

SHARPS INJURY REDUCTION USING SHARPSMART™ — A REUSABLE SHARPS MANAGEMENT SYSTEM

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Abstract: Sharps injury (SI) among Healthcare Workers (HCW) is a common and serious issue associated with a risk of disease transmission to HCW. The cost of SI management is a drain on hospital resources. Engineered controls (EC) are the most effective means of SI reduction but their cost precludes widespread adoption in many countries. Sharps containers are associated with 10-13% of Total SI yet have received little attention as a means of SI reduction. A newly developed reusable sharps containment system (Sharpsmart) was trialed in 8 hospitals in three countries. The system was associated with an 86.8% reduction of Container Related SI (CRSI) ($p=0.012$); a 25.7% reduction in Non-CRSI ($p=0.003$); and a 32.6% reduction in Total SI ($p=0.002$). The study concludes that the Sharpsmart system is an effective EC in reducing SI.

Author Keywords: Sharps injury; Needlestick injury; Percutaneous injury; Sharps containers; Sharpsmart safety devices; Engineered controls

1. Introduction

Sharps injury (SI) among Healthcare Workers (HCW) remains a serious issue. Preliminary results from the first multi-centre study in the UK¹ give an SI rate of 17 per 100 occupied beds (OB)/yr and this, assuming an equal number of HCW work outside hospitals,²

equates to 154 000 SI annually in UK. A recent USA Exposure Prevention Information Network (EPINet) study³ found the SI rate among participating hospitals to be 22/100 OB/yr which, using the above parameters, equates to 563 000 SI annually in the USA. In Australia the rate of reported SI is 20 per 100 OB/yr,⁴ equating to an annual SI incidence of 47 000. Preliminary data from 12 pilot sites in

Canada reported an SI reporting rate of 18.8 per 100 OB/year,⁵ which using the above parameters, may suggest an annual incidence of 84,000 SI.

The seriousness of SI lies in the risk of acquisition of bloodborne pathogens. Worldwide, more than 100 HCW have contracted HIV from work-related SI and many thousands have contracted HBV or HCV. Notwithstanding the emotional costs to injured HCW and their families, the financial cost of each SI follow-up is between US\$500-\$2500⁶ and the annual costs associated with treatment of infection can be tens of thousands per infected HCW and ultimate cost up to US\$1 million.⁷ A recent Scottish report estimates that SI cost NHS Scotland £260 000 annually not including the value of lost output for an infected HCW or the cost of replacing staff.⁸ The Scottish report warns that this cost could rise significantly with a successful high cost claim – such a lawsuit for US\$12 million was recently awarded to a US intern who contracted HIV.⁹

Such consequences have elicited much research into SI reduction - the three most effective means cited being engineered controls (EC) such as needleless systems and safety syringes, education, and modification of hazardous work practices. Studies have shown that using all three in a multi-intervention approach coupled with continued and focused efforts is necessary to reduce overall SI.^{10,11,12} Of particular note is the multi-intervention success of the large CCLIN-GERES study in Northern France.¹³ Modification of work practices alone is not sufficient as it is hampered by the difficulty in changing staff behaviour.¹⁴ Education is essential for every intervention and can be effective on its own¹⁵ but requires large resources^{10,11,16} The large SIROH study in Italy, where EC are seldom used, has shown that reliance on education and behaviour modification alone has not brought about a significant reduction in overall SI.¹⁷ Engineered controls are the most effective of the three interventions - reducing SI by up to 84% within their device-specific procedures.¹⁸ Ironically however, USA hospitals have the largest choice of EC yet EPINet studies have only shown a decrease in overall SI rate in the last two surveys.^{3,19} It is apparent that widespread adoption of EC is hampered by

their cost.^{6,20,21} With the recent passing of the USA federal Needlestick Safety and Prevention Act, EC costs will decrease markedly over the next four to five years and hopefully enable their universal adoption. There remains however an immediate need for effective systems in the reduction of total SI, particularly systems that have minimal impact on hospital resources.

Sharps containers are an example of EC yet have received little attention in the last decade, being somewhat overshadowed as a "safety device" by their patient-related counterparts. However, sharps containers play an important role in sharps management and little has been said of the fact that container-related sharps injuries (CRSI) account for a remarkably consistent 11-13% of total SI.^{1,3,5,22,23,24} Compared to other EC, a sharps containment system designed with effective passive safety may be a simple, cost effective investment in overall SI reduction.

This paper outlines a collaborative study to determine the impact on SI of a new reusable sharps containment system developed to eliminate CRSI (Sharpsmart™, The Daniels Corporation International Ltd, Melbourne).

