ORIGINAL ARTICLE

Needlestick Injury Rates According to Different Types of Safety-Engineered Devices: Results of a French Multicenter Study

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OBJECTIVES.   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 ($P < .001$, χ^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.

The introduction of disposal containers for sharp objects and the introduction of safety-engineered devices (SEDs) have substantially reduced the incidence of needlestick injury (NSI). SEDs are sharp devices with an integrated safety feature designed to shield the needle or nonneedle sharp object after use.[1] In the United States, the Needlestick Safety and Prevention Act was adopted in November 2000, shifting the focus from behavior to devices and requiring the use of SEDs to prevent exposure to bloodborne pathogens as well as the documentation of all NSIs. In France, SED use is officially recommended.[2]

Compared with conventional devices, SEDs have been shown to reduce the risk of NSIs by 22%–100%.[3-7] Prospective multicenter studies performed in France in 1990 and 1999–2000 by the Accidental Blood Exposure Study Task Force (GERES), a not-for-profit university-based research group for the prevention of occupational infections among healthcare workers (HCWs), showed a 4-fold reduction in NSIs during the 1990s, largely due to the introduction and widespread use of SEDs.[8]

As SED use grows, the proportion of NSIs due to these devices increases. For example, in a New York City tertiary care center, 27% of reported percutaneous injuries were associated with SEDs during the 2001–2002 postintervention period.[1] Likewise, the GERES survey in 2000 showed that 23 (18%) of 130 documented NSIs were due to SEDs.[8] SED-associated NSIs may occur through mechanical failure of the safety feature, incomplete activation, user noncompliance, or an inherently risky activation procedure. Not all devices used for different types of invasive procedure have undergone the same degree of technical improvement, and SEDs of different generations coexist in the marketplace.[9] Broadly speaking, SEDs are in 2 categories: active devices that require 1- or 2-handed activation by the HCW after use and passive devices that are automatically operated throughout the use of the device.

A French regulation (a decree on May 4, 1994, that translated a European directive into French legislation) states that employers are responsible for staff safety with regard to biological risks. A ministerial circular published in 1998 lists the elements for a multidimensional preventive program that is to be performed in the hospitals.[2] This list includes the requirement to use SEDs and to train HCWs in their use. Nevertheless, to date there are no reference standard criteria for labeling a device as "safety-engineered," and manufacturers usually market new devices as safety engineered without reproducible criteria. The effect of a new SED on NSI-risk reduction can be determined only in routine healthcare settings, through lengthy studies with adequate statistical power. Very few authors have compared the efficacy of different SEDs that are used for the same invasive procedure.[10,11] GERES, with support from the French agency for health product safety (Agence Française de Sécurité Sanitaire des Produits de Santé), therefore conducted a multicenter survey to assess and compare the frequency, incidence rates, and circumstances of NSIs associated with different SED designs.

METHODS

This multicenter survey took place from January 1, 2005, through December 31, 2006, in a network of French hospitals that agreed to participate, on a voluntary basis, for a period of one year (either 2005 or 2006) or 2 years (2005 and 2006). We focused only on devices equipped with a needle. Hospitals were eligible if, during the study period, they purchased SEDs that incorporated an integrated safety feature designed to shield the needle after use.

Routine surveillance of blood and body fluid exposure, in hospitals that agreed to participate, was conducted on the basis of the voluntary reporting of exposures by HCWs to the occupational medicine department of their hospital. Thus, all NSIs involving such SEDs that were reported voluntarily by HCWs to their occupational medicine department during the study period were documented prospectively during 2005 and 2006 by using a standardized anonymous questionnaire described elsewhere[12-14] and routinely used for blood and body fluid exposure surveillance in hospitals in France. The following circumstances were recorded: the task during which the NSI occurred, the type and brand of device involved, the cause of injury, and whether the safety mechanism was activated. Each participating hospital was asked retrospectively at the end of each year of the study (2005 and 2006) to report the types, brands, and numbers of SEDs purchased during the whole year. The latter number was used as the denominator for SED-related NSI incidence rates, expressed per 100,000 units purchased. SEDs were defined as recommended in the 1998 French ministerial circular[2] and in GERES guidelines.[15]

