Safety Engineered Device Usage and Activation in Six Western U.S. Hospitals

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Abstract
Background. The 2001 Needlestick Safety and Prevention Act requires US healthcare facilities to use safety engineered devices (SED) to protect healthcare workers. However a recent increase in US occupational exposures may indicate SED use may be sub-optimal. This post-disposal audit (PDA) examined sharps container contents to ascertain the frequency and correctness of SED use in a sample of hospitals in US West.
Methods. Reusable sharps containers (RSC) were selected from hospitals serviced by a licensed processing facility in Fresno CA in Sept 2018. Using established PDA methodology and wearing protective apparel, the operator opened and decanted RSC, separated hollow-bore needles (HBN) from other sharps and enumerated HBN into: capped/uncapped non-SED; activated/non-activated/tampered SED; and blunt non-activatable draw-up SED. WinPepi v2.78 was used to calculate probability (set at ≤0.05) and rate ratios (RR) at 95% confidence limits.
Results. 435 liters of contents from 30 RSC from 6 hospitals contained 2,089 HBN comprising: 429 (21%) non-SED; 1,493 (72%) activatable SED; and 167 (8%) draw-up SED. Of the activatable SED: 1,442 (96.6%) were activated correctly; 50 (3.3%) were not activated (or partially); and 1 (0.1%) tampered. Of Total HBN: 20.5% were not SED; 10.6% were discarded "sharp"; 12.4% of needles were capped. Results varied widely between hospitals.
Conclusions. Although most SED were activated fully, the proportion of HBN that were not SED (one-fifth) or were disposed of "sharp" or capped (one-quarter), indicates increased use of SED and greater adherence to work-practice policies are required. PDA are a valuable adjunct to SI reduction strategies.

Keywords: Safety engineered devices, activation, sharps injury, needlestick, work practice, regulations, occupational, healthcare.

Introduction

Safety engineered devices (SED) can significantly reduce exposure risk,[1] and the OSHA 2001 Needlestick Safety and Prevention Act (NSPA) requires U.S. healthcare facilities to implement SED and work practice controls to reduce employee exposure.[2] However, in 2012 all U.S. databases showed that the profound impact of the NSPA on SI rates in 2001,[3] had not been sustained.[4-6] In 2013 the author hypothesized that healthcare workers (HCW) must not be using SED as frequently or as correctly as believed, and conducted a pilot SED audit in Florida and found half the HBN in sharps containers were not SED, and 22% of the SED present were not activated correctly.[7] In September 2018 at the Association of Occupational Health Professionals (AOHP) annual conference, it was revealed that U.S. sharps injuries had fallen only 7% since 2001 and have increased significantly each year from 2015 to 2017.[8] So the question again arose – is the increasing SI due to infrequent SED use and/or low activation rates? In the safest clinical setting, ideally the contents of sharps containers would show zero to very few non-SED (i.e. no capped or uncapped needles of any type – attached to syringes or not) and all activatable SED activated. This paper presents the results of a second SED audit

conducted in the U.S. West to ascertain if SED use is suboptimal.

Methods

Approval was obtained from a licensed facility for processing reusable sharps containers (RSC) (Daniels Health, Fresno CA) to examine the contents of RSC (Sharpsmart, Daniels Health) arriving from hospitals in the region. Over a 1.5-day period in September 2018, RSC were selected from 6 hospitals. Ethical approval for the study was waived as no patients, specimens, patient data or HCF staff were involved. The factory's device-mining area was used as it is isolated from factory staff. Patient-room RSC were selected from transporters arriving from HCF and depending on availability, up to 5 RSC of 14.5 fill-line litres capacity were selected from each HCF. Patient-room RSC were selected as clinical units have the highest availability and use of SED.[1] If the RSC contents were identified as laboratory or operating-room sharps, the RSC was closed and another chosen. Author selection-bias was minimized by having the plant-supervisor select RSC from hospitals as they arrived during the study and the author was unaware of hospital names until RSC were selected. Larger hospitals are serviced several times weekly and thus had a higher probability of being selected during the audit.

