Sharps injury reduction using a sharps container with enhanced Engineering: A 28 hospital non-randomized intervention and cohort study

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Background: The decrease in reported sharps injuries (SI) in the United States has markedly slowed. Additional devices and strategies need investigation. Sharps containers are associated with SI, and more than 90% of these injuries are related to container design. This study addresses the hypothesis that containers with enhanced engineering can reduce SI.

Methods: In a before/after intervention study from 2006 to 2008, we examined the impact of conversion to a sharps container with enhanced engineering (the Device) on SI categories in 14 Ascension Health hospitals (study group). The Device's safety features included large horizontal aperture, sensitive counterbalanced door, large atrium, and passive overfill prevention. Study group results were also compared with a control cohort of 14 contemporaneous size-matched, Ascension Health hospitals (control group).

Results: The Device was associated with significant reductions in after-procedure (30%), disposal-related (57%), and container-associated (81%) SI in the study group. No significant reductions occurred in container-associated sharps injuries in the control group. Hospitals using the Device had significantly fewer total SI than control hospitals.

Conclusion: Enhanced aperture design can significantly reduce container-associated sharps injuries. Other factors contributing to reduced injuries may include 1-hand deposit, safe closure, hand restriction, and preassembly. These results, from a country where sharps safety devices are widespread, are particularly applicable to countries where safety devices are not extensively used.

Key Words: Sharps injury; needlestick injury; sharps container; sharps injury reduction; safety devices; engineered controls; reusable.

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INTRODUCTION

The fall in sharps injuries following enactment of the 2001 revised US Occupational Safety and Health Administration Bloodborne Pathogen Standard [1] was dramatic – a 34% drop the year after enactment.[2] However, due either to unavailability of safety devices for specific procedures, difficulties in safety device use, or increased reporting, SI incidence has changed little since [3,4] and the zero SI target set by CDC in 2001[5] has proved elusive. Additional devices and strategies need investigation. Commercial sharps containers became the norm in US hospitals in the early 1980s; however, their adoption changed the profile of SI by creating a new SI hazard: *container-associated sharps injuries* (CASI). Apart from counterbalanced doors and size, sharps container design has changed little in two decades. Few investigations have researched the impact of human factors engineering in eliminating CASI.

Prior to the 2001 revision of the Standard, CASI commonly accounted for 10-20%,[6-14] and up to 36% of total SI.[15] With the uptake of safety devices designed to disarm the sharp, CASI decreased. However, recent US databases show sharps containers are still associated with 5-6% of total SI.[3,4] At this proportion, and using SI incidence rates from the databases, CASI would account for a conservative 24,000 SI to US healthcare workers annually.

In the early years of commercial sharps container usage when most containers had a small aperture and point-first deposition, the causes of CASI were reported as overfilling, penetration, depositing sharp, and emptying.[6,13,16-18] However, with the addition of counterbalanced and levered doors, new CASI categories emerged, including sharps retained in opening, protrusion, collisions with hand, and falling/bouncing out of the sharps container.[3,6,14]

The most common mechanism of CASI is being stuck by one's own sharp while placing it in the container ("deposit SI"), accounting for 62% of CASI in the 2007 Massachusetts survey[3] and 75% in the 2007 EPINet study.[4] The next two most common CASIs are "protrusion" (ie, the point of a sharp extending beyond the aperture for reasons other than overfilling), and "retention" (ie, the sharp is retained in the atrium/door and although not protruding, may cause injury via flip-up or when a hand is inserted past the aperture plane). If all sharps were disarmed prior to disposal, there would be no CASI. The persistence of non-disarmed sharps at disposal is due to non-use or non-availability of safety device, failure to activate or partial activation of safety devices, or occasionally even an activated safety device.[3,4]

The earliest moves to reduce CASI included the abandonment of cutters on top of receptacles, flimsy cardboard containers and scavenged containers.[16,19,20] Osterman advocated the use of commercial sharps containers in 1975 and recommended thick walls and wide apertures.[21] Subsequent recommendations to reduce CASI included increased puncture resistance,[10,13,19,22] visualization of fullness,[7,11,19,23] hand-restriction,[19,20] secure closure,[7,20] bracketry,[19] clear labeling,[19] counterbalanced doors,[14] stability,[7] and one-handed deposit.[7] The National Institutes for Occupational Safety and Health has published a comprehensive document summarizing these design recommendations.[24] However, in 1995, Weltman concluded very few sharps containers met all these requirements.[7] In 2003, after finding CASI accounted for 10.9% of SI in California hospitals, Gillen et al called for a redesign of disposal containers.[25]