The choice of SEDs and the training of HCWs in their use took place before and apart from the study and were left to the discretion of each hospital; the occupational health department and the nosocomial infection control committee are responsible for the application of the ministerial guidelines in each hospital.[2] We classified SEDs according to the passive or active nature of the safety activation mechanism. Active devices were then subdivided into those with a protective sliding shield, those with a protective needle shield aligned to the bevel-up position and toppling over the needle, and those with a semiautomatic safety feature (ie, an automatic safety feature requiring 1-handed activation by pushing a button or a plunger). With regard to phlebotomy devices (ie, a phlebotomy needle or winged steel needle attached to a vacuum holder further including a needle inside the holder that is adapted to be received by a vacuum tube or a blood culture bottle), NSIs involving the needle located inside the holder were excluded, because SEDs focus on the needle designed to penetrate the skin.

Data were analyzed using Epi-Info, version 6.04d (Centers for Disease Control and Prevention). Device-specific NSI rates were compared using Poisson approximation. The 95% confidence interval (CI) was used to define statistical significance.

RESULTS

Sixty-one hospitals participated in the study, of which 40 participated in both 2005 and 2006. The hospitals consisted of 54 public and 7 private institutions located throughout France. The participating hospitals totaled approximately 43,000 beds in 2005 and 33,000 beds in 2006.

A total of 504 NSIs due to SEDs were reported during the 2-year survey period, representing 9.8% of all NSIs reported during that period. Full information was available for 475 of these NSIs, of which 453 were SED-related as defined in Methods. More than 22 million SEDs were purchased during the study period, and a mean of 6 different safety devices (range, 1–14) were available in each participating hospital. Forty different SEDs were identified, of which 22 were associated with documented NSIs. Table 1 shows the NSI incidence rates for each type of SED. The mean overall frequency of NSIs was 2.05 injuries per 100,000 SEDs purchased.

NSI incidence rates are shown in Table 2 according to the type of safety system. Among the active SEDs, those with a manually activated protective sliding shield were significantly less effective than those with a toppling shield, which in turn were significantly less effective than those with a semiautomatic safety feature ($P < .001$, χ^2 test). Passive devices included in the study, self-retracting lancets (7 different brands), intravenous catheters (2 different brands), and insulin pen needles (1 brand), were associated with the lowest NSI incidence rate. Self-retracting lancets accounted for 97% of the total number of passive devices purchased and for 40% of the number of NSIs by passive devices.

SEDs with manually activated safety features (the first 2 rows in Table 2) were associated with 10.7 times more NSIs than SEDs with semiautomatic or automatic safety features (the last 2 rows in Table 2). (For SEDs with manually activated

TABLE 1. Needlestick Injury (NSI) Incidence Rates According to the Type of Safety-Engineered Device

Type of device	No. of devices purchased	No. of NSIs reported	No. of NSIs/1×10^5 devices purchased
Insulin pen needles	22,540	0	0.00
Lancets	8,624,518	2	0.02
Arterial blood syringes	624,946	7	1.12
Prefilled syringes	4,342,861	55	1.27
Vacuum tube blood-collection devices	2,248,630	48	2.13
Fistula needles	45,156	1	2.21
Injection needles and/or syringes	184,207	5	2.71
Intravenous catheters	1,801,107	68	3.78
Winged steel needles	4,176,912	257	6.15
Implantable port needles	62,003	10	16.13

safety features, there were 4.39 NSIs per 1×10^5 devices purchased [95% CI, 3.96–4.82 NSIs per 1×10^5 devices purchased], and for SEDs with semiautomatic or automatic safety features, there were 0.41 NSIs per 1×10^5 devices purchased [95% CI, 0.30–0.52 NSIs per 1×10^5 devices purchased].) The same gradient of SED efficacy was observed when the types of procedure were taken into account, as shown in Table 3.