Using an established protocol for post-disposal audits (PDA),[9,10] the operator wore a face shield, long-sleeve gown, thick apron, covered leather shoes and heavy-duty gloves. Each RSC was opened and the contents gently decanted onto a large stainless-steel bench with raised edges to prevent sharps spill-off and for operator protection. Only HBN devices were enumerated as these have the greatest risk of BBP transmission.[1,11] Using long tongs, the contents of each RSC were sorted item by item into:

- Hollow-bore SED
  - Activatable
    - Correctly and fully activated
    - Partially activated or non-activated
    - Tampered with (safety mechanism removed)
  - Non-activatable (blunt draw-up needles or blunt plastic cannulae)
- Hollow-bore Non-SED
  - Uncapped needles
  - Uncapped needle-syringes
  - Capped needles
  - Capped needle-syringes
- Solid sharps and solid SED (e.g. suture needles, scissors, scalpels, auto-retract lancets)
- Non-sharp wastes (e.g. syringes, wrapping, gloves, containers, trays, tourniquets)

Safety engineered devices connected by tubing to a non-SED HBN were classified as 'non-SED'. Upon completion of the audit, sharps waste was returned to the factory system for destruction and disposal. WinPepi v2.78 was used to statistically compare results between studies.[12] Pearson's $\chi 2$ test was used for the analysis of proportions; *P* values were 2-sided; statistical significance set at $P \leq .05$; and risk ratios calculated at 95% confidence limits.

Results

Four hundred and thirty-five litres of contents from 30 RSC from 6 hospitals (5 from California; 1 from Idaho) were examined (Table 1). The 2,089 HBN enumerated comprised 429 (21%) non-SED; 1,493 (72%) activatable SED; and 167 (8%) draw-up SED (Table 2). Of the activatable SED: 1,442 (96.6%) were activated correctly;

50 (3.3%) were not activated (or partially); and 1 (0.1%) tampered with. Of Total HBN: 20.5% were not SED (12.4% capped needles; 8.1% uncapped needles); and 10.6% of all HBN were discarded "sharp" (i.e. uncapped needles and non-activated or tampered SED)(Table 2). Results varied widely between the 6 hospitals. Numbers and percentages within device categories and sub-categories are shown in Table 2, with blunt draw-up SED separated from activatable SED so that device categories can be recalculated to suit other categorization methods. The mean number of HBN enumerated from each hospital was 348 (range 163-494). It was visually obvious that many devices had been used for procedures involving blood.

Table 1. Number of hospitals, RSC, liters of sharps and HBN examined

Region	Number of hospitals	Number RSC	Litres of sharps	Number HBN
U.S. West	6	30	435	2,089

RSC reusable sharps containers; HBN hollow bore needles

DISCUSSION

The results of this study are significantly improved on those of the 2013 SED audit in Florida.[7] It is not clear whether the improvement is due to time, regional differences in work-practice policies, SED availability, or HCW behavior. Notwithstanding the reasons, Table 3 shows that, compared to the earlier study, the 2018 study shows: SED use was higher (P <0.001); SED were fully-activated more frequently (P <0.001); uncapped needles were fewer (P <0.001); capped needles were fewer (P <0.001); and total sharps discarded "sharp" were fewer (P <0.001). Thus 2018 results indicate sharps practices are significantly safer over those of 2013, with, most importantly, the overall percentage of devices being disposed "sharp", being reduced by 75% (Table 3). With such an improvement, why then is the national SI rate increasing? Perhaps the answer is in the quality of SED or the quality of SED education. Or both.

Quality of SED

In addition to asking, "*Are we using SED frequently enough*?", we should ask, "*Are we using the safest, clinically-acceptable SED available*?"

