Sharps injuries: Containing the problem

Every year, an estimated 400,000 US healthcare workers suffer accidental injury from medical sharps, a proportion of which are associated with sharps containers. Consultant microbiologist **Terry Grimmond** outlines the international trends in sharps injuries and prevention, and explains how legislation, new Sharps Container Standards and human factors engineering can help to reduce the problem.

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From 1991 to 2001, annual sharps injuries (SI) to US healthcare workers fell from a million to 400,000. Other countries have had similar reductions. Unfortunately, the US reduction has plateaued and new initiatives are needed. This article, focusing mainly on the US, examines SI controls and the impact sharps container engineering has had on SI.

Only 30 years ago, SI were considered inconsequential. Few were reported, safety devices were non-existent, commercial sharps containers were rare, hepatitis B vaccine was not available, needles were recapped and discarded into plastic rubbish bags, and most workers who suffered SI simply said "oops" and continued their work.

The SI 'awakening' began with McCormack and Maki's seminal study in 1981[1]. This pre-AIDS study disturbingly revealed that 8.2% of healthcare workers reported SI annually. Two years later, the first healthcare worker occupationally contracted HIV – SI suddenly became very consequential, and the healthcare world changed forever.

McCormack et al's 1991 follow-up study showed that an alarming 18.7% of healthcare workers reported SI annually, indicating that more than a million were suffering SI each year. Education alone was not enough; engineered controls (safety devices) were needed to shift safety away from behaviour.

Engineered controls

Engineered controls "…isolate or remove the blood-borne pathogens hazard from the workplace". They include sharps containers, needleless systems and any sharp with "engineered sharps injury protection (ESIP)" – in other words, a mechanism to disarm the sharp at the end of or immediately after the procedure.

"Modifications in the design of needled instruments" were proposed by Jagger et al in 1986[2]. The industry quickly rallied and US-registered patents for safety devices jumped from four in 1984 to 500 in 1991. However, the newly-available safety devices were more expensive than standard ones, and few hospitals were convinced the expense was justified. Then the Occupational Safety and Health Administration (OSHA) stepped in.

Although the Occupational Safety and Health Act of 1970 required employers to offer personal protective equipment, and employment free from recognised hazards, it did little to motivate employers to reduce blood-borne pathogen (BBP) risk. Following petitions from healthcare workers unions, in 1991 the OSHA promulgated the BBP Standard, which brought the existing BBP requirements together with more specific actions, including hepatitis B vaccination. However, it too failed to reduce SI nationally.

In 2001, the OSHA enacted the revised BBP Standard and shifted emphasis from safe behaviour to safer devices. It required employers to: develop an exposure control plan that reflected annual examination of safer technology; involve frontline staff in the process; and maintain a log of SI. Subsequently, OSHA clarified that the selection of engineered controls cannot be made on cost alone or limited by contractual agreements, and that if effective and safer devices are available, they must be used. The legislation was effective – the SI rate fell 34% in 2001. But the two largest databases in US, Massachusetts and EPINet, have shown that SI incidence has changed little since (see *Figure 1*, page 12).

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Research confirms the trilogy of SI reporting, BBP education and the 'hierarchy of SI controls' (eliminate, isolate, work practice/administrative controls, PPE) effectively reduces SI. I cannot stress the importance of reporting SI at individual, clinical unit, institutional and national levels enough. Without reporting, there is no evidence, and without evidence, there is no support and no allocation of resources.

The international picture

Not all countries adopted BBP-specific legislation – several already had occupational health laws that were sufficient to require employers to adopt ESIP when the risk was identified. However, legislation in some form has been the mainstay of SI change[3]. France and Italy had an early requirement for safety devices, and Tosini et al's large French study confirmed that passive safety devices (those that do not require separate activation by the healthcare worker) reduce SI significantly more than active safety devices[4].

Internationally, we still have a long way to go – Pruss-Uston et al estimate that, globally, three million healthcare workers are injured with BBP-contaminated sharps each year. Despite nationwide use of ESIP in the US, approximately 400,000 hospital and community-based healthcare workers still suffer an SI annually. This is virtually unchanged since 2002. In Canada the figure is 70,000; in UK 100,000; and in the European Union more than one million. In developing countries, the rates of SI, and, sadly, the risk of BBP exposure, are higher.

Broadly speaking, what healthcare workers are doing when SI happen is similar across the world: 40-50% of SI occur during a procedure; 20-35% occur after a procedure but before disposal; 5-15% are due to inappropriate disposal (placed in trash, left on floor/bed, etc); and 5-15% are associated with a sharps container. In countries not using safety devices, disposal SI are higher.

Legislation and healthcare workers' input

No new ESIP legislation has emerged in US since 2001's revised BBP Standard. However, 2010 was a watershed year for the European Union. A directive was issued requiring the 27 member states to eliminate BBP exposure by eliminating the unnecessary use of sharps, adopting safety devices, adopting safe disposal methods, banning recapping, supplying PPE, and putting reporting, investigation and follow-up procedures in place. Like the US, the European Union's legislation was brought about by strong lobbying by healthcare workers unions, and such lobbying, whether by individuals, associations or unions, is vital for change to occur. The aim is not SI control, it is SI elimination, and elimination requires greater effort as incidence decreases.