Finally, we investigated the circumstances of the 453 NSIs according to safety feature activation. One hundred sixty-eight NSIs (37.1%) occurred during the invasive procedure (while introducing needle, by accidental needle withdrawal during procedure, or during needle withdrawal at the end of procedure) before activation of the safety feature was appropriate or possible, and these were assessed as not preventable by the SED used by the injured HCW. One hundred thirty-three NSIs (29.4%) occurred during activation of the safety feature. One hundred six NSIs (23.4%) involved user failure to activate the safety feature after completing the invasive procedure. Only 46 NSIs (10.2%) occurred after activation of the safety feature, of which nearly half (18 [39.1%] of 46) were due to incomplete activation by the user and the remainder (28 [60.9%] of 46) were due to failure of the safety feature (as declared by the HCW involved). The circumstances of the NSIs are shown in Table 4 according to SED design and the phase of the invasive procedure.

DISCUSSION

During this 2-year multicenter survey, 453 fully documented NSIs that involved SEDs were reported. The overall NSI incidence rate was only 2.05 injuries per 100,000 SEDs purchased, in keeping with the rate of 2.9 injuries per 100,000 SEDs purchased that was observed in the previous GERES study[8] and also with other published data.[16] The SED-specific NSI rates found here were lower than those reported elsewhere with conventional devices (2.1 vs 2.7–4.9 NSIs/1×10^5 vacuum tube collection devices purchased; 3.8 vs 8.5–15.8 NSIs/1×10^5 catheters purchased; 6.2 vs 10.1–13.2 NSIs/1×10^5 winged steel needles purchased)[8,17,18] and were similar to those observed in the 2000 GERES survey and elsewhere. For example, the NSI rate associated with intravenous catheters was 3.6 NSIs/1×10^5 intravenous catheters purchased in the GERES 2000 survey[8] and 3.78 NSIs/1×10^5 intravenous catheters purchased in the present study. Likewise, the NSI rate associated with resheathable winged steel needles was 6.15 NSIs/1×10^5 resheathable winged steel needles purchased in the present study, and 6.41 NSIs/1×10^5 resheathable winged steel needles purchased in an American study of such devices.[19]

We found that some SEDs were more effective than others in preventing NSIs. Knowledge of the most effective designs is important, both to guide the choice among available devices

TABLE 2. Needlestick Injury (NSI) Incidence Rates According to the Type of Integrated Safety Feature

Type of safety feature	No. of devices purchased	No. of NSIs reported	No. of NSIs/1×10^5 devices purchased (95% CI)
Active device			
Manually activated protective sliding shield	5,829,655	303	5.20 (4.61–5.78)
Manually activated protective toppling shield	3,266,450	96	2.94 (2.35–3.53)
Semiautomatic safety feature	4,161,295	49	1.18 (0.85–1.51)
Passive device			
Automatic safety feature	8,875,480	5	0.06 (0.01–0.11)

NOTE. CI, confidence interval.

TABLE 3.   Procedure-Specific Needlestick Injury (NSI) Incidence Rates According to Safety-Engineered Device Design

| | No. of NSIs/1 $\times$ 10^5 Devices Purchased (95% CI) | | | |
| | Active device | | | |
Invasive procedure	With manually sliding shield	With manually toppling shield	With semiautomatic safety feature	Passive device
Arterial and venous blood sampling	5.72 (4.96–6.49)	2.89 (2.30–3.47)	…	…
Vascular catheterization	4.34 (3.24–5.44)	…	2.54 (0.51–4.58)	1.31 (0.00–2.80)
Subcutaneous injection with prefilled syringes (LMWH)	3.08 (1.47–4.69)	…	1.05 (0.73–1.38)	…

