and compliance with universal precaution protocols was mandatory in order to maintain employment. The targeted population comprised employees (nurses, physicians, lab technicians, housekeeping, phlebotomists, and other) of the Clinical Center at the US National Institutes of Health (NIH).

The authors reported a statistically significant, consistent annual decrease in NSI per 1000 patient discharges, from 18.4 in 1988 to 11.6 in 1991 ($p < 0.005$). Using any denominator definition (NSI/1,000 discharges, NSI/FTE, NSI/patient acuity, or NSI/2,000 devices used), the decrease was observed for all categories of HCW evaluated. Furthermore, patient acuity (hours of care required per patient per day) increased by 16 % between 1988 and 1991, suggesting that the number of injuries reported decreased while exposure-time increased. The main weakness of this evaluation stems from the use of pre-post comparisons, which preclude causal inference due to the inability to control for confounding due to unrelated changes overtime [89].

The other three training evaluations summarized here were considered to be of poor quality. *Birnbaum* enrolled HCW in several acute care hospitals to participate in training regarding either universal precautions or "body substance isolation" [90]. Although the training appeared to focus on the avoidance of needle recapping, the primary outcome assessed was NSI, assessed via self-administered questionnaires. The authors reported a decrease in injury rates that was not statistically significant, from 0.17 during 90 days preceding the program to 0.08 in the 90 days following training ($p = 0.076$).

Corlett et al. evaluated a "no touch" technique for abdominal wall closure following laparotomy [91]. Surgeons were randomly assigned to use the traditional technique with manual wound closure during suturing, or to use a "no touch" technique in which the wound edges are held by toothed forceps. The investigators assessed the number of glove perforations occurring during closure. They found no significant differences in perforations occurring during surgery but prior to wound closure (9/50 "hands in", 12/50 "no touch"; p = 0.62), and reported a significant protective effect of the "no touch" technique during wound closure (16/50 "hands in", 3/50 "no touch"; p = 0.0017). Although this intervention used a strong design to evaluate the new surgical technique, there was no indication that the surgeons had any experience with the "no touch" method prior to randomization, and there was no discussion of compliance included in the paper.

In another pre-post intervention comparison, *Linnemann* et al. reported no effect of universal precautions training on the rate of NSI [92]. Results of this evaluation were likely to have been biased towards the null due to implementation of two additional other safety interventions in the two-years preceding the universal precautions training.

A previously described ecological study by *D'Arco* et al. investigated a multidisciplinary approach to needlestick prevention [43]. From 1987 to 1988, three concurrent needlestick prevention protocols were implemented. These included installation of rigid disposal containers, staff training regarding HIV and AIDS risks, and training regarding the importance of reporting NSI. A 12 % increase in NSI reports was observed from 1987 to 1988, suggesting success in motivating staff to report NSI.

Edmond et al. reported no effect of an education intervention program paired with installation of bedside needle disposal units (described above) [73]. The details and goals of the educational program were not discussed in the paper. The outcome of interest was frequency of recapped needles with counts obtained through direct observation of nurses at work.

Training components were included in the programs described by *Dale* et al. and *Gartner*, but were not separately evaluated for efficacy in reducing NSI [42; 48; 93].

4.3   Summary

We obtained 278 unique papers for individual, preliminary review to identify evaluation studies. Several additional articles were added from the bibliographies of key review papers, and from the updated PubMed search. Sixty-one papers were ultimately included in this review.

The majority of intervention programs were implemented in the United States, a not unexpected result bearing in mind the history of the NSI discussion and political development.

Overall, the literature regarding interventions to reduce the incidence of NSI among health care workers may be considered to be of intermediate quality. Each category of replacement equipment discussed included a small number of reasonably well-planned and executed evaluations that adequately controlled for potential biases. The majority of papers reviewed, however, had one or more methodological flaws that precluded any firm conclusion regarding intervention effectiveness.

Among the fourteen papers describing replacements for traditional hollow-bore needles, the data generally favored protection against NSI by the new safety-engineered equipment. The twenty-five papers evaluating replacements for other sharp devices were less well-done, and showed some inconsistent results. However, especially in the case of needleless IV systems, where the majority of the studies have been rated of low quality, these systems seem to be able to reduce NSI to a large extent. Introduction of assistive devices, new types of or locations for needle disposal boxes and double gloving protocols appeared to be generally protective against NSI, but the majority of the programs evaluating these types of interventions were too methodologically flawed to allow for firm conclusions to be drawn.

The programs that focused on safety training resulted, at least, in improved completeness of NSI reporting. Reductions in NSI could not be definitively linked to training, however, in part due to inability to control for biases due to study design and in part due to concurrent introduction of other intervention programs. Some might suggest that combination programs, especially those incorporating overall safety training with use of safety equipment, are more effective than interventions that focus on only one

aspect of prevention. Combination programs are not designed to allow for inferences about effectiveness of individual program components, however, and so cannot be used to determine which element of a given program was (most) effective at reducing NSI.

Table 12 (see page 98) summarizes the results reported in the best quality intervention evaluations. The relative improvements in NSI rates varied considerably by type of intervention, though differences in study units (denominators) preclude direct compare-sons across intervention types. In three trials, replacing hollow-bore needles with safety-engineered devices resulted in approximately a two-fold improvement in NSI rates [33 to 35; 47]. The introduction of needleless IV systems showed no statistical significant difference between intervention and control group in one trial [33], but was very effective in another [47]. In single studies, the use of blunt suture needles reduced surgical glove perforations from 50 % to 7 % [60] and the Suture Mate reduced glove perforations from 27 % to 8 % [72]. An intervention consisting of moving needle disposal boxes closer to the work area successfully decreased needle recapping from 30 % to 26 % in one evaluation [76], while training staff in universal precautions reduced the NSI rate at one facility from 13/100 FTE to 8/100 FTE [89].

5   Cost effectiveness

Higher purchase prices for safety engineered devices compared to standard devices have been reported to be the major reason for the slow introduction of new, safer equipment in hospitals in the US in the 1990's [10]. Depending on the type of equipment, the purchase price per item was estimated to be 3 to 30 times higher for a safety vs. a standard device [94]. A quantitative economic analysis of the costs and benefits of the introduction of safer devices could help to determine whether or not new equipment offers advantages over conventional equipment [4].

Costs and benefits usually are categorized as direct, indirect and intangible. Direct costs include the cost differences associated with the introduction of safety devices compared to standard devices, such as differences in the purchase price, the number of devices needed, and the costs for disposal and waste [95]. It is important to note that direct costs, especially equipment purchase price, might be dependent on calendar time and health care provider-specific contracts with suppliers or Group Purchasing Organizations (GPO) [10; 96]. Indirect costs include administrative overhead associated with inventory changeover, training and device evaluation [10]. Of particular importance in the US are possible high costs of liability lawsuits brought by injured HCW against their employers. Intangible costs, which by definition cannot be expressed in monetary terms, are mainly associated with negative influences on HCW morale, pain, anxiety etc. following a NSI. If infection results from NSI, intangible costs are also felt by colleagues and/or family members of the injured HCW [22]. Additional intangible costs include the potential negative impact on the ability of an institution with a poor injury record to recruit new employees [97].

