Bibliography:

Efficacy of Safety-Engineered Sharp Medical Devices
Studies from 2001-2010

2010

Tosini W, Ciotti C, Goyer F, Lolom I, L'Hériteau F, Abiteboul D, Pellissier G, Bouvet E. Needlestick injury rates according to different types of safety-engineered devices: results of a French multicenter study. Infection Control and Hospital Epidemiology 2010;31(April):402-7.
ABSTRACT: To evaluate the incidence of needlestick injuries (NSIs) among different models of safety-engineered devices (SEDs) (automatic, semiautomatic, and manually activated safety) in healthcare settings. DESIGN: This multicenter survey, conducted from January 2005 through December 2006, examined all prospectively documented SED-related NSIs reported by healthcare workers to their occupational medicine departments. Participating hospitals were asked retrospectively to report the types, brands, and number of SEDs purchased, in order to estimate SED-specific rates of NSI. Setting. Sixty-one hospitals in France. RESULTS: More than 22 million SEDs were purchased during the study period, and a total of 453 SED-related NSIs were documented. The mean overall frequency of NSIs was 2.05 injuries per 100,000 SEDs purchased. Device-specific NSI rates were compared using Poisson approximation. The 95% confidence interval was used to define statistical significance. Passive (fully automatic) devices were associated with the lowest NSI incidence rate. Among active devices, those with a semiautomatic safety feature were significantly more effective than those with a manually activated toppling shield, which in turn were significantly more effective than those with a manually activated sliding shield ($P < .001$, chi(2) test). The same gradient of SED efficacy was observed when the type of healthcare procedure was taken into account. CONCLUSIONS: Passive SEDs are most effective for NSI prevention. Further studies are needed to determine whether their higher cost may be offset by savings related to fewer NSIs and to a reduced need for user training.

2009

De Carli G, Puro V, Jagger J. Needlestick-prevention devices: we should already be there [letter]. Journal of Hospital Infection 2009;71(2):183-4 (Epub 2008 Dec 4).

Sakamoto F. Effect of safety-engineered device implementation on needlestick injury rates. Kankyokanseishi [Japanese Journal of Environmental Infections] 2009;24(2):100-5. [in Japanese with abstract in English]
ABSTRACT: The effects of four types of safety-engineered devices (SEDs) on needlestick injury (NI) rates were evaluated during a six-year period (2002-2007) at a 520-bed teaching hospital. The devices were winged steel needles (WSNs), IV catheters (IVCs), lancets (LANs), and implantable port access needles (IPNs). A total of 471 NIs were reported, of which more than 60% were caused by hollow-bore needles. Device-specific NI rates were significantly lower for SEDs than non-SEDs in the use of WSNs (11.0 vs. 25.1 per 100,000 devices delivered, $p<0.01$) and IVCs (1.0 vs. 6.6 per 100,000 devices delivered, $p<0.01$). Use of SEDs was also associated with significantly lower risks of NIs in the use of WSN (RR 0.44; 95% CI, 0.31 to

0.61) and IVC (RR = 0.16, 95% CI, 0.05-0.50). There were strong (r = -0.94, p<0.01) and moderate (r = - 0.53, p=0.15) negative correlations between yearly SED use rates and NI rates in the use of WSNs and IVCs, respectively. Safety-engineered LANs and IPNs had been used for less than 1 year, and although NI rates for SEDs were lower than non-SEDs (LAN = 0.0 vs. 0.8 per 100,000 devices delivered, p = 0.42; IPN = 0.0 vs. 41.2 per 100,000 devices delivered, p = 0.19), the differences were not significant. In addition to introducing SEDs, promoting their use to replace non-SEDs is effective in reducing NI rates.

2008

Whitby M, McLaws ML, Slater K. Needlestick injuries in a major teaching hospital: the worthwhile effect of hospital-wide replacement of conventional hollow-bore needles. American Journal of Infection Control 2008 Apr;36(3):180-6.