NOTE.   Empty cells represent devices unavailable or rarely used at the time of the study. CI, confidence interval; LMWH, low-molecular-weight heparin.

and to help manufacturers develop new safety technology for sharp objects. Our systematic analysis of device-specific rates of NSI suggests that SEDs with automatic or semiautomatic activation of the safety feature are more effective than SEDs that require full user intervention. Indeed, SEDs with automatic or semiautomatic safety features were 10 times less likely to be associated with NSIs than were devices in which activation of the safety feature was fully manual. SEDs with a push bottom or plunger were significantly safer than those with a toppling shield, which, in turn, were significantly safer than those with sliding protection. According to the manufacturers' instructions, most active devices with a sliding shield require 2-handed activation, whereas most active devices with a toppling shield require 1-handed activation. NSIs seem to be more frequent when the user's passive hand is required to approach the needle and when the activation mechanism is not sufficiently intuitive. Passive devices are associated with the lowest NSI incidence rates. In particular, self-retracting lancets (passive devices for capillary blood sampling) had by far the lowest NSI incidence rate of all the types of SED studied here (0.02 NSIs/1 $\times$ 10^5 self-retracting lancets purchased), in keeping with previous reports.[8,20,21] New implantable-port safety needles had the highest NSI incidence rate (16.1 NSIs/1 $\times$ 10^5 implantable-port safety needles purchased). However, the use of nonsafety needles was associated with much higher rates of NSIs in the GERES surveys conducted in 1990 (410 NSIs/1 $\times$ 10^5 devices purchased), when no safety devices were available, and also in 2000 (25.0 NSIs/ 1 $\times$ 10^5 devices purchased), when accessory safety devices were available to protect the passive hand (spatulas for hand-free stabilization of the implantable port during withdrawal of Huber needles) and when training in best practices had improved.[8]

One would expect NSI rates associated with devices with different activation mechanisms to correlate with the risks inherent in the procedure for which they were designed. Nevertheless, the gradient of NSI rates associated with different safety features was unaffected when the type of invasive procedure was taken into account (injection with prefilled syringes, vascular catheterization, and arterial/venous blood sampling). A reference study conducted by the Centers for Disease Control from 1993 through 1995 showed a reduction in phlebotomy-related NSIs ranging 23%–76%, depending on the SED tested.[10] Three different SEDs were tested, corresponding to each of the 3 subgroups of active devices in our classification: a winged steel needle with a protective sliding shield and 2 vacuum tube blood-collection devices, one with a protective toppling shield and the other with an automatic safety feature activated by pushing the tube. Interestingly, the same gradient was observed in this study (3.1 NSIs/1 $\times$ 10^5 purchased devices with the manually sliding shield, 1.2 NSIs/1 $\times$ 10^5 purchased devices with the manually toppling shield, and 0.9 NSIs/1 $\times$ 10^5 purchased devices with the semiautomatic safety feature). Moreover, a study conducted in a university hospital showed that a passive safety-designed intravenous catheter was more effective than an active IV catheter with a semiautomatic safety feature.[11]

Almost 40% of the NSIs in our study occurred while the

TABLE 4.   Timing of Needlestick Injury (NSI) Relative to Activation of the Safety Feature and According to Safety-Engineered Device Design

| | No. (%) of NSIs | | | |
| | Active device | | | |
Timing of injury	With manually sliding shield	With manually toppling shield	With automatic safety feature	Passive device
Before activation was possible or appropriate	114 (37.6)	28 (29.2)	26 (53.1)	0 (0)
During activation	91 (30.0)	39 (40.6)	3 (6.1)	0 (0)
After activation (incomplete activation or failure of the safety feature[a])	21 (6.9)	8 (8.3)	12 (24.5)	5 (100)
Not activated after procedure	77 (25.4)	21 (21.9)	8 (16.3)	0 (0)
Total	303 (100)	96 (100)	49 (100)	5 (100)