Direct financial benefits derive from reductions in NSI brought about by the use of safer devices. These include medical expenses for the baseline and follow-up laboratory testing for the injured HCW and the source patient, as well as the costs for PEP (post exposure prophylaxis). Indirect savings result from reductions in lost work time (lost productivity) associated with the time required for reporting, tracking and treatment of NSI and possibly the source patient. Intangible benefits are complementary to intangible costs, and include workplace morale, employee retention, and the institutional ability to attract and recruit new employees as needed.

Both costs and benefits might affect more than one entity (e.g. health care provider, health insurance, social security system), so interpretation of the results of cost-benefit analyses depends on the unit of analysis used in the calculations (hospital or societal level, and specific national health system).

5.1   Estimated costs of NSI

There is a broad range of costs of NSI reported in the literature (see examples in Table 13, see page 99). A recent report of the US General Accounting Office describes a range of estimated average costs per NSI between $ 500 and $ 3,000 [22]. Several factors contribute to these differences, making valid comparisons difficult.

First, analysts include different factors in their analyses, and hospitals calculate costs differently. This is especially true for indirect costs. For example *Jagger* et al. [101] estimated costs of NSI for two US hospitals for the time period 1995 to 1997, based on the data recorded in the EPINet. Both hospitals were large. One was located in a high-HIV prevalence area, the other one in a low-HIV prevalence area. Even though the recorded average costs of NSI in both hospitals were similar (US $ 672 vs. US $ 539), *Jagger* et al. found remarkable differences in the way the hospitals calculated overall costs. For example, one hospital included the cost of lost work time, the other did not; the costs for testing were very different between hospitals. The costs associated with seroconversion were not considered.

Second, both direct and indirect cost estimates depend on characteristics that differ between hospitals, including HBV vaccination status of the HCW, the status of the patient population with respect to BBP, and the specific institutional protocols for evaluation, treatment and follow-up after NSI [97; 98]. A low risk, low cost situation arises when the source patient was known to be negative for BBP. A high risk, high cost situation, e.g. if the source patient was HIV positive, may increase costs by a factor between 3 to 10 [19; 33; 81; 97; 101; 103].

Finally, any cost estimates are strongly time-dependent in a double sense: Early estimates [78] did not include any testing or PEP for HCV or HIV [98]; the latter has accounted for the larges increase in NSI costs over the last decade [19]. Cost estimates are also time-dependent in that the value of money changes over time. Even if

adjusted to a standard calendar year value using inflation factors as provided by *Lee* et al. [19]. For various US estimates, these estimates may be imprecise if the components contributing to the total costs did not inflate at the same rate.

5.2   Cost-benefit analysis

Two main approaches can be distinguished regarding the published analysis: the first approach projects costs and benefits expected with future use of safer devices, on a state or hospital level, or bases estimates on empirical data for one or more specific devices and various model assumptions. The second approach consists of tracking actual costs and savings (direct and indirect). This approach is generally conducted in parallel with the introduction of safer devices in hospital, as part of the evaluation process.

5.2.1 State and national estimates

Cost-benefit estimates on a state or national level have been published in the US in preparation of regulatory actions: in 1998 in California and in 2000 on the national level.

Based on estimates provided by two manufacturers but excluding indirect costs and costs arising in the case of seroconversion, the California OSHA cost-benefit analysis estimated the average cost of a NSI at US $ 2,234 to US $ 3,832 for initial screening and treatment. In total, costs for hospitals increased by about US $ 104 million/year for implementation, and an additional US $ 81 million/year was projected for maintaining required needlestick injury logs [10]; (http://www.dir.ca.gov/oshsb/sharps2.html). Based on an estimated elimination of 96,000 NSI, total savings for screening and treatment were estimated at US $ 291 million/year, with a net savings of US $ 106 million/year, statewide.

The US General Accounting Office (GAO) published in 2000 estimates of the costs and benefits of the implementation of needlestick prevention in hospitals [22]. Based on CDC NaSH data the report estimated that 29 % (69,000) annual NSI events (236,000) would be preventable using needles with safety devices. Furthermore, an additional 25 % reduction was expected by eliminating unnecessary use of sharps and

21 % by using safer work practices. The cost estimate for NSI was derived from published estimates and used in a cost-benefit scenario on three levels: $ 500, $ 1,500 and $ 2,500. Included in the estimates were "postexposure treatment" costs, which probably included costs for testing and PEP and excluded indirect costs. The estimates explicitly excluded costs arising from seroconversion. Increased costs for needles with safety features were calculated by estimating the number of different needles used by hospitals/year and assuming either a factor 1.5, 2 or 3.5 as a multiple of the cost of a standard needle. The estimates did not include costs for training or changing work practices. Table 14 (see page 100) shows the result of this cost-benefit modeling approach: the use of needles with safety features is cost efficient when the costs of postexposure treatment are moderate or high and the added costs per feature are low, as was the case in 1/3 of the presented scenarios. Additionally, the GAO estimated the number of preventable cases of HBV (25) and HCV (16) per year, but did not include this estimation in the cost-benefit analysis.

In sum, the GAO model is restricted to costs and benefits that occur at hospitals and included only selected costs arising with NSI and with the implementation of new safety devices. It is based on many assumptions regarding the number of NSI, the number of preventable NSI, the average increase in purchase prices for safety devices etc., but can serve as a useful tool for estimating the effect of different scenarios.

5.2.2 Costs and benefits for individual hospitals

Examples of projected costs and benefits for specific hospitals are provided by *Jagger* et al. [98], *Dugger* [104], *Laufer* and *Chiarello* [99] and *Hofmann* et al. [102].

In 1986, *Jagger* et al. investigated the average cost per NSI for six safer needle devices in a large US hospital. The average cost per NSI was estimated at $ 405, including costs for testing of the HCW and source patient, PEP for HBV (due to the time, no HIV or HCV PEP included) and the cost of time needed for health personnel time to carry out the testing and provide PEP. Based on the purchase price of standard devices, the average costs of NSI would equal 36 % of the average costs of replacement devices. Therefore, a strategy that would prevent 100 % of NSI and increase costs up to 36 % would break even. The estimated 100 % reduction was seen as

realistic for IV line connectors (a needleless system), but not for other devices considered [98].

Dugger described the introduction in 1990 of safer needles and needleless IV systems in a large US hospital. Before the implementation, costs of safer devices were estimated at $ 172,000, with no disposal and indirect costs considered. However, revenue gains were expected from "chargeable items" and through the introduction of a secondary backflush technique that saved on the number of primary IV tubing sets. The hospital expected a revenue increase of around $ 20,000 after all of these products were introduced. Costs for NSI were taken from the literature ($ 1,000). Based on a 69 % reduction per half year, total estimated savings were $ 55,000. Costs of NSI have not been calculated in this study, and no cost-benefit analysis was conducted. Overall, it was not obvious in this paper which of the costs and savings were estimated a priori and which actually occurred [104].