It is logic that with increasing use of SED, they will be involved in an increasing proportion of SI.[13] And it is reasonable to assume that most of these SI will occur prior to SED activation (i.e. during the procedure when the device is sharp). However if we examine EPINet data on SED SI, it shows that a good proportion of SED SI occur during and after activation.[13] And EPINet data from 2014-2017 found 20% of

Table 2. Number and proportion of devices by hospital and device sub-category

Hospital	Sharp Category	Non-safety HBN					SED requiring Activation				Draw-up SED (syr/syr-ndl)	Total No. HBN
		Uncapped needles	Uncapped Syr-Ndl	Capped needles	Capped Syr-Ndl	Total Non-safety HBN	Activated correctly	Partially or Not activated	Tampered with	Total SED Activatable		
1 (CA)	No. HBN	46	18	122	51	237	246	10	1	257	0	494
	% of HBN	9.3%	3.6%	24.7%	10.3%	48.0%	49.8%	2.0%	0.2%	52.0%	0.0%	100%
	% of category	19.4%	7.6%	51.5%	21.5%	100.0%	95.7%	3.9%	0.4%	100.0%		
2 (CA)	No. HBN	0	60	0	5	65	334	5	0	339	3	407
	% of HBN	0.0%	14.7%	0.0%	1.2%	16.0%	82.1%	1.2%	0.0%	83.3%	0.7%	100%
	% of category	0.0%	92.3%	0.0%	7.7%	100.0%	98.5%	1.5%	0.0%	100.0%		
3 (ID)	No. HBN	12	3	61	8	84	283	7	0	290	0	374
	% of HBN	3.2%	0.8%	16.3%	2.1%	22.5%	75.7%	1.9%	0.0%	77.5%	0.0%	100%
	% of category	14.3%	3.6%	72.6%	9.5%	100.0%	97.6%	2.4%	0.0%	100.0%		
4 (CA)	No. HBN	6	1	3	0	10	97	2	0	99	54	163
	% of HBN	3.7%	0.6%	1.8%	0.0%	6.1%	59.5%	1.2%	0.0%	60.7%	33.1%	100%
	% of category	60.0%	10.0%	30.0%	0.0%	100.0%	98.0%	2.0%	0.0%	100.0%		
5 (CA)	No. HBN	19	2	0	1	22	250	10	0	260	0	282
	% of HBN	6.7%	0.7%	0.0%	0.4%	7.8%	88.7%	3.5%	0.0%	92.2%	0.0%	100%
	% of category	86.4%	9.1%	0.0%	4.5%	100.0%	96.2%	3.8%	0.0%	100.0%		
6 (CA)	No. HBN	3	0	5	3	11	232	16	0	248	110	369
	% of HBN	0.8%	0.0%	1.4%	0.8%	3.0%	62.9%	4.3%	0.0%	67.2%	29.8%	100%
	% of category	27.3%	0.0%	45.5%	27.3%	100.0%	93.5%	6.5%	0.0%	100.0%	0	
Total	**No. HBN**	**86**	**84**	**191**	**68**	**429**	**1442**	**50**	**1**	**1493**	**167**	**2089**
	% of HBN	**4.1%**	**4.0%**	**9.1%**	**3.3%**	**20.5%**	**69.0%**	**2.4%**	**0.0%**	**71.5%**	**8.0%**	**100%**
	% of category	**20.0%**	**19.6%**	**44.5%**	**15.9%**	**100.0%**	**96.6%**	**3.3%**	**0.1%**	**100.0%**		

ndls needles; syr-ndls syringe-needles; HBN hollow bore needles; SED safety engineered device; CA California; ID Idaho.