Participation of healthcare workers at national and international level requires resources, and the present imbalance of manufacturers and clinical users at many national and international sharps container standards is a sad reflection of the scarcity of healthcare resources. All too frequently Standards associations are hamstrung in preventing decisions being made by well-resourced manufacturer majorities who can attend every meeting.

Two recent examples are the US ASTM F2132 standard review, where manufacturers outvoted users and halted the review, and the current ISO TC 84 SC meetings where healthcare workers are outnumbered ten to one. Healthcare workers must find a way to voice their safety needs, otherwise decisions will be made by those who may not give SI elimination the priority it warrants.

Container-associated SI

It's hard to believe now, but prior to 1980, sharps were recapped and discarded into rubbish bags or scrounged containers, and up to 30% of environmental service staff suffered SI annually.

First recommended in 1975, commercial sharps containers became widely used in the US in the 1980's, and were adopted to enable needles to be discarded without recapping and allow safer containment. However, they initiated a new subset of SI: container-associated SI (CASI).

In the early years of commercial sharps container usage, when most containers had a small aperture and required point-first deposition, the causes of CASI were reported as overfilling, penetration, depositing sharp and emptying. 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[5] (see *Causes of CASI*, page 12). Of the causes of CASI listed, 90% are likely due to small apertures and insensitive trays.

Before the 2001 revision of the Standard, CASI commonly accounted for 10-20% of total SI. With the uptake of safety devices designed to disarm the sharp, CASI decreased. But they are still associated with 4-11% of total SI, and account for a conservative 24,000 SI to US healthcare workers annually[5]. ››

Sharps container design

The earliest moves to reduce CASI included the abandonment of cutters on top of containers, as well as flimsy or scavenged containers.

Osterman first recommended stronger walls and wider apertures in 1975. Subsequent studies recommended visualisation of fullness, increased puncture resistance, hand-restriction, secure closure, bracketry, clear labelling, counterbalanced doors, stability and one-handed deposit.

Very few sharps containers meet all these requirements, and in 2003, after finding CASI accounted for 10.9% of SI in Californian hospitals, Gillen and colleagues called for their redesign. Apart from counterbalanced doors and size, sharps container design had changed little in 20 years.

Sharps container standards

The OSHA requires sharps containers, like other safety devices, to be examined annually to determine if safer containment options are available. Its criteria for sharps containers are simple: closable; puncture-resistant; labelled appropriately; and leakproof on the sides and bottom. The US ASTM F2132 standard covers puncture-resistance only. Clinical needs markedly exceed these requirements, and users are advised to refer to the comprehensive guidelines published by the National Institute for Occupational Safety and Health and patient care research organisation ECRI.

The first sharps container standard (UK), published in 1990, included five performance tests and five design specifications. Other countries subsequently developed more demanding standards, reflecting healthcare workers' increasing concerns with sharps container safety. The two latest standards from Canada (2007) and South Africa (2008) have up to nine tests and 18 design specifications. The engineering necessary to meet these safety requirements may mean increased costs; however a recent hospital liability alert issued by a major US law firm warns hospital decision-makers against placing cost over safety, particularly when the evidence of increased safety has been published and is in the public domain[7].

Needle safety devices were developed so that sharps safety could be less dependent on human behaviour. The same principle applies to sharps containers – enhanced engineering reduces dependence on human behaviour. The conservative estimate of 24,000 US CASI is not acceptable. ■

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Human factors engineering

Human factors engineering (HFE) is the study of user interfaces to control use-related hazards. The US Food and Drug Administration promotes the term 'use-related' error (vs 'user-related') and states that most use-errors with medical devices are due to device design, rather than user-fault or device failure.

HFE accommodates a wider spectrum of human behaviour, and when effectively applied to sharps containers, CASI decreased significantly. In two large, multi-centre, international studies, hospitals converted to one particular HFE-designed sharps container; in both studies CASI fell significantly, to the lowest rate published in international literature[5,6]. The container in both studies (Sharpsmart, developed by Daniels Sharpsmart) has 26 parts, is highly engineered and is the product of five years of HFE research with clinical users. The container places less of the onus for safety on the user, does not require staff to constantly monitor fullness (it shuts itself off when full), and passively protects users 24 hours a day. The studies confirm the French finding that passive safety devices are associated with less SI. Extrapolating from the US study, 19,000 SI could be prevented in the US if such HFE features were possible in all sharps containers[5].

Causes of CASI

- Depositing into sharps container –
  - SI caused by own sharp (aperture too small)
  - SI from sharp in sharps container (overfilling; insensitive door)
  - sharps bounced out (aperture too small)
- Sharp protruded from sharps container (insensitive door)
- Sharp penetrated sharps container (walls not strong enough)
- Placing hand in sharps container (no restrictive door)
- Manipulating sharps container (no restrictive door; closure not secure).

[1, 2, 3, 4, 5, 6, 7] *References available on request.*

Fig 1. Sharps injury incidence in the US (1997-2008): EPINet and Massachusetts

The two databases confirm the 2001 fall-rate was not sustained. The slight fall in 2000 is likely due to 12 months' notice of the 2001 Act. The Centers for Disease Control and Prevention's 'Zero by 2010' target will not be achieved.