Laufer and *Chiarello* conducted a cost-effectiveness analysis using pooled data from ten US hospitals. Using additional assumptions, they estimated the average cost of a NSI at $ 363 in 1992, and included testing and PEP for HBV and HIV as well as "personnel" costs. HCV and costs in case of seroconversion were not included. For two participating hospitals, a cost-effectiveness analysis was conducted comparing two categories of safer devices, injection equipment and IV delivery systems. The safety syringe was reported to lead to a reduction of 30 % in the half-year observation period at a cost of $ 984 per injury prevented. The needleless IV system in the other hospital led to a 94 % reduction in injuries at $ 1,877 per injury prevented. The incremental costs of introducing the IV needleless system were higher than the costs of the equipment selected by the first hospital. It should be noted that the objective of the *Laufer* and *Chiarello* study was to introduce the methodology to infection control practitioners rather than to carry out a formal analysis for a specific institution(s) [99].

Hofmann et al. [102] estimated the costs of a NSI for a large German hospital at € 487. The estimate included cost for testing of the HCW and source patient, PEP and lost work time for the HCW. However, the portion of the costs affecting the hospital was estimated to be only € 148; the largest part of the costs was estimated to affect the worker's accident insurance. Among cost-saving factors, the authors reported on

the high HBV vaccination status of the HCW population (90 %) and that, in 90 % of NSI cases, it was possible to determine the serological status of the source patient. The authors further estimated the costs and benefits that would occur through the complete substitution of safer devices for standard equipment at this hospital. They estimated the incremental purchase costs of safer devices to be € 156,000 annually. Based on the estimated average cost of NSI, a full year average number of NSI (N = 166), and under the assumption of an 85 % reduction of NSI and that the reporting rate would not change, the implementation would lead to a net benefit for the worker's accident insurance of € 69,000 and to a net increase in costs for the hospital of € 135,000. Overall net savings would, according to their model calculations, only have been reached if the basic number of NSI was about 300, or twice the number observed. A simple continuation of their model shows that the break-even point for this hospital could not be reached (holding all other factors constant) below a basic number of reported NSI of about 1,250. A further discussion and assessment of this study is not possible because details were not yet published at the time of the preparation of this report.

5.2.3 Intervention-based analysis

Several of the studies discussed or mentioned in the evaluation section also evaluated the costs and benefits of their interventions. Theses studies are presented following according to the categorization used in the previous chapter.

5.2.3.1 Replacement of hollow-bore needles

Orenstein et al. completed a twelve-month prospective evaluation in a 900-bed urban hospital in the US in 1992 of the Becton-Dickinson 3 ml Safety-Lok syringe and of the Baxter InterLink intravenous system. The direct costs of NSI were estimated at $ 260, including testing and PEP, employee's lost time, and other health personnel time. The purchase costs were ten times higher for the safer devices. After accounting for the 61 % reduction in NSI, a net increase in costs of $ 15,000 per half-year ($ 789 per NSI prevented) was reported [33].

5.2.3.2 Needleless IV systems

Gartner described the introduction of a needleless IV system in a 500-bed acute care US hospital in 1990. The cost of a NSI was estimated at US $ 371 and included testing, one HBV vaccine, lost employee working time and probably costs for health care personnel involved in caring for injured HCW. The increase in the purchase price of the new system was US $ 6,542 per half-year, only a 16 % increase over baseline. In this report, there was a drastic reduction in equipment needs, since the new system was largely reusable. The number of IV-related needlesticks decreased from 17 to 2 within a half-year after implementation, leading to savings of US $ 5,595. Therefore, the new system led to a net increase of $ 94 per half-year [48]. Similar results, cost savings through reduced tubing use, from about $ 10 per patient to $ 8 per patient were reported by *Skolnick* et al., but the authors had no data related to costs of NSI [58].

Fassel et al. reported direct costs for NSI of US $ 531 but provided no details as to which costs were included in the calculation. The annual incremental costs of the new system (Interlink) were $ 195,000 in 1992. If fully implemented (there was residual use of conventional equipment during the observation period), savings would amount to $ 42,000, leading to total incremental costs of about $ 153,000/year [56].

The cost-benefit analysis of *Orenstein* et al. has already been described, above, together with the implementation of a safety syringe [33].

Yassi et al. evaluated the implementation of the InterLink System (Baxter) in a large Canadian hospital in 1992/1993. The costs of NSI were estimated to range from CAN $ 83 for a known seronegative source patient to CAN $ 559 for a known seropositive source patient. Estimated costs included testing, PEP for HBV (no Zidovudine prophylaxis; no HCV testing) and lost work time of affected employees, health personnel treating the injured HCW, and administrative costs. The incremental annual costs for the needleless system were estimated to be about CAN $ 47,800, a 14 % increase. The authors, like others above, also reported a decrease in the number of pieces of equipment needed with the new system. There was an additional saving of 15 % (CAN $ 13,200) from reduced disposal costs, because the new system is not classified as sharps [54].

After the implementation of the needleless system, *Yassi* et al. reported that the number of NSI decreased by 122 within one year. Using this hospital-wide number, the authors calculated the range of net savings in costs from NSI between CAN $ 10,100 and CAN $ 68,214. The overall range of net increase in costs/net benefits therefore was between a net annual increase of CAN $ 24,400 and a net savings of CAN $ 33,700. However, as noted, the authors used for their cost-benefit analysis the total reduction in NSI in the hospital, not the NSI related specifically to the replacement equipment. Using only the reduction in NSI expected from the replacement equipment, the annual net increase in costs would have been between CAN $ 30,500 and CAN $ 7,700 [54].

Mendelson et al. conducted a cost-benefit analysis for their 1991 intervention in which a needleless IV access system was introduced (see evaluation section). The cost per needlestick was estimated at US $ 636, including testing and PEP as well as work time for health personnel time involved in the evaluation, counseling and management of the injured HCW, and cost for lost work time of the injured HCW. The purchase price of the safer system was about four times higher than the cost of the standard device. The projected annual hospital-wide incremental costs of the needleless IV access system compared to the conventional heparin-lock system were about US $ 116,000 and the savings through the reduction of NSI about US $ 33,000 (based on projected 52 injuries prevented). The net increase in costs, therefore, was US $ 83,000, or US $ 230 per bed. The cost per injury prevented was estimated to be about $ 1,600 [47].

5.2.3.3 Retractable lancets

Roudot-Thoraval et al. introduced several interventions (devices with retractable needles for vacuum-tube phlebotomy, safe devices for hypodermic needles and protected short catheters) to reduce NSI in a large hospital in France beginning in 1990. The authors compared pre-intervention NSI rates with the average rates in 1995 to 1997. The total annual costs of safer devices and of training were calculated as US $ 309,000 (in 1998 US dollars). The cost of NSI was calculated at US $ 1,796 including costs for blood testing, PEP and lost work time. The underlying assumption was 100 %

compliance with the management guidelines. This would have led to costs of about US $ 2,300 (calculated by the authors) per injury prevented, based on a reduction of 76 NSI. However, the empirical, real cost per NSI was only US $ 325, due to a poor compliance with treatment guidelines, which led to costs of about US $ 3,700 (calculated by the authors) per injury prevented [67]. Two problems make the assessment of this publication difficult:

a) There are large inconsistencies in the text and the data reported in the table regarding annual purchase and training costs and,

b) According to the text, the total purchase costs of safety devices and not the incremental purchase costs were used for the analysis.