2. Methods

The Sharpsmart System comprises: a pre-assembled, reusable sharps container range based on three container sizes of 6.5, 14.5 and 23.5 fill-line litres, manufactured from a highly puncture-resistant plastic polymer and possessing a large opening, passive overflow protection and hand-entry prevention; multiple bracketry options for ergonomic and safe siting of containers; site inspections to advise on optimal siting of containers; multimedia education and training of staff in correct use of the containers. The system is coupled to a factory-based, fully automated, robotic decanting and sanitisation process (WashSmart™).

The containers are delivered to the hospital in dedicated transport enclosures and are distributed to wards by hospital staff. When full the containers are sealed by hospital staff and transported to the loading dock where they are placed in the dedicated transport enclosures, which are collected by the servicing company and returned to the

factory. At the factory the containers are decanted and sanitised using the automated WashSmart™ process before redistribution to hospitals. Decanted sharps waste is destroyed at the factory under appropriate local regulations.

In November 2000, invitations to participate in the SI study were forwarded to the seven hospitals in Australia and New Zealand that had converted fully to the new Sharpsmart system and to four hospitals in the UK that had recently completed trials. In participating hospitals, retrospective sharps injury data was retrieved from written and/or electronic SI records in 1999/00 before adoption of Sharpsmarts and in 2000/01 during their use. During the period of fitting the system (several days to weeks) no SI data were utilized.

Categorisation of SI was based primarily on the International Health Care Worker Safety Center's (IHCWSC) EPINet criteria.

2.1 Data retrieved

All SI reports in both study periods were examined and the following data retrieved:

- Total number of reported SI (from all sharp items, e.g. needles, scalpels, scissors)
- How the injury occurred - using 7 standard, post-patient EPINet categories (E) and seven additional categories:
 1. Recapping (E)
 2. Other after use, before disposal (E)
 3. Item left on disposal container (E)
 4. Putting item into disposal container (E)
 5. Due to overfilled container
 6. Due to container opening/nature of sharp item
 7. Due to other reasons
 8. Protruded from disposal container (E)
 9. Pierced side of disposal container (E)
 10. Picking up from floor after bouncing out of container
 11. Picking up from floor after spillage or rupture of container
 12. Pierced side of inappropriate disposal container (E)
 13. While collecting rubbish from waste bin
 14. All other (predominantly during patient procedure)

Of the above categories, 3-11 were grouped as CRSI. When records were insufficient to categorise SI per the above scheme, the staff member suffering the injury was contacted and further details obtained. In addition to SI data the average daily OB and average daily total full-time equivalent staff (FTE) for both study periods were sought from each hospital.

Three major parameters, CRSI, Non-CRSI and Total SI per 100 OB/yr and per 100 FTE/yr, were compared for the two study periods. In addition all 14 SI categories were calculated per 100 FTE/yr and compared. All data were assessed statistically using a Paired t-test and significance was set at $P < 0.05$. The study did not receive industry or grant funding.

3. Results

All seven fully converted hospitals and one trial hospital participated in the study. In the trial hospital the study was confined to 4 clinical areas of exclusive Sharpsmart use. The eight acute-care hospitals (Australia: 5; New Zealand: 2; Scotland: 1) ranged in size from 86 to 990 available beds. Apart from SI education for orientation of new staff, and the education of staff in the Sharpsmart system, no other EC or SI reduction protocols were introduced or trialed by the hospitals during the two study periods. Among the 8 hospitals, the pre-Sharpsmart period ranged from 7.7 to 16 months; mean: 12 months; median: 12 months. The Sharpsmart study period ranged from 1 to 12 months; mean: 7.4 months; median: 7 months. All hospitals supplied OB and FTE data excepting Hospital H where FTE was not available for the 4 clinical areas.

Prior to adopting the system, 9 brands of disposable containers and one brand of reusable container (not Sharpsmart) were used by the 8 hospitals. In all hospitals sharps containers in both study periods were sited as close as practical to the point of sharps generation.

Tables I and II depict the SI parameters for each hospital for the two study periods. With Sharpsmart use, all hospitals had decreases in Total SI and Non-CRSI rates and seven had decreases in CRSI (Hospital G had no reported CRSI in both periods) (Tables I and

II). For the eight hospitals, the total SI rate per 100 OB/yr decreased from 20.3 to 13.6 (32.7% reduction, P=0.002) and total SI/100 FTE/yr decreased from 4.3 to 3.0 (32.1% reduction, P=0.002) (Table I). The CRSI rate per 100 OB/yr decreased from 2.3 to 0.3 (86.8% reduction, P=0.012) and the CRSI/100

FTE/yr decreased from 0.5 to 0.07 (86.6% reduction, P=0.011) (Table II). Non-CRSI/100 OB/yr decreased from 18.0 to 13.3 (25.7% reduction, P=0.003) and Non-CRSI/100 FTE/yr decreased from 3.9 to 2.9 (25.0% reduction, P=0.006) (Table II).