BACKGROUND: Needlestick injury (NSI) with hollow-bore needles remains a significant risk of bloodborne virus acquisition in health care workers. The impact on NSI rates after substantial replacement of conventional hollow-bore needles with the simultaneous introduction of safety-engineered devices (SEDs), including retractable syringes, needle-free intravenous (IV) systems, and safety winged butterfly needles, was examined in an 800-bed Australian university hospital. METHODS: NSIs were prospectively monitored for 2 years (2005-2006) after the introduction of SEDs and compared with prospectively collected preintervention NSI data (2000-2004). RESULTS: Preintervention hollow-bore NSI rates over 10 years persisted at a constant rate between 3.01 and 3.77 per 100 full-time equivalent employees (FTE) (P = .31). Rates for 2005 (1.93; 95% CI: 1.48-2.47 per 100 FTE) and 2006 (1.50; 95% CI: 1.11-1.97 per 100 FTE) were significantly lower than the average rate for the preintervention years (3.39; 95% CI: 2.7-4.24 per 100 FTE, P = .00004). This represents a fall of 49% (43.1%-55.7%) in hollow-bore NSI, contributed to by the virtual elimination of NSI related to accessing IV lines. More importantly, high-risk injuries were also reduced 57% by retractable syringe use with an overall budgetary increase of approximately US $90,000 per annum. CONCLUSION: Introduction of SEDs results in an impressive fall in NSI with minimal cost outlay.

2007

Azar-Cavanagh M, Burdt P, Green-McKenzie J. Effect of the introduction of an engineered sharps injury prevention device on the percutaneous injury rate in healthcare workers. Infection Control and Hospital Epidemiology 2007;28(2):165–170.

OBJECTIVE. To evaluate the effect of introducing an engineered device for preventing injuries from sharp instruments (engineered sharps injury prevention device [ESIPD]) on the percutaneous injury rate in healthcare workers (HCWs). METHODS: We undertook a controlled, interventional, before-after study during a period of 3 years (from January 1998 through December 2000) at a major medical center. The study population was HCWs with potential exposure to bloodborne pathogens. HCWs who sustain a needlestick injury are required by hospital policy to report the exposure. A confidential log of these injuries is maintained that includes information on the date and time of the incident, the type and brand of sharp device involved, and whether an ESIPD was used. INTERVENTION: Introduction of an intravenous (IV) catheter stylet with a safety-engineered feature (a retractable protection shield), which was placed in clinics and hospital wards in lieu of other IV catheter devices that did not have safety features. No protective devices were present on suture needles during any of the periods. The incidence of percutaneous needlestick injury by IV catheter and suture needles was evaluated for

18 months before and 18 months after the intervention. RESULTS: After the intervention, the incidence of percutaneous injuries resulting from IV catheters decreased significantly (P<.01), whereas the incidence of injuries resulting from suture needle injuries increased significantly (P<.008). CONCLUSION: ESIPDs lead to a reduction in percutaneous injuries in HCWs, helping to decrease HCWs' risk of exposure to bloodborne pathogens.

Lamontagne F, Abiteboul D, Lolom I, Pellissier G, Tarantola A, Descamps JM, Bouvet E. Role of safety-engineered devices in preventing needlestick injuries in 32 French hospitals. Infection Control and Hospital Epidemiology 2007;28(1):18-23.
ABSTRACT- Objectives: To evaluate safety-engineered devices (SEDs) with respect to their effectiveness in preventing needlestick injuries (NSIs) in healthcare settings and their importance among other preventive measures. Design: Multicenter prospective survey with a 1-year follow-up period during which all incident NSIs and their circumstances were reported. Data were prospectively collected during a 12-month period from April 1999 through March 2000. The procedures for which the risk of NSI was high were also reported 1 week per quarter to estimate procedure-specific NSI rates. Device types were documented. Because SEDs were not in use when a similar survey was conducted in 1990, their impact was also evaluated by comparing findings from the recent and previous surveys. Setting: A total of 102 medical units from 32 hospitals in France. Participants: A total of 1,506 nurses in medical or intensive care units. Results: A total of 110 NSIs occurring during at-risk procedures performed by nurses were documented. According to data from the 2000 survey, use of SEDs during phlebotomy procedures was associated with a 74% lower risk (P<.01). The mean NSI rate for all relevant nursing procedures was estimated to be 4.72 cases per 100,000 procedures, for a 75% decrease since 1990 (P<.01); however, the decrease in NSI rates varied considerably according to procedure type. Between 1990 and 2000, decreases in the NSI rates for each procedure were strongly correlated with increases in the frequency of SED use (r=0.88; P<.02). Conclusion: In this French hospital network, the use of SEDs was associated with a significantly lower NSI rate and was probably the most important preventive factor.