Ascension Health comprises 67 acute care hospitals and is the largest Catholic and nonprofit health system in US. The group adopted sharps safety devices early and found these devices had markedly reduced SI, but that the annual decrease in SI had slowed. To assist SI reduction strategies, CASI was identified as a subset to address. A literature search revealed

an international study[12] reporting significant SI reductions with a particular sharps container (the Device) that had enhanced engineering features and accommodated the recommendations cited above. The 2003 study did not involve US hospitals but the Device had since become available in the United States. After clinical trials revealed a high frontline-staff opinion, the Ascension Health hospitals converting to the Device accepted Ascension Health's Supply Chain and Risk Management divisions' invitation to participate in a formal evaluative study. The study was designed to test the hypothesis that the Device's engineered safety features would reduce CASI and hopefully, total SI.

METHODS

Setting and Study Design

The primary study utilized a before/after intervention model among the 14 Ascension Health hospitals that adopted the Device (study group). Prior to the intervention, these hospitals used single-use sharps containers (Kendall, Covidien, Crystal Lake IL and BD (Becton, Dickinson and company), Franklin Lakes NJ). Containers used in patient rooms and emergency rooms generally had a 2 to 4 gallon capacity with horizontal apertures and counterbalanced trays. Those used in operating rooms (OR) and labs were commonly 12- to 17-gallon capacity with large open apertures, sometimes with foot-operated closures. Containers were replaced when full by healthcare facility (HCF) staff.

The Device was a reusable sharps collector manufactured by Daniels Corporation International Pty Ltd for Daniels Sharpsmart Inc (Chicago, IL). The patient room model had engineered enhancements including a large horizontal aperture (100mmH x 300mmW), 195mm deep atrium (throat of collector), sensitive counterbalanced tray, hand-safe activation feature for light sharps, one-hand deposit, automatic lock-out when full (passive overfill protection), hand entry restriction, tamper-proof locks whose activation did not require fingers to be placed near the aperture, and highly puncture-resistant walls. In OR, labs and radiology units, the Device was available in an 8-gallon, open-aperture model. All Device models were delivered fully assembled. In the week of installation, in-service training in use and handling of the Device was conducted in all user-departments and to all shifts. The Device was replaced when full by HCF staff in 8 hospitals and by external contractors in 6.

The Device was adopted by study group hospitals between 2006 and 2007, and the study concluded in February 2008. No other hospital-wide SI intervention was introduced during the 2-year study period. In-service training on the use of the device was implemented on the day the device was installed and repeated over the following week to capture other staff. Employee descriptions of their SI were obtained retrospectively from each hospital's Ascension Health-standardized detailed SI log for 12 months prior to, and for 12 months after, adoption of the Device. Staff who suffered sharps injuries were not aware of the study at the time of their injury report. Data for the month in which conversion to the Device took place were excluded in order to remove risk of placing SI in an incorrect study period.

Sharps Injury Categorization

Sharps injuries in study group hospitals were categorized as follows:

- During-procedure,
- After-procedure-but-before-disposal (e.g. device activation, reprocessing, transporting to container, recapping);
- Container associated (CASI), where the following modification of Massachusetts' classification system was utilized[3]:
  - While placing sharp in container, injured by sharp being disposed;

- While placing sharp in container, injured by sharp already in container (either protruding or retained in atrium);
- While placing sharp in container (unclear if sharp in container or being disposed);
- Protruding from open container (injury not during deposit of a sharp);
- While placing sharp in container, injury due to overfilled container;
- While manipulating container (closing, moving, handling, shaking, entering);
- Sharp object bounced out during/after disposal into container;
- Punctured sharps container.

- Inappropriate disposal (e.g. SI due to sharps left on bedside cabinet, over-bed table, food tray, floor, bed, in linen, or discarded inappropriately to trash bags or bins).

In study group hospitals, when SI classification was not clear from the hospital's SI Log, clarification was sought from the original incident form on file. If further clarification was required, the injured staff member was contacted. After-procedure-but-before-disposal CASI and inappropriate disposal SI were also combined as "total post-procedure SI."

Cohort Study

To determine if the results of the intervention study might be due to variables other than the Device, the results were compared to those of a bed-size matched contemporaneous cohort of 14 Ascension Health hospitals not using the device (control group). During the study, control group hospitals used single-use sharps containers (BD and Kendall) with the exception of one hospital which used a reusable sharps container (different from the Device).