Table 3. Statistical comparison of 2018 (West) and 2013 (Florida)[7] studies

	2013			2018					
	No.	Total	%	No.	Total	%	RR	CL95	p
Activatable SED									
Correctly activated	711	907	78.4%	1442	1493	96.6%	1.23	1.19-1.28	<0.001
Non-activated	196	907	21.6%	50	1493	3.3%	0.16	0.11-0.21	<0.001
Tampered	0	907	0%	1	1493	0.1%		NS	
All HBN									
Uncapped needles	649	1987	32.7%	170	2089	8.1%	0.25	0.21-0.29	<0.001
Capped needles	431	1987	21.7%	259	2089	14.4%	0.57	0.50-1.66	<0.001
devices disposed "sharp"	845	1987	42.5%	221	2089	10.6%	0.25	0.22-0.28	<0.001

SED safety engineered device; HBN hollow bore needles; RR risk ratio; CL95 95% confidence Limits; p probability

SED SI occur after activation,[13] which indicates that the activated mechanism, is failing to protect the user. SI during and after SED activation has risen significantly from 34% in the 4 years 2004-2007, to 50% in 2014-2017 (p <0.001).[13] This increase may indicate that HCW workloads are causing HCW to not activate the mechanisms mindfully as sharps injuries increase when HCW are rushed, stressed, or fatigued.[14-17] With SI and workloads increasing a more aggressive stand is needed nationally. We must consider moving to semi- and fully-auto SED whenever staff evaluations find them clinically acceptable.[18,19]

What level of SED use and activation should be our target?

SED Usage. Several HBN clinical procedures (e.g. some biopsy needles, pediatric sharps, pre-filled syringes, spinal needles) do not yet have commercially-available SED thus it is not yet possible to achieve "100% SED usage" in an acute care hospital. In this study, the overall SED usage rate was 79.5% i.e. 20.5% of HBN were non-SED (capped and uncapped). Stringer states that an SED usage of 93% meant that too many non-SED were still being used.[9] However, not even a 100% score on SED usage may be acceptable as not all safety devices are safe.[20,21]

In the 30 years of SED development there have been several "generations" with each new generation being safer, commonly via one-handed semi-auto or fully automated activation.[18,19,22] In U.S., UK and British Columbia it is a violation of regulations to continue to use SI-prone SED when a safer, clinically acceptable SED is commercially available for evaluation.[2,23,24]

SED activation. Non-activated SED carry the same SI risk as non-SED.[20] Although activation rates of 95-100% can be achieved with semi-auto and auto SED,[20] acceptable

activation rates have not yet been defined, however 100% activation should be the target.[9,19,20]

For SI to decrease, SED must be activated correctly every time,[21] as 32% of SI can be prevented if all SED are activated.[19]

Activated SED not only reduce the original user's risk they also reduce the risk for downstream exposure to others.[22] It is poor use of resources to evaluate SED, pay their extra cost, educate staff in their use, and then use them as conventional devices. Non-activation indicates either: staff dissatisfaction with the SED (perhaps through non-involvement in the selection process); or inadequate education and training in SED use.[20,25]

The targets. After conducting SED audits in 80 hospitals in U.S,[7] UK,[26] Australia,[10] and Canada (unpublished), the author believes that, with safe SED selection, effective work-practice policies and heightened education, the following targets are achievable and should be adopted:

- SED activation rate of 100%,
- zero SED tampering
- non-SED usage rate of <2% of all HBN (i.e. 98% of all HBN should be SED)

The <2% non-SED allows for: HBN procedures where no commercial SED are yet available or deemed clinically unsuitable; capped/uncapped needles to be occasionally removed from syringes (e.g. replaced by another needle).

In this study: one hospital almost achieved the <2% non-SED target (with 3%); no hospital achieved 100% SED activation (highest was 98.5%); and 5 of 6 hospitals achieved zero tampered SED. In unpublished studies within the U.S., of 29 hospitals the author has sampled, 8 achieved <2% non-SED; and two achieved 100% SED activation. No hospital has yet achieved both. The targets listed above are achievable.