Valls V, Lozano MS, Yanez R et al. Use of safety devices and the prevention of percutaneous injuries among healthcare workers. Infection Control and Hospital Epidemiology 2007;28:1352-60.
ABSTRACT: To study the effectiveness of safety devices intended to prevent percutaneous injuries. Design: Quasi-experimental trial with before-and-after intervention evaluation. Setting: A 350-bed general hospital that has had an ongoing educational program for the prevention of percutaneous injuries since January 2002. Methods: In October 2005, we implemented a program for the use of engineered devices to prevent percutaneous injury in the emergency department and half of the hospital wards during the following procedures: intravascular catheterization, vacuum phlebotomy, blood-gas sampling, finger-stick blood sampling, and intramuscular and subcutaneous injections. The nurses in the wards that participated in the intervention received a 3-hour course on occupationally acquired bloodborne infections, and they had a 2-hour "hands-on" training session with the devices. We studied the percutaneous injury rate and the direct cost during the preintervention period (October 2004 through March 2005) and the intervention period (October 2005 through March 2006). Results: We observed a 93% reduction in the relative risk of percutaneous injuries in areas where safety devices were used (14 vs 1 percutaneous injury). Specifically, rates decreased from 18.3 injuries (95% confidence interval

[CI], 5.9-43.2 injuries) to 0 injuries per 100,000 patients in the emergency department (P=.002) and from 44.0 injuries (95% CI, 20.1-83.6 injuries) to 5.2 injuries (95% CI, 0.1-28.8 injuries) per 100,000 patient-days in hospital wards (P=.007). In the control wards of the hospital (i.e., those where the intervention was not implemented), rates remained stable. The direct cost increase was euro0.558 (US$0.753) per patient in the emergency department and euro0.636 (US$0.858) per patient-day in the hospital wards. Conclusion: Proper use of engineered devices to prevent percutaneous injury is a highly effective measure to prevent these injuries among healthcare workers. However, education and training are the keys to achieving the greatest preventative effect.

2006

Tuma SJ, Sepkowitz KA. Efficacy of safety-engineered device implementation in the prevention of percutaneous injuries: a review of published studies. Clinical Infectious Diseases 2006;42:1159–1170.

SUMMARY: Nearly 6 years have passed since the Needlestick Safety and Prevention Act of 2000 was signed into law. We reviewed studies published since 1995 that evaluated the effect of safety-engineered device implementation on rates of percutaneous injury (PI) among health care workers. Criteria for inclusion of studies in the review were as follows: the intervention used to reduce PIs was a needleless system or a device with engineered sharps-injury protection, the outcome measurements included a PI rate, the intervention was evaluated in a defined population with clear comparison groups in clinical settings, and outcomes and denominators used for rate calculations were objectively measured using consistent methodology. All 17 studies reported substantial decreases in device-associated or overall PI rates after device implementation (range of reduction, 22%–100%). The majority of studies (np12) were uncontrolled before-after trials with limited ability to control for confounding variables. In addition, implementation of safety engineered devices was often accompanied by other interventions, and direct measurement of outcomes was not performed. Nevertheless, safety-engineered devices are an important component in PI prevention.

2005

Iinuma Y, Igawa J, Takeshita M, et al. Passive safety devices are more effective at reducing needlestick injuries [letter]. Journal of Hospital Infection 2005;61:360–1.

2004

Rogues AM, Verdun-Esquer C, Buisson-Valles I, Laville MF, Lashéras A, Sarrat A, Beaudelle H, Brochard P, Gachie JP. Impact of safety devices for preventing percutaneous injuries related to phlebotomy procedures in health care workers. American Journal of Infection Control 2004; 32:441–4.

BACKGROUND: Use of protective devices has become a common intervention to decrease sharps injuries in the hospitals; however few studies have examined the results of implementation of the different protective devices available. OBJECTIVE: To determine the effectiveness of 2 protective devices in preventing needlestick injuries to health care workers. METHODS: Sharps injury data were collected over a 7-year period (1993-1999) in a 3600-bed tertiary care university hospital in France. Pre- and postinterventional rates were compared after the implementation of 2 safety devices for preventing percutaneous injuries (PIs) related to phlebotomy procedures. RESULTS: From 1993 to 1999, an overall decrease in the needlestick-

related injuries was noted. Since 1996, the incidence of phlebotomy-related PIs has significantly decreased. Phlebotomy procedures accounted for 19.4% of all percutaneous injuries in the preintervention period and 12% in the postintervention period (RR, O.62; 95% CI, 0.51-0.72; P < .001). Needlestick-related injuries incidence rate decreased significantly after the implementation of the 2 safety devices, representing a 48% decline in incidence rate overall. CONCLUSIONS: The implementation of these safety devices apparently contributed to a significant decrease in the percutaneous injuries related to phlebotomy procedures, but they constitute only part of a strategy that includes education of health care workers and collection of appropriate data that allow analysis of residuals percutaneous injuries.