Peate described the implementation of automatic self-retracting lancet in a population of 477 active-duty emergency medical system workers for a municipal fire department in the US between 2000 and 2001. The average cost of a NSI was US $ 1,035 including physician evaluation and counseling, testing and PEP. The author mentioned additional direct and indirect costs, but it is unclear whether or not these were included in the estimates. Annual purchase costs increased minimally (US $ 366) and the net annual savings due to use of safer devices were estimated at US $ 5,160 [68].

5.2.3.4 Disposal containers

In an early evaluation study, *Ribner* et al. reported on the introduction of a rigid, puncture resistant disposal system during the year from 1983 to 1984. The costs of disposal related NSI were estimated at US $ 183, including "personnel time" (not specified), HBV testing and PEP. Due to the time period, no HCV or HIV testing or PEP was offered. Costs were high in this study due to the fact that, in most cases, the origin of the needle remained unknown. The annual increase in purchase costs was US $ 3,081. With a 75 % reduction (n = 21) in disposal related NSI, the net annual savings was estimated at US $ 750 [78].

Hatcher compared NSI rates with the use of a straight drop disposal box vs. use of a letter drop box in a university medical center in the US in 1999. She reported that the occupational health division conducted a direct cost analysis of a single NSI,

estimating costs to be between US $ 532 and US $ 3,437 (if the source patient was known seropositive). In her final cost-benefit analysis, *Hatcher* used the average of the two California OSHA estimates, arriving at a total of US $ 3,033. The reason for substituting state OSHA estimates for institution-specific costs estimates was not explained. With annual purchase costs increasing by $ 10,000 and an estimated annual reduction in NSI of 24, the author calculated a net savings of more than US $ 62,000 [81].

5.3   Summary

In general, the reported costs of NSI are underestimated. Although calculations usually included costs of testing and PEP, and sometimes the cost of labor and lost work time, costs associated with seroconversion were generally not considered. Reasons included:

a) only a relatively small subset of HCW would be affected;

b) the possible costs depend on the situation (age, health status, type of infection, severity of disease) of the HCW [22]; and

c) from a hospital-based view, these costs are usually borne by a third party payer, e. g. workers compensation or a health insurance plan, and not the employer himself [23].

It is difficult to predict how even these underestimated costs might be borne on a societal level. For example, the costs of antiviral therapy after HCV seroconversion have been estimated to be € 10,000 for 24 weeks or € 20,000 for 42 weeks in Germany [20]. A possible additional cost for an HCV infected HCW is a liver transplant – estimated to be around € 100,000 in Germany [20] and $ 140,000 in the US [103]. In the US, the average annual costs for treating a person with HIV was been estimated in 1996 to be between $ 20,000 and $ 25,000 [22].

The costs associated with the introduction of safer devices were also underestimated. Costs associated with inventory changeover, healthcare worker training, and device evaluations were usually not considered in any of the available cost or cost-benefit analysis.

That the majority of the available empirical cost-benefit analysis discussed the imple-
mentation of needleless IV systems might be due to the fact that these systems offer the
opportunity for a complete elimination of NSI in this area. Even when the same type of
equipment was under consideration, the reported results were in conflict due to differ-
ences in calculations: some investigators were able to offset the higher purchase costs
associated with the safety devices with the smaller number of sets needed, while others
were not.

Finally, most of the cost-benefit evaluations were done during the early 1990s; their
relevance to the current day cannot be assessed. The purchase prices for both the
safer devices and the standard devices are likely to have changed, in addition to the
cost of other factors contributing to the total cost of a NSI.

6   Discussion

This report presents a comprehensive review of the literature on the epidemiology of NSI, on international surveillance for work-related NSI, on preventive measures and on the costs of NSI interventions.

Overall, the epidemiological patterns of reported NSI were consistent internationally, based on surveillance data, and over time, based on the literature review: those with the most patient contact, nurses and physicians, are the most likely to report NSI and NSI were likewise more likely to occur in locations where sharps were used the most: patient rooms and operating rooms. In spite of an overall trend toward increases in reported NSI rates, underreporting continues to present a problem for the development of accurate risk estimates.

The literature on interventions to reduce the incidence of NSI among health care workers was of generally intermediate quality. While the overall impression offered by the literature is one of reasonable effectiveness of safety engineered devices and administrative controls the majority of papers reviewed had one or more methodological flaws that precluded any firm conclusion regarding intervention effectiveness. Because a variety of study units (denominators) were used, it was not possible to make direct, quantitative comparisons of the effectiveness of different types of interventions. However, we agree with the conclusions of *Hanrahan* and *Reutter* [7] and with *Porta* et al. [18], who suggested that engineering controls seem to be generally more effective than training to modify work practices at reducing the incidence of NSI, and that replacement devices that work passively are more likely to be successful than devices requiring activation by HCW.

The literature on the economic consequences of NSI and the implementation of safer devices was mostly from a hospital point-of-view, and did not include costs to third party payers (e.g. health insurance companies). The cost analysis presented were not directly comparable because the results strongly depended on which costs and benefits were included in the estimation, the time period when the studies were conducted and, if based on a specific hospital, on the characteristics of the hospital, its employees and the patient population. Our general impression is that costs of NSI intervention

programs, as well as the financial benefits of program success were underestimated. Although no firm scientific conclusion can be drawn from the limited literature, the study results suggesting that, from a hospital point of view, it might be difficult to reach the break-even point in most scenarios. The possible exception is in the area of disposal-related devices; the few studies that considered alternative sharps disposal methods indicated limited to moderate incremental costs of the safer devices on the one hand, and relatively high costs of a NSI on the other. Finally, there are intangible costs and benefits associated both with NSI and with the introduction of safer devices which cannot be expressed in monetary terms, but which might affect the working climate and might therefore be of relevance for employers.

7   Recommendations

The authors whose work is summarized in the literature review section offered a number of recommendations for reducing the risk of NSI. We feel the following recommendations are supported by the results of the intervention programs that formed the basis of the QBCR:

☐   Avoid use of sharp or needled devices whenever possible [2; 3; 7; 21];

☐   Improve the design of sharp equipment to reduce the likelihood of accidental injury [2 to 7];

☐   Locate disposal containers close to work sites to reduce the necessity of transporting uncapped devices, avoid over filling disposal containers and use containers designed to exclude hands and fingers [2; 3; 5];

☐   Modify work practices to reduce risks. For example: avoid recapping used syringes, or use one-handed recapping techniques with assistive devices, set up instrument trays with uniform orientation of all sharps, segregate sharp from non-sharp equipment, separate used from unused sharps, and use forceps to dispose of contaminated devices [2 to 5]; and

☐   Improve and standardize reporting of sharps injuries to facilitate surveillance and comparability of data across institutions and countries [5; 7].