Total SI and Total CASI figures were obtained for 2006 and 2007 from Ascension Health standardized corporate summaries of SI categories from the 14 control group hospitals. Detailed SI logs were not examined in control group hospitals.

Full Time Equivalent Staff (FTE) data were obtained for all hospitals for each study period and used as the SI denominator. SI-categories per 1000 FTE were used to compare SI rates before and after intervention with the Device and between the study and control groups.

In study group hospitals, average daily census data was obtained for the year prior to adoption of the Device to enable comparison of SI per 100 occupied beds (OB) with national databases.

The study was reviewed and approved by the Ascension Health System Office. Approval by ethical review boards was waived as no patients or patient specimens were involved and no staff names were revealed.

Statistical analysis

Data were entered into and analyzed by WIN Episcope 2.0 statistical software package (freeware, University of Zaragoza, Zaragoza, Spain). Statistical significance was defined as a *P* value of less than or equal to .05. The χ^2 test was performed, and risk ratios and 95% confidence intervals calculated.

RESULTS

Intervention Study

Over the 2-year study period, total FTE in study group hospitals fell 0.6% from 19,880 to 19,755. In the year prior to Device adoption, average daily census for the 14 study group hospitals was 2,363, giving an SI rate of 21.6 per 100 OB.

Following intervention with the Device, CASI decreased from 11.4% to 2.2% ($P < .001$) of Total SI (Table 1). In the year the Device was being used, during-procedure SI increased significantly; however, all post-procedure SI categories/1000FTE decreased. CASI, total disposal and total after-procedure SI decreased significantly (Table 2). Total SI/1000FTE fell by 3.1% ($P = .6$) in the year of Device use (Table 2).

Table 3 shows detailed CASI categories in study group hospitals before and after adoption of the Device. Deposition, protrusion and container manipulation SI were markedly reduced with Device use. No SI due to container penetration was reported in either year.

Cohort Study

In year 1, no significant difference was observed in Total SI or CASI between study group and control group hospitals. Over the two years of the study, Total FTE in control group hospitals increased 1.0%, from 18807 to 19077. In control group hospitals, CASI fell from 9.9% to 9.1% ($P = .71$) (see Table 1). Control group hospitals had a 1.1% ($P = .87$) rise in Total SI/1000FTE over the two-year period (see Table 2). When this was analyzed against the fall in Total SI/1000FTE with use of the Device, the difference between the two groups achieved significance with $P = .04$ (Table 2).

In control group hospitals, of the 101 CASI, 58 were during deposit, 36 were protrusion, 1 was container penetration, and 6 were sharp left on container. Deposition and protrusion/retention injuries together accounted for 93% of the 159 CASI associated with non-Device containers and 91% of the 11 CASI associated with the Device.

Table 1. Annual SI incidence by major category: study and control hospitals

		Study Group		Control Group	
		No Device	Using Device	2006	2007
During procedure	(A)	234	298		
After-procedure-but-before-disposal	(B)	177	151		
Container associated	(C)	58	11	52	49
Inappropriate disposal	(D)	42	32		
Total SI	(E=A+B+C+D)	511	492	527	540
Total disposal related	(C+D)	100	43		
Total post procedure	(B+C+D)	277	194		
CASI as % of Total SI	(C/E x 100)	11.4	2.2*	9.9	9.1^

CASI, container-associated sharps injuries; SI, sharps injuries.

*$P = < .001$.

^$P = .71$

TABLE 2. SI rates per 1000 FTE in user and non-user hospitals

	Study Group (Used Device in Year 2)							Control Group (Not using Device)	
	During procedure SI (A)	After-procedure-but-before-disposal SI (B)	Container associated SI (C)	Inappropriate disposal SI (D)	Total disposal related SI (C+D)	Total post-procedure SI (B+C+D)	Total SI (A+B+C+D)	Container associated SI	Total SI
Year 1:	11.8	8.9	2.9	2.1	5.0	13.9	25.7	2.8	28.0
Year 2:	15.1	7.6	0.6*	1.6	2.2	9.8	24.9+	2.6*	28.3+
Change	+28%	-14%	-81%	-23%	-57%	-30%	-3%	-7%	+1%
P value	0.004	0.17	<0.001	0.26	<0.001	<0.001	0.60	0.71	0.87
RR	1.2	0.86	0.19	0.77	0.43	0.70	0.97	0.93	1.01
95% CI	1.1-1.5	0.7-1.1	0.1-0.4	0.5-1.2	0.3-0.6	0.6-0.9	0.9-1.1	0.6-1.4	0.9-1.1

95% CL, 95% confidence interval; FTE, Full-time equivalent; RR, relative risk; CASI, container-associated sharps injury; SI, sharps injury.
* Significant reduction in CASI in study group over control group ($p < 0.001$; RR = 0.22; CI = 0.11-0.42).
+ Significant reduction in Total SI in study group over control group ($p = 0.04$; RR = 0.88; CI = 0.78-0.99).