Sohn S, Eagan J, Sepkowitz KA, Zuccotti G. Effect of implementing safety-engineered devices on percutaneous injury epidemiology. Infection Control and Hospital Epidemiology 2004;25:536-42.
OBJECTIVE: To assess the effect of implementing safety-engineered devices on percutaneous injury epidemiology, specifically on percutaneous injuries associated with a higher risk of blood-borne pathogen exposure. DESIGN: Before-and-after intervention trial comparing 3-year preintervention (1998--2000) and 1-year postintervention (2001--2002) periods. Percutaneous injury data have been entered prospectively into CDC NaSH software since 1998. SETTING: A 427-bed, tertiary-care hospital in Manhattan. PARTICIPANTS: All employees who reported percutaneous injuries during the study period. INTERVENTION: A "safer-needle system," composed of a variety of safety-engineered devices to allow for needle-safe IV delivery, blood collection, IV insertion, and intramuscular and subcutaneous injection, was implemented in February 2001. RESULTS: The mean annual incidence of percutaneous injuries decreased from 34.08 per 1,000 full-time-equivalent employees preintervention to 14.25 postintervention (P < .001). Reductions in the average monthly number of percutaneous injuries resulting from both low-risk (P < .01) and high-risk (P was not significant) activities were observed. Nurses experienced the greatest decrease (74.5%, P < .001), followed by ancillary staff (61.5%, P = .03). Significant rate reductions were observed for the following activities: manipulating patients or sharps (83.5%, P < .001), collisions or contact with sharps (73.0%, P = .01), disposal-related injuries (21.41%, P = .001), and catheter insertions (88.2%, P < .001). Injury rates involving hollow-bore needles also decreased (70.6%, P < .001). CONCLUSIONS: The implementation of safety-engineered devices reduced percutaneous injury rates across occupations, activities, times of injury, and devices. Moreover, intervention impact was observed when stratified by risk for blood-borne pathogen transmission.

2003

Alvarado-Ramy F, Beltrami EM, Short LJ, et al. A comprehensive approach to percutaneous injury prevention during phlebotomy: results of a multicenter study, 1993-1995. Infection Control and Hospital Epidemiology 2003; 24:97-104.
OBJECTIVE: To examine a comprehensive approach for preventing percutaneous injuries associated with phlebotomy procedures. DESIGN AND SETTING: From 1993 through 1995, personnel at 10 university-affiliated hospitals enhanced surveillance and assessed underreporting of percutaneous injuries; selected, implemented, and evaluated the efficacy of phlebotomy devices with safety features (i.e., engineered sharps injury prevention devices [ESIPDs]); and assessed healthcare worker satisfaction with ESIPDs. Investigators also evaluated the preventability of a subset of percutaneous injuries and conducted an audit of sharps disposal

containers to quantify activation rates for devices with safety features. RESULTS: The three selected phlebotomy devices with safety features reduced percutaneous injury rates compared with conventional devices. Activation rates varied according to ease of use, healthcare worker preference for ESIPDs, perceived "patient adverse events," and device-specific training. CONCLUSIONS: Device-specific features and healthcare worker training and involvement in the selection of ESIPDs affect the activation rates for ESIPDs and therefore their efficacy. The implementation of ESIPDs is a useful measure in a comprehensive program to reduce percutaneous injuries associated with phlebotomy procedures.