If HCW are potentially exposed to blood borne pathogens as a result of NSI, implement post-exposure follow-up of the injured HCW. If the viral status of the donor patient is unknown, implement follow-up of the patient also [3]. Post-exposure infection rates may be reduced by prompt prophylactic anti-viral treatment [3; 7], and this should be considered in the development of risk reduction and management plans.

8   Bibliography

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Table 1:
Overview of preventive measures to reduce NSI

Approach	Measure	Concrete measures
Safety engineered devices	Retraction or shield for sharp instruments[1]	▪ Retractable lancets used for blood sampling by heel stabs and finger sampling; ▪ Retractable needles used for injections and immunizations; ▪ Shields added to needles for injections and venepuncture which are activated by the operator at the end of the procedure; ▪ Protected disposable scalpels with a shield that can be activated before passing the instrument between staff and before disposal; ▪ Blunt suture needles ▪ Intravenous cannula with blunting or guarding of the needle of the introducer that is activated when removed from the plastic cannula
Personal protective equipment – PPE	Gloving	▪ Single gloving ▪ Double gloving
Disposal	Improvement of disposal	▪ Location ▪ Rigidity ▪ Modification ▪ Box design
Training	Specific training for staff with NSI risk	▪ Health care workers: Training for devices in use or introduction of safety devices; anti-stress programs ▪ Disposal service: Training for disposal handling ▪ Management: Need for introduction of safety devices to reduce NSI
Organization	Shift schedule Work environment Other	▪ Schedule regarding health and personal demands ▪ Good lighting etc.

1) Source: *Waclawski* (2004) [15]

Table 2:
Summary of needlestick literature search strategies and results

PubMed search terms/keywords[a]	Results (#)	Notes
1. needlestick* OR sharps	2,309	Overall pool of publications
2. (needlestick* OR sharps) AND epidemiology	560	Epidemiology focus (Aim 1)
3. (needlestick* OR sharps) AND (intervention OR prevention OR "infection control"[MESH[b]] OR "accident prevention" [MESH] OR "preventive medicine" [MESH])	1,561	
3.a. (needlestick* OR sharps) AND (((prevention OR "infection control" [MESH] OR "accident prevention" [MESH] OR "preventive medicine" [MESH]) AND (study OR studies)) OR evaluation OR intervention)	512	Evaluation focus (Aim 2) Subset of search 3
4.a. (needlestick* OR sharps) AND protective devices	275	
4.b. (needlestick* OR sharps) AND equipment safety [MH]	117	MH: Main subject heading
4.c. Combine results of 4.a and 4.b. and remove duplicates	369	Safety devices focus (Aim 2) Combination of 2.c. and 2.d.
5. Combine results of 2., 3.a., and 4.c. and remove duplicates	1,069	Number of unique references

a. Initial searches were completed on November 4, 2004 and updated on April 26, 2005. All searches were limited to human subjects. Other terms were not restricted by field unless indicated. The searches are numbered sequentially, in the order in which they were completed.
b. the National Library of Medicine's (NLM) controls the vocabulary thesaurus MeSH (Medical Subject Heading). It consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity.

Table 3:
Distribution of countries represented by surveillance data and intervention programs

	Surveillance data	Number of interventions
Germany	√	1
United States	√	45
Canada	√	2
France	√	3
Great Britain	√	6
Australia		4
New Zealand		2
Other[1]		6

1) Other countries: Belgium, Denmark, Finland, India, Ireland, Italy

Table 4:
Needlestick injury rate by country

Country (year(s))	Needlestick injuries/100 occupied hospital beds
Australia (1995-98)[a]	6.08
France (2002)[b]	5.1
Germany (1997)[c]	(493,730/year)
Scotland (1998-99)[d]	8.6
Spain (2002)[e]	13.4
Japan (2000)[a]	9.77
USA (2002)[f]	20.36
USA (June 1995-December 2001)[g]	30
UK (2002)[h]	11.6

a. http://www.emanet.org/safety/2-4_epid_ita.html (2006-01-17)

b. Surveillance des Accidents avec Exposition au Sang, 2002

c. http://www.emanet.org/safety/2-3_epid_ger.html (2006-01-17)

d. "Needlestick injuries: Sharpen your awareness." Report of the Short Life Working Group on needlestick injuries in the NHS Scotland (National Health Service for Scotland)

e. http://www.bdeurope.com/temp/72943 (2004-11-10)

f. EPINet data: http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm (2006-01-17)

g. NaSH data: http://www.cdc.gov/ncidod/dhqp/nash.html (2006-01-17). See text for comparison between NaSH and EPINet data

h. http://www.bdeurope.com/temp/403369.pdf (2004-11-10). U.K.: United Kingdom.

Table 5:
Distribution of needlestick injuries (NSI), by occupation and country

| Country (year) | NSI (n) | Distribution of reported NSI by occupation in % | | | | | |
		Nurse	Physician	Student[a]	Phlebotomist[a]	Laboratory	Other
France (2002)[b]	6,241	62.5	11.0	10.8	NR[c]	1.6	14.1
Germany (1997)[d]	494	60	25	NR	-	11	4
Italy (Jan. 1994-July 2002)[e]	19,024	58.1	16.8	9.6	NR	2.2	13.3
Scotland (1998-99)[f]	2,439	63	17	NR	NR	NR	20
Spain (1998-2000)[g]	10,836	59.9	11.2	9.6	NR	1,5	16,7
USA (2002)[h]	1,918	44	15	2	6	6	27
USA (June 1995-Dec. 2001)[i]	16,922	44	28	4	NR	15	9
UK (2002)[j]	1,445	41	14.5	3.4	3.1	NR	38

a. Student includes nursing and medical students. Phlebotomy includes phlebotomy, venipuncture, intravenous team, etc., see also glossary (page 101)

b. Surveillance des Accidents avec Exposition au Sang, 2002

c. NR: Not reported

d. http://www.emanet.org/safety/2-3_epid_ger.html (2006-01-17)

e. http://www.bdeurope.com/temp/115826.pdf (2004-11-10)

f. "Needlestick injuries: Sharpen your awareness." Report of the Short Life Working Group on needlestick injuries in the NHS Scotland

g. http://www.eucomed.be/docs/Ingles%2019-03-03%20Brussels.pdf; (2005-01-15)

h. EPINet data: http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm (2006-01-17)

i. NaSH data: http://www.cdc.gov/ncidod/dhqp/nash.html (2006-01-17). See text for comparison between NaSH and EPINet data

j. http://www.bdeurope.com/temp/403369.pdf (2004-11-10). U.K.: United Kingdom.