Table 3. Container-associated SI by category in study group hospitals

Container-associated SI category	Year 1, Without Device	Year 2, Using Device
While placing sharp in container, injured by sharp being disposed	31	9
While placing sharp in container, injured by sharp already in container (either protruding or retained in atrium)	8	1
While placing sharp in container, injured by sharp (mechanism unstated	4	0
Protruding from open container (injury not during deposit of a sharp) (4 closing, 1 moving container, 1 moving protruding sharp, 1 reaching past container, 2 unspecified)	9	0
Punctured sharps container	0	0
Sharp object bounced out during/after disposal	2	1
While manipulating container (1 shaking, 1 retrieving sharp)	2	0
Overfilled sharps container	2	0
Total	58	11

SI, sharps injury.

DISCUSSION

We investigated CASI because these injuries account for a small but significant proportion of total SI, are seldom investigated as an SI prevention strategy, and are affected markedly by container design.[7,9,11-14] The FDA reports that most use errors with medical devices are due to device design, rather than user-fault or device failure.[26] Hyman agrees, and in stressing the importance of human factors analysis in design of safety devices, suggests better design can reduce or eliminate use-errors.[27] Prior to adopting the Device, among the 28 hospitals, CASI comprised 10.1% of total SI, indicating container design was an area worthy of investigation.

In the study group, the Device was associated with significant reductions in after-procedure (-30%), disposal-related (-57%) and container-associated (-81%) SI. Additionally, non-significant reductions were apparent in inappropriate disposal, after-procedure-but-before-disposal, and total SI (Table 2). When compared to control group hospitals, hospitals using the Device experienced significantly fewer CASI and Total SI (Table 2). The decrease in CASI with use of the Device is similar to that achieved in other countries.[12]

Mirroring US databases reports,[3,4] the most common pre-intervention CASI mechanism in study hospitals was deposit SI (injured by own sharp), which accounted for 31 of 58 (53%) of CASI (Table 3). In traditional sharps containers, deposit injuries are most likely due to small apertures (ie, sharp caught aperture edge), shallow atria (sharp did not enter container completely), or inappropriate aperture shape for the sharp being deposited (sharp snagged or caught aperture edge). Safety of larger apertures is supported by the rarity of deposit SI in OR (where large-aperture containers are commonly used) and by focus-group analysis studies.[7,12,14,21,23] Small or restricted apertures were developed primarily to inhibit hand access and/or stop spillage if the container tipped over.[7,10,19] Human factors analysis indicates however, that small apertures create a greater SI risk via deposit injuries than risks posed through hand-entry or spillage. Aperture design may also cause deposit SI if the tray, lid or aperture requires manipulation/holding while depositing the sharp, as this places both hands dangerously in the same plane and may cause "collision" CASI. It is postulated that the Device's larger aperture, deeper atrium and single-hand deposit were instrumental in the 74% decrease in Deposit SI.

Once again mirroring US databases,[3.4] the study's next two most commonly reported pre-intervention CASI mechanisms were protrusion and retention (injured by sharp already in container), accounting for 17 of 58 (33%) of CASI. Protrusion and retention SI are likely because of insufficiently sensitive counterbalanced doors. Counterbalanced doors were developed to prevent overfilling, restrict hand entry, and minimize spillage in toppled containers, but can create new hazards if they are not well designed. For example, the sharp may remain in the atrium because it is too light or partly rests on aperture edge and does not activate the door. It is not uncommon to see sharps resting on the container door in hospitals that use such containers, as clinical staff seldom have time to check whether their sharp was tipped by the door into the base of the container. Many of these sharps are deposited into the container with the weight of the next sharp, but occasionally may be flipped up by a deposited sharp, or may stick a hand if it is inserted past the aperture plane. Protrusion SI can also occur when wing-needles and tubing catch on the edge of apertures or doors, or when inadequately assembled containers allow a sharp to protrude through a lid-base or closure-base gap. It is postulated that the Device's sensitive tray, deep atrium, "hands away from aperture" closure mechanism, extended door-ledge for manually tipping light sharps, and pre-assembly led to the 94% reduction in protrusion/retention CASI.