Mendelson MH, Lin-Chen BY, Solomon R, Bailey E, Kogan G, Goldbold J. Evaluation of a safety resheathable winged steel needle for prevention of percutaneous injuries associated with intravascular-access procedures among healthcare workers. Infection Control and Hospital Epidemiology 2003; 24:105–12.
OBJECTIVE: To compare the percutaneous injury rate associated with a standard versus a safety resheathable winged steel (butterfly) needle. DESIGN: Before-after trial of winged steel needle injuries during a 33-month period (19-month baseline, 3-month training, and 11-month study intervention), followed by a 31-month poststudy period. SETTING: A 1,190-bed acute care referral hospital with inpatient and outpatient services in New York City. PARTICIPANTS: All healthcare workers performing intravascular-access procedures with winged steel needles. INTERVENTION: Safety resheathable winged steel needle. RESULTS: The injury rate associated with winged steel needles declined from 13.41 to 6.41 per 100,000 (relative risk [RR], 0.48; 95% confidence interval [CI95], 0.31 to 0.73) following implementation of the safety device. Injuries occurring during or after disposal were reduced most substantially (RR, 0.15; CI95, 0.06 to 0.43). Safety winged steel needle injuries occurred most often before activation of the safety mechanism was appropriate (39%); 32% were due to the user choosing not to activate the device, 21% occurred during activation, and 4% were due to improper activation. Preference for the safety winged steel needle over the standard device was 63%. The safety feature was activated in 83% of the samples examined during audits of disposal containers. Following completion of the study, the safety winged steel needle injury rate (7.29 per 100,000) did not differ significantly from the winged steel needle injury rate during the study period. CONCLUSION: Implementation of a safety resheathable winged steel needle substantially reduced injuries among healthcare workers performing vascular-access procedures. The residual risk of injury associated with this device can be reduced further with increased compliance with proper activation procedures.

2002

McCleary J, Caldero K, Adams T. Guarded fistula needle reduces needlestick injuries in hemodialysis. Nephrology News and Issues 2002;16:66–70, 72.
ABSTRACT: Use of large-gauge, hollow-bore, arteriovenous fistula needles (AVFNs) and high-pressure accesses are unique factors inherent to the hemodialysis (HD) setting. The dialysis patient population has a higher incidence of hepatitis C (HCV) than the general population (8.4% compared to 1.8%) and the incidence of Human Immunodeficiency Virus (HIV) has increased tenfold from 1985 to 2000. HD health care workers (HCWs) are twice as likely to sustain a high-risk needlestick injury (NSI) as HCWs in all other settings. All of these factors leave HD HCWs at a high risk of exposure to bloodborne pathogens (BBPs). Although published data on NSI reduction with guarded AVFNs is lacking, many HD facilities have rushed to implement guarded

AVFNs to comply with Occupational Safety and Health Administration's (OSHA) newly revised Bloodborne Pathogens Standard (29 CFR 1910.1030). For this study, we evaluated the effectiveness of one design of AVFN guard (MasterGuard Anti-Stick Needle Protector, Medisystems Corporation) by comparing its NSI rate to that of unguarded AVFNs. The unguarded AVFN injury rate was 8.58 NSIs per 100,000 unguarded AVFNs (in 81,534 cannulations) compared to zero NSIs per 100,000 guarded AVFNs (in 54,044 cannulations). The guarded AVFN showed a statistically significant NSI reduction compared to the unguarded AVFN ($p < 0.029$). This study demonstrates that using a guarded AVFN will help reduce HCWs' risk of exposure to BBPs in the dialysis setting.

2001

Peate WF. Preventing needlesticks in emergency medical system workers. Journal of Occupational and Environmental Medicine 2001; 43:554–7.

ABSTRACT: Emergency medical system (EMS) workers frequently use sharp devices in injury-prone circumstances that involve limited visibility, confined spaces, rapidly moving vehicles, and uncooperative victims. This study examined the efficacy of an automatic self-retracting lancet in reducing needlestick injuries and related direct and indirect costs. Subjects were 477 active-duty EMS workers. Counseling, laboratory testing (hepatitis B and C, hepatic function enzymes, and human immunodeficiency virus), antiviral prophylaxis, and immunizations were provided according to US Public Health Service guidelines. Baseline and biennial laboratory testing for hepatitis B and C and liver function enzymes were conducted. After the introduction of a spring-loaded automatic-retracting type glucometer lancet device, needlestick injuries decreased from 16 per 954 EMS worker-years to 2 per 477 EMS worker-years. The annualized cost of treatment declined from $8276 to $2068. The change to a self-retracting device decreased the number of needlestick injuries and was cost-effective with a minimal increase in device cost (annualized $366 per year).