But, simply meeting these targets will not ensure SI will be minimized. As stated earlier, to reduce SI rates significantly, these targets need be supplemented by adopting two additional aggressive strategies:

- Moving to semi-auto or auto SED. These safety mechanisms require nil or minimal user action and are associated with significantly lower SI rates.[9,18,19,20,27,28,29]
- Instituting staff-wide competency-based SED training and education.[22,25,27,30,31] And, as the decision to not activate an SED is made by the individual, hospital sharps policies should ensure that staff take ownership for their own safety.[27]

Post-disposal audits

Post-disposal audits of SED usage and activation are not new,[9,20, 20,25,31,32] and when conducted using a safe, established methodology, are a useful adjunct to sharps injury investigation. Sharps injury databases, either institutional or national, give valuable insights of SED involvement in the injury, but such databases are dependent on voluntary reporting and only show data on devices causing SI; they do not give an indication of SED use and activation in near-misses or when no injury occurred.[19] Likewise purchasing reports cannot give SED usage and activation. Post-disposal audits can serve this purpose and If conducted or commissioned by individual hospitals or in larger national studies, can assist with defining and targeting additional SI-prevention strategies, particularly comprehensive, competency-based education and training,[19,22,25,27,30,31] with continuous education reinforcement being essential.[19]

Non-activation or non-use of SED may also lead to discovery of user-dissatisfaction

through non-involvement in the selection process.[22,30] When sharps containers are source-labelled, activation rates can be traced back to the clinical unit from which they came and, following staff interviews, retraining and/or SED changes can be specifically targeted.

The OSHA NSPA prohibits needle recapping and needle removal[2] and PDA can include valuable information on these prohibited actions.[7,20] Post-disposal audits can also highlight the need for national SED legislation.[10]

Tampering of SED

Tampered SED (removal of the safety mechanism) was evident in one SED in one hospital of this study. It has been found previously in several hospitals in two PDA[22,26] and sought but not found in two other PDA.[7,10] It is hoped it is a rare occurrence as it indicates user-frustration and their belief the SED is safer without the safety mechanism.[22] It may also indicate the user (or staff-group) was not involved in the evaluation process and/or the hospital was part of a larger purchasing group which made the decision for them.[22] Tampering, like non-activation, renders the SED a conventional device, is financially wasteful, and likely increases user-risk. When tampered SED are detected it needs be source-investigated to interview and work with the dissatisfied users.[22]

Study Limitations and Strengths

Limitations of the study included: the exclusion of solid sharps (e.g. sutures); the exclusion when noticed, of surgical or laboratory RSC; the usage and activation of SED at the 6 hospitals may not be representative of all hospitals regionally or nationally; results from the selected RSC may not reflect the hospital's sharps practices as a whole; it is not possible to determine whether the significant improvement in results of this study over the Florida study is due to differences in study-hospitals' policies, purchasing or HCW behavior; the finding of capped needles does not confirm these needles were recapped after use as capped-needles may have been removed from syringes to allow fitting of other needles; it was not possible to determine if some uncapped needles had lost their caps in the decanting process; with some capped needles, capped syringe-needles and capped non-activated SED, it was not possible to tell if they had been discarded unused; also, it was not possible to know whether the sharp-user's risk assessment dictated that SED were not required, not appropriate or not available in certain procedures. Strengths of the study were in: the number of sharps containers selected; the number and selection-process of the hospitals sampled; the separate enumeration of blunt draw-up safety needles; the enumeration of tampered SED; and the enumeration of capped and uncapped needles.

Conclusions

- SED activation in all 6 hospitals was at a high level however 100% activation must be the objective.
- A >98% proportion of SED usage should be the target in all hospitals (non-SED <2%).
- The reasons for the national increase in SI are not fully explained by these results.
- Less user-dependent SED and more competency-based learning may be indicated.
- Post-disposal audits provide valuable SED usage and activation data.

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Conflict of Interest statement
None declared

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