Table 6:
Hollow-bore devices causing needlestick injuries (NSI), by country

| | | Distribution of reported NSI by type of device in % | | | | | | | |
| | | Needle | | | | Other | | | |
Country	NSI (n)	Syringe[a]	Winged	Suture	Hypo-dermic[b]	Unspeci-fied[c]	IV[d]	Blood collection[e]	Other
France[g]	6,241	16.5	3.5	40.6	NR	16	9.8	6.0	7.6
Germany[h]	1,807	25.8	4.7	6.5	f	43.7	2.0	0.1	17.2
Italy[j]	19,024	55	NR	NR	NR	NR	3	4	33
Spain[i]	7,215	38	9	15	9	11	23	6	
USA[k]	1,456	50	8	21	1	3	5	5	6
USA[l]	3,564	43.6	16.7	20.5	NR	0	7.7	3.8	7.7
UK[m]	1,445	32.3	6	8.8	3	12.2	6.3	6.9	24.5

a. Includes disposable and pre-filled syringes
b. Unattached hypodermic needle
c. Includes unspecified and unknown needle types
d. Intravenous catheter stylet
e. Needle holder or vacuum tube for blood collection
f. Hypodermic included with syringe
g. Surveillance des Accidents avec Exposition au Sang, 2002
h. http://www.nadelstichverletzung.de (2006-01-17)
i. http://www.bdeurope.com/temp/115826.pdf (2004-11-10)
j. http://www.bdeurope.com/temp/72943.pdf (2004-11-10)
k. EPINet data: http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm (2006-01-17)
l. NaSH data: http://www.cdc.gov/ncidod/dhqp/nash.html (2006-01-17). See text for comparison between NaSH and EPINet data
m. http://www.bdeurope.com/temp/403369.pdf (2004-11-10). U.K.: United Kingdom.

NR = not reported

Table 7:
Activity during needlestick injury (NSI) occurrence, by country

Country	NSI (n)	Activity during NSI occurrence by country in %					
		During use			During disposal		
		During use[a]	Recapping[b]	After use	Appropriate	Inappropriate[c]	Other
France[d]	6,241	20.7	4.6	NR	10	12.7	52
Germany[e]	2,083	35.1	3.98	5.57	24.3	6.43	24.63
Italy[f]	19,024	40-50	1-18	25-34	8-23	NR	6-8
Scotland[g]	NR	73	5	11	11	NR	NR
Spain[h]	10,621	70	10	NR	4	13	3
USA[i]	1,913	54.6	3.6	16.4	6.6	11.5	7.3
USA[j]	8,225	47	6	19	13	10	5
UK[k]	1,445	35.1	5.7	21.1	7.4	10.5	20.6

a. During single or multi-step procedure.
b. Recapping or disassembly.
c. Includes inappropriate placement of used device and inappropriate disposal (e. g. container too full, wrong type).
d. Surveillance des Accidents avec Exposition au Sang, 2002
e. http://www.nadelstichverletzung.de (2006-01-17)
f. http://www.bdeurope.com/temp/115826.pdf (2004-11-10)
g. "Needlestick injuries: Sharpen your awareness." Report of the Short Life Working Group on needlestick injuries in the NHS Scotland
h. http://www.bdeurope.com/temp/72943.pdf (2004-11-10)
i. EPINet data: http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm (2006-01-17)
j. NaSH data: http://www.cdc.gov/ncidod/dhqp/nash.html (2006-01-17). See text for comparison between NaSH and EPINet data.
k. http://www.bdeurope.com/temp/403369.pdf (2004-11-10). U.K.: United Kingdom.
NR = not reported

Table 8:
Location of occurrence of needlestick injuries (NSI), by country

| Country | NSI (n) | Location of occurrence of NSI in % | | | | | |
		Patient room	OR[a]	Treatment room	Outpt[a]	ER[a]	Other
France[b]	6,241	40	8.5	16.5	NR	2.4	32.4
Germany	NR[c]	NR	NR	NR	NR	NR	NR
Italy[d]	19,024	38	21	NR	NR	NR	41
Scotland[e]	NR	53	16	NR	7	3	21
Spain[f]	10,542	37	23	12	4	NR	24
USA[g]	1,920	31	29	9	5	9	17
USA[h]	16,855	34	25	8	9	8	16
UK[i]	1,445	40.5	20.6	10.1	3.1	NR	25.7

a. OR: Operating room/theater; Outpt: Outpatient clinic; ER: Emergency room/emergency department

b. Surveillance des Accidents avec Exposition au Sang, 2002

c. NR: Not reported

d. http://www.bdeurope.com/temp/115826.pdf (2004-11-10)

e. "Needlestick injuries: Sharpen your awareness." Report of the Short Life Working Group on needlestick injuries in the NHS Scotland

f. http://www.bdeurope.com/temp/72943.pdf (2004-11-10)

g. EPINet data: http://www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm (2006-01-17)

h. NaSH data: http://www.cdc.gov/ncidod/dhqp/nash.html (2006-01-17). See text for comparison between NaSH and EPINet data.

i. http://www.bdeurope.com/temp/403369.pdf (2004-11-10). U.K.: United Kingdom

Table 9:
Screening Criteria

Inclusion

- Language (English, German, French)

- Goal: Reduction of NSI* in the workplace

    - Equipment or engineering controls

    - Training programs

    - Both

Exclusion

Language (*not* English, German, French)

No intervention (guidelines or recommendations)

Target population not employed in health care

*NSI: Needlestick injury

Table 10:
Exclusion criteria, preliminary literature review

Reason	Count
Analysis insufficient or absent	17
NSI* prevention not measured	20
Product development or testing; patient outcomes; vaccination or injury reporting.	
Total excluded	37

*NSI: Needlestick injury

Table 11:
Quality indicators for Quality Based Critical Review (QBCR)

Characteristic	Quality indicator
Clarity of reporting	Rationale for intervention documented; intervention procedures, setting, target population, methods and results clearly described.
Intervention design characteristics	Duration of intervention; outcomes defined in advance; objective outcomes included; appropriate comparisons selected; intervention procedures pre-tested; training provided in use of new equipment; transitional periods appropriately excluded from analysis; results disseminated to affected employees.
Statistical rigor	Denominator selection; unit of analysis; reasonable statistical power; appropriate analytical methods employed; bias, confounding and effect modification considered.
Interpretation	Alternative explanations for results considered; results not over-generalized.