Overfilling was the mechanism of 2 CASI in the pre-intervention period (none with Device). Containers without counterbalanced doors, ie, "point-first" design but also including serpentine apertures, are prone to overfilling - a major cause of CASI in the past.[9,12-14,16,18] Institutions using such containers will be familiar with the axiom, "If staff can get another sharp in, they will" (no doubt a reflection of workloads). Overfilling is currently not a major cause of CASI in the United States where counterbalanced-door containers are common in patient areas, but will be an issue in countries where straight drop containers are used. Overfilling can also be prevented by timely exchange of containers

either by institution staff [13,16] or outside contractors.[8,23] Timely removal will not however, reduce other aperture-related CASI.[8] In six study group hospitals the Device was changed out by external staff, however it is postulated that the Device's counterbalanced door, which self-locks in the upright position when the last sharp is deposited (passive overfill protection), eliminated overfilling SI.[12]

Sharps injuries due to penetration of containers were not reported in study group hospitals pre or post intervention. One penetration SI was reported in a control group hospital, resulting in an overall rate for the 28 hospitals of 0.5 per 1000 SI. In the cumulative EPINet data 2001-2007[4] and Massachusetts data 2002-2007,[3] penetration SI were reported in 0.9 per 1000 SI.

The Device was associated with significant reductions in both after-procedure-but-before-disposal SI and inappropriate disposal SI. It is not clear how the Device was associated with this reduction over other sharps containers, but it may be due to the Device's multiple bracketry enabling ergonomic siting, and/or the absence of cabinets, enabling high collector visibility. A similar reduction in non-CASI, post-procedure SI was documented in a previous study of the Device.[12]

In study group hospitals in the year the Device was being used, during-procedure SI increased significantly, most likely due to the increase in number of SI reported by medical staff. If the increase was indicative of increased reporting of all SI categories, it highlights the reductions achieved with the Device. The Device's impact is further highlighted[28,29] by the statistically significant SI reductions despite the SI incidence in study group hospitals (21.6 per 100 OB) being considerably lower than that reported by US databases.[3,4] Extrapolating from CASI incidence in control group hospitals and FTE levels in both groups indicates if study group hospitals had not adopted the Device, 39 additional staff would have suffered a sharps injury. If the reduction in all post-procedure SI were assumed to be due to the Device, 91 additional staff would have suffered a sharps injury. Extrapolating the CASI reduction on a national level, in excess of 19,000 SI could be prevented in the US if the enhanced engineering features were possible in all sharps containers.

Sharps safety devices were developed so that sharps safety could be less dependent on human behavior.[22,27,30,31] We believe this principle applies to sharps containers – enhanced container engineering increases disposal safety by reducing dependence on human behavior. This study supports the prophetic words of Jagger and Bentley, who in 1999 stated that even when safety devices are widely adopted, well-designed sharps containers will still be required.[32]

CONCLUSION

The majority of CASI occurs during deposition and via protrusion/retention. This study indicates that a larger aperture, larger atrium and sensitive tray, together with 1-hand deposit, safe closure activation, and pre-assembly significantly decreased CASI compared with other sharps containers used in the study hospitals. The study demonstrates that containers engineered to accommodate human factors in the clinical setting can markedly reduce CASI.

Strengths of this study included: the sample size (approx 19,000 FTE and 14 hospitals studied in detail and an additional 19,000 FTE and 14 hospitals used for comparison); inclusion of all hospitals adopting the Device (no bias in study group hospital selection); analysis using 2 research models (internal intervention model coupled with a contemporaneous non-user cohort model with the same purchasing and affiliation system; size of Ascension Health, enabling selection of control group hospitals of equal number and similar size to study group hospitals thus approximating SI risk characteristics; blind nature of incident reporting (injured HCW were unaware of the study); and standardization of SI

categorization and recording mechanisms throughout the Ascension Health hospitals in both groups. Limitations of the study included the reliance on SI logs (voluntary reporting) and on staff incident description records to categorize SI; the assumption that SI reporting rates and procedures were identical in all hospitals for both periods and both hospital study groups; the assumption that control group hospitals' categorization of CASI were correct; and the assumption that the non-randomly chosen control group hospitals had similar SI risk characteristics to the study group hospitals.

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