Table I Descriptive characteristics and sharps injury rates per 100 OB/yr and 100 FTE/yr before and during Sharpsmart use in 8 participating hospitals

Hospital	Before Sharpsmart Use				During Sharpsmart Use			
	Aver. FTE	Aver. OB	SI per 100 OB/yr	SI per 100 FTE/yr	Aver. FTE	Aver. OB	SI per 100 OB/yr	SI per 100 FTE/yr
A	265	122	17.9	8.2	295	139	15.0	7.1
B	550	185	24.5	7.1	648	189	21.9	6.4
C	2,098	608	21.7	6.3	1,985	595	17.5	5.2
D	2,281	450	21.3	4.2	2,295	456	8.0	1.6
E	5,323	790	20.9	3.1	5,455	790	15.0	2.2
F	849	203	18.2	4.4	882	238	11.8	3.2
G	634	154	13.6	3.3	605	144	6.9	1.7
H	-	77	9.1	-	-	80	0.0	-
Total	12,085	2,589	20.3	4.3	12,165	2,631	13.6*	3.0 [†]

*32.7% decrease, P=0.002. [†]32.1% decrease, P=0.002.

Table II Container Related Sharps Injuries (CRSI) and Non-CRSI per 100 OB/yr and per 100 FTE/yr before and during Sharpsmart use in 8 participating hospitals

Hospital	Before Sharpsmart Use				During Sharpsmart Use			
	CRSI per 100		Non-CRSI per 100		CRSI per 100		Non-CRSI per 100	
	OB/yr	FTE/yr	OB/yr	FTE/yr	OB/yr	FTE/yr	OB/yr	FTE/yr
A	0.6	0.28	17.3	7.9	0	0	15.0	7.1
B	0.8	0.25	23.6	6.9	0	0	21.9	6.4
C	2.5	0.71	19.2	5.6	0.3	0.10	17.1	5.1
D	4.4	0.88	16.9	3.3	1.3	0.27	6.7	1.3
E	2.4	0.36	18.5	2.7	0	0	15.0	2.2
F	0.5	0.12	17.7	4.2	0	0	11.8	3.2
G	0.0	0	13.6	3.3	0	0	6.9	1.7
H	3.9	-	5.2	-	0	-	0	-
Total	2.3	0.50	18.0	3.9	0.3*	0.07 [†]	13.3 [#]	2.9 [†]

*86.8% decrease, P=0.012. [†]86.6% decrease, P=0.011.

[#]25.7% decrease, P=0.003. [†]25.0% reduction, P=0.006

Table III depicts how the SI occurred in both study periods. The percentage of Total SI categorized as CRSI was 11.6% (60/516)

prior to using Sharpsmarts and 1.1% (3/271) with Sharpsmarts. Of the three CRSI in the Sharpsmart period one occurred while placing

a butterfly-needle into the Sharpsmart. The second occurred when the HCW found the nearest Sharpsmart full and incurred an SI while walking to another container (although not falling within agreed categories for CRSI, the SI coordinator for the hospital elected to classify it as CRSI). The third was classified as CRSI by default - a staff member had stated “During disposal” in her report but

when sought for clarification was no longer an employee. In the absence of firm data the SI coordinator for the hospital classified it as CRSI. At the same hospital, six other HCW who had stated “During disposal” were contacted and stated that the SI occurred while transporting the sharp for disposal (Non-CRSI).

Table III Number, rate/100 FTE and significance of specific category sharps injuries before and during Sharpsmart use in 8 participating hospitals

How injury occurred	Before Sharpsmart		During Sharpsmart		P value (FTE)	
	No.	SI/100 FTE	No.	SI/100 FTE		
CRSI						
Item left on disposal container	0	0	0	0	-	
Putting item into disposal container	44	0.37	3	0.07	0.01	
Due to overfilled container		22	0.19	0	0	0.06
Due to container opening or nature of sharp item		13	0.11	1	0.05	NS
Due to other reasons		9	0.07	2	0.02	NS
Pierced side of disposal container	0	0	0	0	NS	
Picking up from floor after bouncing out of container	4	0.03	0	0	NS	
Picking up from floor after spillage/rupture of container	4	0.03	0	0	NS	
Protruded from disposal container	8	0.07	0	0	0.06	
Non-CRSI						
Recapping	18	0.15	12	0.10	NS	
Other after use, before disposal	175	1.44	97	0.99	NS	
Pierced side of inappropriate disposal container	1	0.01	0	0	NS	
While collecting rubbish from waste bin	56	0.46	14	0.14	NS	
Other (predominantly during patient use)	206	1.78	145	1.68	NS	
Total (CRSI + Non-CRSI)	516		271			

4. Discussion

Our data indicate that a significant decrease in SI was associated with use of the Sharpsmart system. The reduction in CRSI alone would equate to a reduction in Total SI of 10.1% (87% of 11.6%), however, when coupled with the Non-CRSI reduction there was a reduction in Total SI of 33%. This compares favourably with other EC such as needleless IV systems and safety syringes, which individually, may bring about reductions in Total SI of up to 30-35%.