Table 12:
Summary of best quality intervention evaluation studies, by intervention type

Intervention type	First author (year)	Change in NSI
Replace hollow-bore needles	*Orenstein* (1995) [33]	0.79/1,000 HCW-d to 0.3/1,000 HCW-d
	Sohn (2004) [34; 35]	34/1,000 FTE-yr to 14/1,000 FTE-yr
	Mendelson (2003) [36]	13.4/100,000 devices ordered to 6.4/100,000 devices ordered
Needleless IV	*Orenstein* (1995) [33]	No statistical significant difference between intervention and control group
	Mendelson (1998) [47]	8 to 0 IV-related NSI
Blunt suture needle	*Mingoli* (1996) [60]	50 % gloves perforated due to sharp needle 7 % gloves perforated due to blunt needle
Suture Mate	*Bebbington* (1996) [72]	27 % gloves perforated without SutureMate 8 % gloves perforated with SutureMate
Box re-location	*Makofsky* (1993) [76]	Recapping from 30.2 % to 26.2 %
Training (Universal Precautions)	*Beekmann* (1991) [89]	13 NSI/100 FTE to 8 NSI/100 FTE

Table 13:
Examples of estimated average costs per NSI for hospitals

Author	Country	Year of publication	Reference Year	Average cost of NSI (in US $)[1]	Comment
Jagger at al. [98]	US	1990	1988	405	
Gartner [48]	US	1993	1990	373	
Laufer and *Chiarello* [99]	US	1993	1991	363	Projection
Terrell and *Williams* [100]	US	1993	1991	320	
Dale et al. [42]	US	1998	1991	310	
Mendelson et al. [47]	US	1998	1991	636	
Fassel et al. [56]	US	1994	1992	531	
Orenstein et al. [33]	US	1995	1992	260	
Dale et al. [42]	US	1998	1995	561	
Jagger et al. [101]	US	1998	1995-97	672 (Hosp. A) 539 (Hosp. B)	
California OSHA*	US	1998	1998 (?)	2,234 3,834	Projection; two different estimates provided by two manufactures (J&J; B&D)
ECRI [95]	US	1998	1998 (?)	540	Projection
Hatcher [81]	US	2002	1999 (?)	3,033	Used average of the two California estimates
Roudot-Thoraval et al. [67]	France	1999	1998	1,796 325	Projection real
Peate [68]	US	2001	2001	1,035	
Hofmann et al. [102]	Germany	2005	2004 (?)	€ 148	Projection; total costs estimated to be € 487

1) in US $, if not otherwise mentioned

* Source: *Tan* et al. [10] and http://www.dir.ca.gov/oshsb/sharps2.html (2006-01-17)

Table 14:
GAO cost-benefit projection

		Cost scenarios for postexposure treatment		
		Low ($ 500 per injury)	**Medium ($ 1,500 per injury)**	**High ($ 2,500 per injury)**
Cost for needles with safety features compared with conventional needles	Low cost (1.5 times more costly)	-$ 47 million	$ 21 million	$ 90 million
	Medium cost (2.0 times more costly)	-$ 129 million	-$ 60 million	$ 9 million
	High cost (3.5 times more costly)	-$ 374 million	-$ 306 million	-$ 237 million

Source: General Accounting Office [22]

Annex

Annex 1: Glossary and abbreviations

AVFN	Medisystems Arteriovenous fistula needle
BBP	blood born pathogens
Bias	systematic error that occurs if there is a difference between what a study is actually estimating and what it is intended to estimate
CDC	US Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI, CL	confidence interval, confidence limits: The range of numerical values in which we can be confident (to a computed probability, such as 90 or 95 %) that the population value being estimated will be found.
Confounding	systematic error resulting from mixing of effects due to one or more risk factors for a disease with the main risk factor of primary interest
Ecological study	An investigation in which correlations between exposures measured at the population (or group) level and rates of disease, measured at the population (or group) level are assessed. Ecologic studies do not allow statements to be made about individuals, just about the population.
Effect modification	factor influencing the relationship between exposure and response, i.e. the effects themselves are modified
EPINet	Exposure Prevention Information Network; a software package developed and maintained at the University of Virginia (US) specifically for tracking and reporting NSI
FTE	full-time equivalent; a way to standardize the size of the employee population regarding work time
GAO	US General Accounting Office
GPO	Group Purchasing Organizations

HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health care workers
HIV	human immunodeficiency virus
Hypodermic	A hypodermic needle is a hollow needle commonly used with a syringe to inject substances into the body, or to take liquid samples from the body, for example taking blood from a vein in venipuncture.
IV	intravenous
MEDLINE	The NLM's bibliographic database covering the fields of medicine and all related fields. MEDLINE contains bibliographic citations and author abstracts from more than 4,800 biomedical journals published in the United States and 70 other countries. The database contains over 12 million citations worldwide dating back to the mid-1960's.
MeSH	Medical Subject Headings, is the National Library of Medicine's controlled vocabulary thesaurus. It consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity
NaSH	National Surveillance System for Hospital Health Care Workers
NIH	National Institute of Health
NLM	National Library of Medicine
NSI	needle stick injury
OR	operating room
OSHA	US Occupational Safety and Health Administration
PEP	post exposure prophylaxis
Phlebotomist	trained person responsible for drawing blood from patients for laboratory tests or blood donations, profession not existent in all countries, e. g. Germany

PubMed	The user interface providing access to bibliographic information that includes MEDLINE
QBCR	quality based critical review (literature evaluation method used in this report to select, analyze and synthesize papers)
RR	relative risk: The ratio of the incidence of a disease among those exposed to the incidence among those not exposed
SD	standard deviation: the square-root of the average difference between individual measurements and the overall (group) average. A measure of variability.
Seroconversion	The development of antibodies to a particular antigen
Statistical power	Statistical power is the probability to detect a statistically significant difference, or effect, if one were to occur. Ideally, studies should have power levels of 0.80 or higher - an 80 % chance or greater of finding an effect if one was really there. The "power" of any study depends on different factors, including sample size, effect size and variability.
VAMP	venous arterial blood management protection
Venipuncture	The puncture of a vein with a needle for the purpose of drawing blood. Also called phlebotomy

Annex 2: QBCR review form

Reviewer Initials: _____

Overall Rating (Good/Fair/Poor)

Rationale:

Author

Year

Introduction

Rationale clear (yes/no)?

FOCUS: *(check as many as apply)*:

                1) Replacement needles ☐

                2) Other Sharps   ☐

                3) Training   ☐

                4) Other Equipment   ☐

Other Equipment – *specify:*

COMPARISON

        1) Concurrent   ☐

        2) Cross-over   ☐

        3) Pre or Post Intervention (or both)   ☐

        4) External Control Population   ☐

        5) No Comparison Group   ☐

        6) Can't tell   ☐

UNITS OF ANALYSIS:

        1) Number of manipulations   ☐

        2) Number of devices used or ordered   ☐

        3) Duty hours   ☐

        4) Number of employees   ☐

        5) Number of hospital beds   ☐

        6) Time period   ☐

        7) Can't tell   ☐

        8) Other   ☐

Other units – per nursing staff, per HCWs, per FTE, inventory units, pt days, daily census, or procedures – *specify:*

_____

METHODS

Training procedure clear (yes/no)?

Data collection methods clear (yes/no)?