[a]   As declared by the user.

devices were being used, that is, before activation of the safety feature was appropriate or possible. The corresponding rate in the CDC study was 59%.[10] All SEDs documented in the study address the risk of exposure after an invasive procedure in the time between needle withdrawal and needle discard into a sharp objects container, even though successive generations of devices have allowed increasingly easy and increasingly early activation of safety, thus reducing the risk. Nevertheless, in a global approach to prevent HCW exposure, the risk during procedure has to be taken into account in future development of safety designs, as is the case, for instance, during suture procedures, by the use of blunt suture needles. Moreover, the statistical significance between NSI rates related to the different types of SEDs remains unaffected even if NSIs that occur during invasive procedures are not taken into account to calculate NSI rates. Almost 25% of NSIs occurred between the end of the procedure and device disposal, owing to user failure to activate the safety feature. The 1997 CDC survey showed a rate of 18% for this type of accident.[10] One-third of NSIs took place during activation of the safety feature. Accidents of this type, peculiar to these devices, seem to result from incorrect user activation of the safety mechanism rather than from failure of the device itself. This type of error may be due to inadequate information for and/or training of HCWs. SEDs are more complex than their conventional equivalents and usually necessitate specific training, particularly in how to activate the safety mechanism at the end of the invasive procedure. One-tenth of NSIs took place despite the safety feature having been activated. In half of these cases, the user reported that the device had failed, whereas the remainder were due to incomplete activation by the user. Thus, more than one-quarter of NSIs (124 [27.4% of 453]) were due to nonactivation or incomplete activation of the safety device and could have been avoided.

Many factors can contribute to user acceptance of SEDs, which may also influence the efficacy of SEDs. These include the design of the device, training provided before and after introduction of the device, ease of use, changes in technique, the perceived risk of occupational infection, and patient safety issues. Devices with fully manual safety features can be activated only after needle withdrawal. Active devices in which an automatic safety feature is activated during withdrawal may reduce injuries occurring during this phase. Nevertheless, HCWs' concerns for patient safety or comfort[10] may reduce the efficacy of such SEDs, because HCWs may delay activation or rate the device as being more difficult to use. Passive devices, which do not rely on user activation, seem to be more effective. Moreover, studies of retractable intravascular devices have shown that active SEDs with semiautomatic safety features generate more blood splatter into the environment than do nonsafety and passive safety devices.[22-24]

This study has several limitations. First, the sample size for some devices or designs was too small for valid comparisons. In addition, NSIs are sufficiently rare to necessitate prohibitive sample sizes in some circumstances: for example, if the baseline injury rate for a given device is 5 injuries per 100,000 devices, then the sample size required to show a 50% reduction in NSIs is one million devices.[25] Another limitation is the reliance of this survey on self-reported injuries. The methodology of the survey did not enable the authors to assess underreporting. Nevertheless, the SED-specific NSI rates found here were similar to those obtained in the GERES observational study conducted in 2000[8] and in other studies.[16,19] Such data underscored the low level of underreporting of NSIs. It is unlikely that the extent of underreporting varied according to the type of SED. Also, our use of the number of devices purchased rather than the number of devices actually used is another possible source of bias. Nevertheless, it is noteworthy that our calculated NSI rates are consistent with those reported elsewhere.

Despite these limitations, we provide clear evidence that passive SEDs are more effective than active SEDs for NSI prevention. Passive devices require no input from the user, and this is particularly important when healthcare personnel are working long hours or night shifts, as well as in emergency situations, all of which are associated with a higher rate of NSIs.[26-28] Furthermore, passive devices eliminate the need for elaborate training. Although the cost of fully automated SEDs can be an obstacle to their use, this drawback might be offset by lesser training requirements and by cost savings associated with a reduction in NSIs (eg, serological tests, counseling, postexposure prophylaxis, time off work, and treatment).

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