Rigid sharps containers and their use in patient rooms was first adopted in the early 1980's and gained impetus with the AIDS epidemic. Their adoption was primarily designed to allow disposal of needles without recapping. Interestingly, all five early studies on sharps containers found that their introduction changed the nature of the SI but made no significant impact on total SI.²⁵⁻²⁹ Their use initiated a new type of SI, “Container Related”, which is a subset of “Disposal Related” SI (DRSI).

Container Related SI are due to many causes including: too small a container opening;

necessity for two-handed insertion; ability to overfill; ability to insert hands; needles protruding through gaps in incorrectly assembled containers; unsafe closure mechanism; sharps jamming in the opening; protrusion through incorrectly closed containers; penetration through container walls; incorrect height of container; sharps spillages when moving container; picking up sharps from floor after they had bounced out or spilled from containers that have come apart or toppled over; inability to safely receive sharps attached to tubing; and staff walking with sharps or leaving them on surfaces because patient-room containers were not noticed. These causes have been frequently mentioned in studies on SI and sharps containers.^{28,30-33} Other studies have proposed that safe containers conveniently placed should reduce DRSI.^{30,31}

This study demonstrates that the design of the Sharpsmart container effectively addressed CRSI issues (87% reduction) and was inherently safer to use through a combination of the container's overfill prevention, no hand entry, wide opening, high puncture resistance, and pre-assembly (protrusion prevention). However, the system was also associated with a change in staff behavior in disposing of sharps (26% reduction in Non-CRSI). It is postulated that this modification in behaviour was due to staff being influenced by nearby siting of containers (less walking with sharps), large size (less likely to be full), bright colour (more noticeable), ergonomic height (no stooping or unsighted opening), and institution-wide pre-implementation training (raised sharps awareness).

Jagger¹⁸ states that the lower the SI rate the more difficult it becomes to demonstrate the efficacy of safety devices, therefore the significant SI reductions with the system, given the low pre-study rate (4.3/100 FTE) when compared to other studies,³⁴ is of particular note. Given that safety devices can themselves be a source of SI,¹⁸ it is also noteworthy that the system had significant reductions in all three SI parameters yet was associated directly with only one SI.

Examination of the SI category data (Table III) indicates that each category was associated with SI reduction in the Sharpsmart period, however the low numbers precluded statistical significance in all but "Putting

items into disposal container". Two other categories, "Due to overfilled containers" and "Protruded from disposal container" approached significance (p=0.06).

The introduction of an effective sharps containment system should reduce CRSI, and therefore DRSI and Total SI. However it is difficult to find studies where sharps containers have been introduced as a sole intervention with product training only, as distinct from continued sharps education, and have achieved a significant SI reduction. McCormick *et al.*³² demonstrated a 56% decrease in CRSI with new patient-room sharps containers but had an increase in Total SI. Haiduven *et al.*³⁵ introduced patient room containers and had no change in DRSI and an increased CRSI. Only the study by Richard *et al.*³⁶ has had DRSI and Total SI reductions attributable primarily to a change to patient-room containers. Our study is the first to report significant decreases in CRSI, DRSI and Total SI with a sharps containment system as the sole intervention. Factors that contributed to the success of the system were its approval by clinical staff, inbuilt passive safety, and little training being required – features that are pre-requisites for successful EC.^{35, 37,38}

A limiting factor to the study was the voluntary nature of self-reporting by HCW. It was assumed that SI reporting rates were similar in all eight hospitals, that reporting trends were similar over the two study periods and that reported SI were a true reflection of actual exposures. Concomitant studies (two regimes studied simultaneously within each hospital) would have reduced time-trend changes but finding "identical" clinical units, and logistic and infrastructure difficulties, make such studies of sharps containers impractical in hospital environments. The retrospective nature of the study and reliance on reports may have been a further limiting factor although in only one instance in 787 was the SI categorized by default. Another limitation may have been the Hawthorne Effect and, although unlikely to have been a significant effect across all eight hospitals, further studies will be needed to eliminate this as a possible contributing factor. The statistical significance of each major SI parameter indicates that the difference in

length of the two study periods was not a limiting factor.

In the UK, one of the Royal College of Nurses' Safe Environment objectives is to introduce safe systems to minimize the risk of sharps injury.³⁹ In the USA, The Centers for Disease Control and Prevention aims to eliminate occupational needlesticks by 2006.⁴⁰ This study has shown that the Sharpsmart system could be a useful additional safety device in helping to meet such objectives.

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