Any obvious bias in data collection methods (yes/no)? *If yes, specify:*

_____

Duration of intervention *(specify)_____*

Duration of follow-up *(specify)_____*

_____

Characteristic	Yes	No	Can't tell	N/A
Target population pre-determined	☐	☐	☐	☐
Target intervention pre-determined	☐	☐	☐	☐
Measures of successful program pre-determined	☐	☐	☐	☐
Pre-testing of new 'tools'	☐	☐	☐	☐
Timing appropriate for specified outcomes	☐	☐	☐	☐

Characteristic	Yes	No	Can't tell	N/A
Some objective measures included	☐	☐	☐	☐
Some active surveillance included	☐	☐	☐	☐
Passive surveillance only	☐	☐	☐	☐
Sources of bias considered in advance *(specify below)*	☐	☐	☐	☐
Appropriate statistical method employed	☐	☐	☐	☐
Target groups large enough to ensure reasonable statistical power	☐	☐	☐	☐

Other Comments:

_____

_____

_____

_____

_____

_____

RESULTS

Characteristic	Yes	No	Can't tell	N/A
Effect modification was considered *(specify below)*	☐	☐	☐	☐
Assessment and control of confounding? *(specify below)*	☐	☐	☐	☐
Transitional period excluded from analysis	☐	☐	☐	☐
Any controlled results?	☐	☐	☐	☐
Results made available to affected groups	☐	☐	☐	☐

Other Comments:

_____

_____

_____

_____

_____

_____

_____

DISCUSSION

Characteristic	Yes	No	Can't tell	N/A
Interpretation of results extended beyond that supported by the data	☐	☐	☐	☐
Alternative explanations, including bias, were considered	☐	☐	☐	☐
Address non-hospital setting risks	☐	☐	☐	☐

Other Comments:

_____
_____
_____
_____

Annex 3: Definitions/guidelines for reviewing articles

Please put your initials on the top of the form in the space indicated. After reading through the article and completing the review form, please indicate your overall rating and rationale for that rating. Space is provided at the top of the form.

Introduction

1) Rationale clear (y/n): Does the author explain the underlying reason for this study? What makes this study approach new compared to past research on the topic?

2) **Focus** describes the type of equipment being replaced:

   a) Replacement needles: standard hollow bore needles for injections or blood draws.

   b) Other sharps: non-hollow-bore needles, non-needle sharps, e. g. IV catheters, lancets, suture needles.

   c) Training: Intervention is training in safety procedures.

   d) Other equipment: non-sharp equipment, e. g. disposal units, double-gloving or new types of gloves, recapping blocks for needles.

3) **Comparison** describes statistical comparison

   a) Concurrent: Intervention group compared with group with non-intervention group; data are collected for the same time period.

   b) Cross-over: The study was *designed* to use the cross-over design, where a single group receives two different interventions and their injury rates are compared. One of the interventions can be standard practice or standard equipment, but length of observation is usually equal and individuals involved in the study are expected to be identical for the two time periods.

   c) Pre/Post intervention: A pre-intervention time period is defined and data are collected for comparison with a period of time that either follows a specifically defined intervention interval or in which new equipment is in use.

d) External control population: An intervention is delivered and data collected only for the intervention period. Injury rates at the intervention site are compared with published injury rates.

e) No comparison group:

i) Injury rates following intervention are merely described, with no comparisons at all, or

ii) Ecological study design, in which new procedures, equipment or training has been introduced universally and administrative data are used to compare injury rates for some time period before and after. There is no reason to expect that the individuals observed in the two time periods are the same, and there is no way to know whether or not the new procedures, equipment, training have been used.

4) **Unit of analysis** is the denominator of the rate or proportion calculation.

a) Number of manipulations, example: injuries per xx injections

b) Number of devices used or ordered, example: injuries per xx hypodermics

c) Duty hours, example: injuries per xx hours at risk or MD hours

d) Number of employees, example: injuries per xx 100 nurses

e) Number of hospital beds, example: injuries per xx 100 occupied beds

f) Time period, example: injuries per month

5) **Methods**

a) Training procedure clear (y/n): Can you describe what training the target population received prior to or concurrent with implementation of the intervention?

b) Data collection methods clear (y/n): Can you describe how injury information or device use information was captured? Were used devices collected and inspected? In-person interviews conducted? Incident reports completed?

c) Any obvious bias in data collection methods (y/n): Was injury reporting active or passive (voluntary)? Was there likely to be pressure on the participants to over or under report?

6) Duration of intervention and follow-up

a) For all designs, duration of intervention is interval in which new equipment/procedure was in use

b) Duration of follow-up

    i) Concurrent comparison – follow-up is the same as intervention interval, since intervention and control groups are observed for the same amount of time.

    ii) Cross-over: duration of follow-up is sum of intervention and non-intervention periods.

    iii) For pre/post design, follow-up is pre plus post

    iv) For external comparison and for ecological studies, duration of follow-up is the time during which injury data were collected in the study population.

7) Study characteristics

a) Target population, intervention predetermined – Can only be true when the study was planned before the interventions were implemented.

b) Measures of successful program pre-determined – The author described what results should be attained in order to deem the study a success (e. g. overall reduction in NSI). If a quantitative estimate was provided (as would be used for a power calculation), please make a note on the form.

c) Pre-testing of new tools means some staff were involved in selecting the devices prior to their general introduction or implementation of intervention

d) Passive surveillance requires voluntary reporting of events (injuries), e. g. using injury report forms.

e) Active surveillance means events were reported through regular surveys or interviews during the study period. An example of active reporting is weekly interviews of all HCW in a particular unit(s),

f) Objective measures are direct observations, not dependent on voluntary reporting

g) Timing appropriate refers to interval during which outcomes were recorded. Are outcomes immediate (NSI)? Then counting injuries right away is appropriate, distant recollections probably not. Is seroconversion an outcome of interest? If so, enough time must elapse between exposure and serological evaluation for seroconversion to occur.

h) Sources of bias considered in advance – Should be discussed in the methods section. Did authors collect any covariates? If so, list them.

i) Appropriate statistical method employed – Applicable if comparisons are presented.

j) Target groups large enough to ensure reasonable power – How many employees observed? What was baseline (pre-intervention) outcome rate? Are there differences evident between the groups that look meaningful, but were not statistically significant? These are indications of inadequate power.

8) **Comments**: Note methodological strengths and weaknesses.

9) **Results**:

a) Effect modification considered – Did the authors evaluate possible effect modification (does not require presentation of stratified or controlled analyses)?

b) Assessment of confounding – Did the authors evaluate possible confounding (does not require presentation of stratified or controlled analyses)?

c) Transitional period excluded from analysis? Transitional period refers to a period following introduction of new equipment policy.

d) Any controlled results – indicate if any controlled results are presented, e. g. from a multivariable model or from a stratified analysis.

e) Results made available to affected groups – Did the authors disseminate the results?

10) **Comments**: Note confounders, effect modifiers considered in analysis.

11) **Discussion**

a) Interpretation beyond scope: Did authors exaggerate the ability of their work to demonstrate a causal relationship? E. g., presenting only descriptive comparisons and using passive reporting procedures makes the conclusion of a causal relationship beyond scope. Did authors assume their study demonstrated a relationship that could be applied more broadly than to their own population? E. g. if nurses were trained, did they assume doctors would benefit from same training?

b) Alternative explanations, including bias were considered: Did the authors discuss other reasons for the results they observed?

c) Address non-hospital setting: Can the results be applied to other health care delivery situations?

Annex 4: Working group Needlestick Injuries

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